

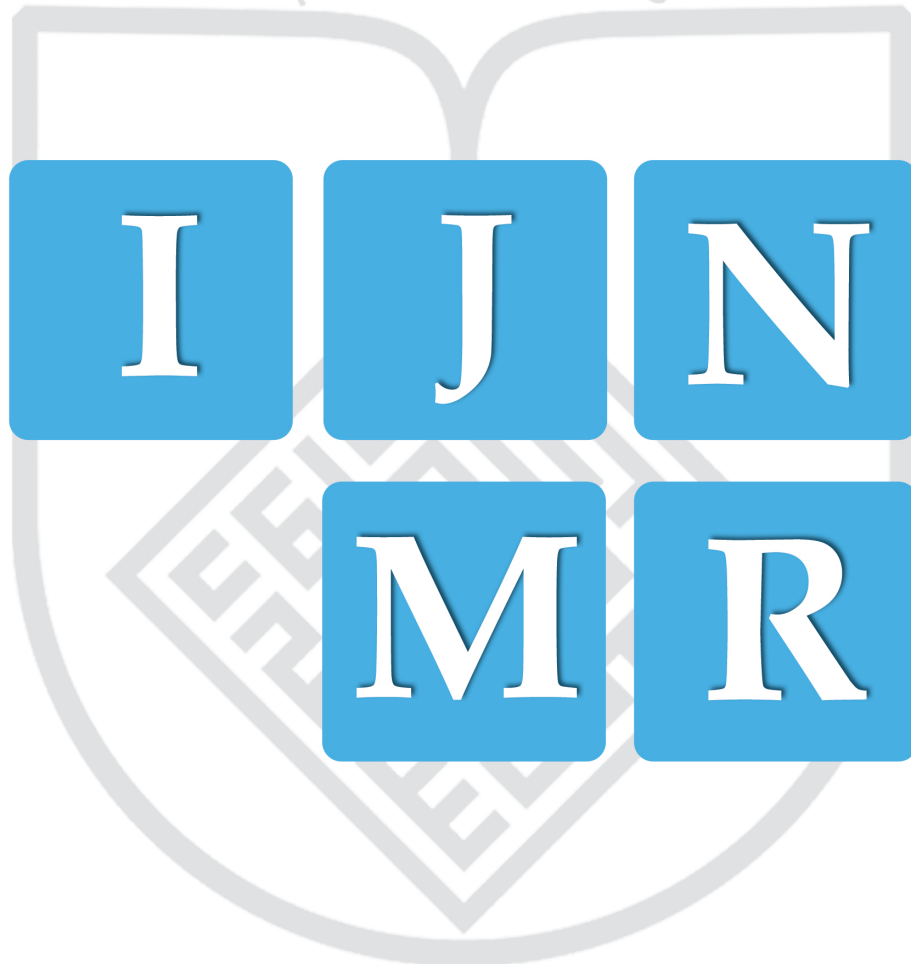
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Relationship between Vaginal Bacterial Infections and Pregnancy Outcomes: A Systematic Review and Meta-Analysis

Abstract

Background: Bacterial infections are among the most serious infections worldwide. They can cause miscarriage, premature birth, stillbirth, and ectopic pregnancy in pregnant women. The aim of this study was to investigate the relationship between bacterial infections and pregnancy outcomes through a systematic review and meta-analysis. **Materials and Methods:** PubMed, Scopus, Web of Science, and Embase databases were searched from January 2000 to December 2018 using appropriate keywords to identify related articles. The final related studies were selected and evaluated using the Newcastle-Ottawa Scale (NOS). **Results:** Results of this meta-analysis based on combining case-control studies showed that the presence of bacterial infections could lead increase in the odds of all pregnancy outcomes like premature infant birth (odd ratio [OR]: 1.50; 95% Confidence Interval [CI], 1.39–1.61), preterm delivery (OR: 1.54; 95% CI, 1.39–1.70), abortion (OR: 1.16; 95% CI, 1.04–1.29), stillbirth (OR, 1.29; 95% CI, 1.12–1.49), and ectopic pregnancy (OR: 1.12; 95% CI, 1.05–1.19). The results showed that the Risk Ratio (RR) of preterm delivery in pregnant women with vaginal infections was 1.57 (95% CI, 1.46–1.67), whereas the RR of abortion was 2.02 (95% CI, 1.72–2.38). **Conclusions:** Based on the results of this meta-analysis, the presence of bacterial infections in pregnant women can lead increase in the risk of pregnancy outcomes especially, preterm delivery, abortion, stillbirth, and ectopic pregnancy. Therefore, it is necessary for obstetricians and gynecologists to pay attention to the diagnosis of these infections in women before pregnancy and during pregnancy in order to prevent the consequences of these infections.

Keywords: Abortion, bacterial infections, ectopic pregnancy, premature births, stillbirths

Introduction

Pregnancy guarantees the survival of the human race.^[1] Today, healthy pregnancy, as an indicator of development, has received growing attention in all healthcare systems.^[2] A normal, healthy pregnancy should last between 38 and 42 weeks.^[3] There is a wide range of factors and diseases that may affect the length of pregnancy. One of these challenging factors is a bacterial infection. Bacterial infections are among the most common infectious diseases, adversely affecting sexual and reproductive health worldwide.^[4,5] These infections can increase the risk of ectopic pregnancy in women, leading to sudden and severe bleeding following a ruptured fallopian tube. Besides, the complications of these infections are not limited to patients. Pregnant women with such infections may suffer from consequences such as miscarriage, preterm delivery,

stillbirth, ectopic pregnancy, and diseases, as well as other complications in the fetus.^[6] The literature review revealed that 5% of pregnant mothers in developed countries and 25% in developing countries are at risk of preterm delivery.^[7] Also, a leading cause of maternal mortality in the first trimester of pregnancy is ectopic pregnancy, in which the embryo implantation occurs outside the uterine cavity, particularly in the fallopian tubes. As a pregnancy emergency, it often requires prompt intervention. The World Health Organization (WHO) reported that 4.9% of maternal deaths are attributable to ectopic pregnancies.^[8,9]

Sexually Transmitted Diseases (STDs) are mainly transmitted through sexual contact (vaginal, anal, and oral sex) and, in some cases, through contaminated blood or blood products. Most STDs, including chlamydia, gonorrhea, and syphilis, can also be transmitted from mother to infant

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during pregnancy and childbirth.^[10] On the other hand, a key point regarding these diseases is that most infections remain undiagnosed and untreated, which may lead to adverse pregnancy outcomes in women.^[11]

Assessing the relationship between these different infections and pregnancy outcomes can be helpful in future planning for more appropriate pre- and postnatal, and neonatal care; therefore, the findings of this study can be effective in changing and updating treatment guidelines. Due to the contradictory results on the relationship between STDs and pregnancy outcomes,^[5-11] this systematic review and meta-analysis investigated and analyzed studies on vaginal bacterial infections and pregnancy outcomes.

Materials and Methods

This systematic review and meta-analysis were conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guideline.^[1] All original published articles (case-control and cohort studies) were searched in PubMed, Scopus, Web of Science, and Embase databases. All the authors searched the databases, hand searching through the reference lists and grey literature (Google Scholar). We searched in these search engines with language limitations (English) from January 2000 to December 2018. The search protocol was developed based on four main roots of “pregnant women,” “maternal outcomes,” “bacterial infection,” and “vaginal infection.” All related components of maternal outcomes including preterm labor, spontaneous preterm delivery, premature birth, ectopic, spontaneous abortion, and stillbirth. Also, all related components of bacterial infection included *Chlamydia trachomatis*, *Trichomonas vaginalis*, *Haemophilus ducreyi*, *Treponema pallidum* (syphilis), *Mycoplasma*, *Neisseria gonorrhoeae*, and bacterial vaginosis. The results were limited to human subjects and refined for pregnant women. In this study, Reference Manager bibliographic software was used to manage the searched citations. Duplicate entries were searched by considering the title of the published papers, authors, publication year, and specifications of the source types. We reviewed the primary search results, and after reviewing each article by title and available abstract, some of the articles were eliminated. The evaluation of the papers was based on the inclusion and exclusion criteria independently performed by two authors (HR and YM). Case-control and cohort articles in English were selected, which investigated the relationship between vaginal bacterial infections and pregnancy outcomes and contained relevant information. In the present meta-analysis, the letter to the editor, review studies, meta-analyses, case reports/case series, clinical/interventional trials, and studies with measurement indicators other than OR and Risk Ratio (RR) were excluded from the analysis.

After three steps of assessment for the titles, abstracts, and full texts, the full text of each selected article was retrieved

for detailed analysis. The data were extracted using a checklist recording name of the first author, publication date, country, study subjects, patient age, gestational age, sample size, detection method, exposure types, outcome types, colonization types, sampling method, RR, OR, and control variables.

To evaluate the possible biases and the quality of studies, the Newcastle-Ottawa Scale (NOS) was used for analytical observational studies (case-control and cohort studies). Informed by the aspects of the studies (including selection, comparability, and outcome), the quality of the studies was determined using the “star” rating system. Scores ranged from 0 (worst case) to 9 (best case). Studies with scores of 0–4, 5–7, and above 7 were categorized as low quality, moderate quality, and high quality, respectively.

All analyzes were performed using STATA version 16 (StataCorp LLC, College Station, Texas, USA).^[2] First, the logarithm and Standard Deviation (SD) of OR and RR logarithm and Confidence Interval (CI) 95% were calculated for meta-analysis. The effect size of the reported studies was different; thus, in case-control studies, OR was reported, and, in cohort studies, RR was reported. The random effect model was used for the analysis. To check the heterogeneity in the meta-analysis, I-square and Q Cochrane indicators were applied. According to the Cochrane criteria, if the I-square percentage is 0–25%, there will be no heterogeneity; 25–50%, heterogeneity will be low; 50–75%, heterogeneity will be high but acceptable; and 75–100%, heterogeneity will be very high. To identify the main source of heterogeneity, subgroup analysis based on important variables (the number of sexual partners, number of samples, type of studies, and geographical location) and meta-regression analysis were used. The publication bias was examined using the Egger’s regression asymmetry test.^[4] Sensitivity analysis was also performed using a random effect model, in which each study was excluded from the research to evaluate the effect of that study on the overall estimate.

Ethical considerations

The study protocol was approved by the Ethics Committee of Kurdistan University of Medical Sciences (IR.MUK.REC.1397.317). The authors avoided plagiarism in any form in writing the present study. Also, the researchers avoided any data fabrication and falsification while drafting this manuscript.

Results

Search results

As shown in Figure 1, 8,838 articles were identified in the initial search. After deleting duplicate data, 5,197 articles were singled out for screening. Following the review of the title and abstract, 476 articles were chosen for the full-text analysis. Accordingly, 394 papers were removed for various

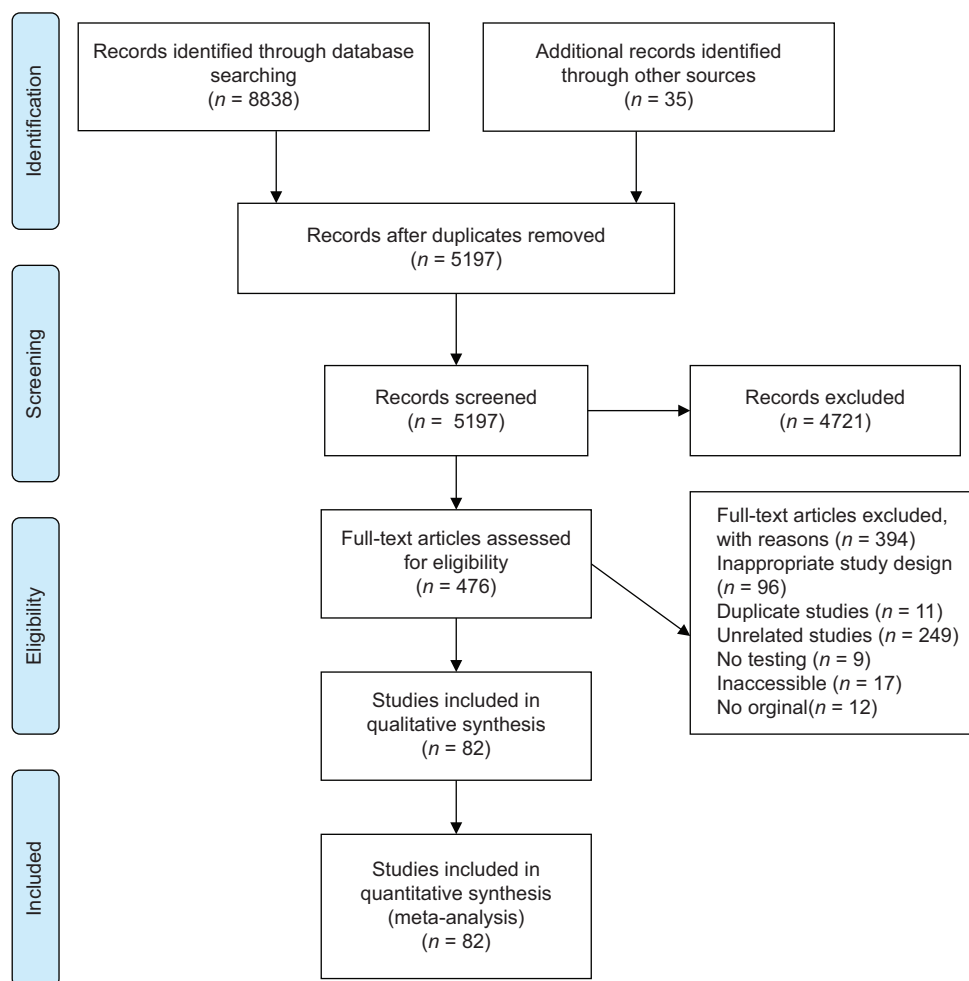


Figure 1: Flowchart of the systematic review of the relationship between genital infections and pregnancy outcomes during 2000–2018

reasons, including improper study design, irrelevance, duplication, improper testing, restricted access, and lack of originality. Finally, after the qualitative evaluation of data, 31 cohort articles [Table 1] and 52 case-control articles [Table 2] were assessed for analysis.

Analysis of case-control studies

1) Preterm births outcomes

Regarding bacterial infections and preterm delivery in pregnant women, 19 case-control studies were included in the meta-analysis. The merging case-control studies showed that pregnant women with bacterial infections (regardless of the type of infection) were 1.5 times more likely to give birth to a premature infant (OR: 1.50; 95% CI, 1.39–1.61). The heterogeneity of this meta-analysis was high (91.06%) with a significance level of 0.001. The highest and lowest ORs in these 19 case-control studies were reported by Harada *et al.* and Baud *et al.*, respectively [Figure 2].^[46,56] The results of publication bias are presented in Figure 3. The results of the Egger's test showed no publication bias in the effect of bacterial infections in preterm delivery in pregnant women (coefficient, 1.04; Standard Error [SE], 0.986; $p = 0.289$). In this study, the subgroup analysis was

performed in case-control studies based on the type of colonization, the type of bacterial infection, and the type of bacterial infection diagnosis method. The analysis of the type of colonization showed that based on the types of samples (blood, vaginal, cervical, and urine), bacterial infections increased the odds of preterm delivery in pregnant women by 1.17 (OR: 1.17; 95% CI, 0.98–1.40), 1.98 (OR: 1.98; 95% CI, 1.76–2.24), 1.23 (OR: 1.23; 95% CI, 1.07–1.42), and 1.65 (OR: 1.65; 95% CI, 1.24–2.19), respectively [Table 3]. Depending on the type of bacterial infection, the results showed different associations, which are of paramount importance. In the case of bacterial infection, the odds of preterm delivery were 1.54 times higher (OR: 1.54; 95% CI, 1.39–1.70), whereas, in the presence of *Ureaplasma urealyticum*, the odds of infection were approximately eight times higher (OR: 7.96; 95% CI, 5.50–11.51). The odds of preterm delivery were different based on the diagnostic method, whereas according to the molecular method, this odds was estimated at 1.40 (OR: 1.40; 95% CI, 1.11–1.76) [Table 3].

2) Abortion outcomes

Regarding the relationship between bacterial infections and abortion in pregnant women, seven case-control

Table 1: The main characteristics of cohort and population-based cohort studies

Authors (Year) (Reference number)	Type of study Country Study population	Age Sample size	Type of infection	Type of outcomes	Measurement of association	Controlled variables
Jacobsson <i>et al.</i> (2002) ^[5]	Cohort Sweden Hospital-based	27 852	Bacterial vaginosis	Premature birth	2.10 (0.90–4.90)	*
Afolabi <i>et al.</i> (2016) ^[6]	Cohort Nigeria Population-based	30.90 46	Bacterial vaginosis	Premature birth	2.68 (1.44–4.98)	*
Aaltone <i>et al.</i> (2002) ^[7]	Cohort Finland Hospital-based	29.50 22	<i>Mycoplasma urealyticum</i>	Premature birth	3.34 (8.80–1.27)	*
Averbach <i>et al.</i> (2013) ^[8]	Cohort USA Population-based	31.50 81	<i>Mycoplasma genitalium</i>	Premature birth, abortion		*
Azargoon <i>et al.</i> (2006) ^[9]	Cohort Iran Hospital-based	* 1,223	<i>T. vaginalis</i> Bacterial vaginosis	Premature birth	5.99 (3.79–9.49) 0.73 (0.22–2.17)	*
Bakken <i>et al.</i> (2007) ^[10]	Cohort Norway Hospital-based	* *	<i>C. trachomatis</i>	Ectopic pregnancy		*
Balu <i>et al.</i> (2003) ^[11]	Cohort USA Hospital-based	26.20 *	Bacterial vaginosis	Premature birth	1.00 (0.70–1.50)	Maternal race and vaginal bleeding during the pregnancy
Blas <i>et al.</i> (2007) ^[12]	Cohort USA Population-based	* *	<i>C. trachomatis</i>	Premature birth	1.46 (1.08–1.99)	Maternal age and education
Bretelle <i>et al.</i> (2015) ^[13]	Cohort France Hospital-based	* *	Bacterial vaginosis	Premature birth	3.90 (1.10– -14.10)	*
Daskalakis <i>et al.</i> (2006) ^[14]	Cohort Greece Hospital-based	* *	Bacterial vaginosis	Premature birth	2.19 (1.21–3.98)	Age, ethnicity, height, weight, gravidity, history of miscarriage or pregnancy termination, smoking *
De Borborema- Alfaia <i>et al.</i> (2013) ^[15]	Cohort Brazil Hospital-based	* *	<i>C. trachomatis</i>	Premature birth		*
Dingens <i>et al.</i> (2016) ^[16]	Cohort USA Hospital-based	* *	Bacterial vaginosis	Abortion	1.15 (0.27–4.96)	Presence of sexually transmitted infections (syphilis, gonorrhea, chlamydia, and/or genital herpes)
Donders <i>et al.</i> (2000) ^[17]	Cohort Belgium Hospital-based	* *	<i>M. urealyticum</i> , Bacterial vaginosis, and <i>M. hominis</i>	Abortion	5.50 (2.90–10)	NR*
Fahmy <i>et al.</i> (2015) ^[18]	Cohort Egypt	* *	Bacterial vaginosis	Premature birth		*
Harper <i>et al.</i> (2012) ^[19]	Cohort USA Hospital-based	* *	Bacterial vaginosis	Premature birth	1.10 (0.80–1.50)	*
Hollegaard <i>et al.</i> (2007) ^[20]	Cohort Denmark	29 NR	<i>C. trachomatis</i>	Premature birth	2.60 (1.10– -6.29)	*

Contd...

Table 1: Contd...

Authors (Year) (Reference number)	Type of study Country Study population	Age Sample size	Type of infection	Type of outcomes	Measurement of association	Controlled variables
Lata et al. (2010) ^[21]	Cohort India Hospital-based	26.50 *	Bacterial vaginosis	Premature birth		*
McPheeters et al. (2005) ^[22]	Cohort USA Hospital-based	* *	Bacterial vaginosis	Premature birth	2.60 (1.70–4.10)	*
Menard et al. (2010) ^[23]	Cohort France Hospital-based	29 790	<i>Gardnerella vaginalis</i>	Premature birth		*
Nelson et al. (2008) ^[24]	Cohort U.S.A Hospital-based	24.20 754	Bacterial vaginosis	Premature birth	1.03 (0.64–1.63)	*
Nelson et al. (2009) ^[25]	Cohort USA Hospital-based	24 50	<i>G. vaginalis</i>	Premature birth	1.21 (0.73–2.01)	*
Nelson et al. (2014) ^[26]	Cohort USA Population-based	23.50 483	Bacterial vaginosis	Premature birth		Baseline (t1) microbiota level measured on a continuum and body mass index
Oakeshott et al. (2002) ^[27]	Cohort United Kingdom Population-based	* 1,189	Bacterial vaginosis	Abortion	1.15 (0.7–1.87)	*
Odendaal et al. (2006) ^[28]	Cohort South Africa Population-based	20.6 343	<i>C. trachomatis</i>	Premature birth		*
Rittenschöber- Böhm et al. (2017) ^[29]	Cohort Austria Population-based	* 3,643	<i>M. urealyticum</i>	Premature birth	1.40 (0.8–2.20)	Risk factors
Rours et al. (2011) ^[30]	Cohort Netherlands Hospital-based	* 4,055	<i>C. trachomatis</i>	Premature birth	1.17 (0.60–2.40)	Maternal age, ethnicity, education, gravidity, and smoking with multiple imputation
Tellapragada et al. (2016) ^[31]	Cohort India Hospital-based	27.10 790	<i>T. vaginalis</i> and Bacterial vaginosis	Premature birth	3.20 (1.02–10.41)	*
Thorsen et al. (2006) ^[32]	Cohort Denmark Hospital-based	28 2,221	Bacterial vaginosis	Premature birth	0.80 (0.50–1.50)	*
Vogel et al. (2006) ^[33]	Cohort Denmark Population-based	28 2,662	<i>M. urealyticum</i> and Bacterial vaginosis	Premature birth	1.30 (0.80–2)	Smoking, previous low birth weight, previous preterm delivery, and <i>Escherichia coli</i>
Watson-Jones et al. (2002) ^[34]	Cohort Tanzania Hospital-based	24.50 380	Syphilis	Premature birth, stillbirth	6.10 (2.50– 15.30)	Gravidity and delivery site
Bylykbashi et al. (2013) ^[35]	Cohort Iran Population-based	NR* 1,223	<i>T. vaginalis</i> and Bacterial vaginosis	Premature birth	5.99 (3.79–9.49)	*

*Not Reported

Table 2: The main characteristics of case-control and copulation case-control studies

Authors (Year) (Reference number)	Country (Age)	Sample size	Type of infection	Type of outcomes	Measurement of association	Controlled variables
Carlini et al. (2002) ^[36]	Italy (*)	Case (709) Control (3,368) T (4,077)	Bacterial vaginosis	Premature birth	2.00 (1.30–3.10)	*
Discacciati et al. (2011) ^[37]	Brazil (24.80)	Case (37) Control (45) T (82)	Bacterial vaginosis	Premature birth	4.06 (0.30–55.09)	Age <19 years, schooling, smoking, previous urinary tract infection, pH >4.5, ethnic group, bacterial vaginosis, and vaginal infection
Isik et al. (2016) ^[38]	Turkey (30.55)	Case (61) Control (139) ** (200)	Bacterial vaginosis	Abortion	*	*
Lim et al. (2010) ^[39]	New Zealand (*)	Case (44) Control (69) ** (113)	Bacterial vaginosis	Premature birth	*	*
Marakoglu et al. (2008) ^[40]	Turkey (*)	Case (20) Control (28) T (48)	Bacterial vaginosis	Premature birth	11.57 (1.26–105.70)	*
Agger et al. (2014) ^[41]	USA (27.70)	Case (54) Control (762) ** (816)	<i>C. trachomatis</i>	Premature birth	1.72 (0.91–3.28)	*
Agholor et al. (2013) ^[42]	Nigeria (28.40)	Case (98) Control (98) ** (186)	<i>C. trachomatis</i>	Ectopic pregnancy	4.70 (2.33–8.83)	*
Ahmadi et al. (2016) ^[43]	Iran (*)	Case (109) Control (109) ** (218)	<i>C. trachomatis</i>	Abortion	2.19 (1.05–4.56)	*
Andrews et al. (2000) ^[44]	America (*)	Case (190) Control (190) ** (380)	<i>C. trachomatis</i>	Premature birth	2.30 (1.01–5.03)	*
Bakken et al. (2007) ^[45]	Norway (*)	*	<i>C. trachomatis</i>	Ectopic pregnancy	1.40 (1.01–1.95)	*
Baud et al. (2011) ^[46]	Switzerland (33.30)	*	<i>C. trachomatis</i>	Abortion	2.30 (1.10–5.10)	Age, origin, education, and number of sex partners
Baud et al. (2015) ^[47]	Switzerland (32.40)	Case (146) Control (261) ** (407)	<i>C. trachomatis</i>	Premature birth		*
Benjamin et al. (2013) ^[48]	Brunei (*)	Case (118) Control (100) ** (218)	<i>C. trachomatis</i>	Ectopic pregnancy		*
Karaer et al. (2013) ^[49]	Turkey (30.40)	*	<i>C. trachomatis</i>	Ectopic pregnancy	2.42 (1.1–5.34)	*
Karinen et al. (2005) ^[50]	Finland (27.20)	Case (104) Control (402) ** (506)	<i>C. trachomatis</i>	Premature birth	1.00 (0.5–2)	*
Mpiima et al. (2018) ^[51]	Uganda (27.50)	Case (25) Control (76) ** (101)	<i>C. trachomatis</i>	Ectopic pregnancy	4.90 (1.15–21.29)	*
Abele-Horn et al. (2000) ^[52]	Germany (29)	Case (172) Control (132) T (304)	<i>M. genitalium</i>	Premature birth	2.80 (1.80–6.20)	Maternal risk factors
Hitti et al. (2010) ^[53]	USA (*)	Case (661) Control (667) ** (1328)	<i>M. genitalium</i>	Premature birth	2.50 (1.20–5)	Maternal age and all other covariates

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Table 2: Contd...

Authors (Year) (Reference number)	Country (Age)	Sample size	Type of infection	Type of outcomes	Measurement of association	Controlled variables
Jurstrand et al. (2007) ^[54]	Sweden (*)	*	<i>M. genitalium</i>	Ectopic pregnancy	2.30 (1.40–4)	Age, LAMP, and CT were included in the mode
Ahmadi et al. (2014) ^[55]	Iran (30.50)	Case (109) Control (109) ** (218)	<i>M. urealyticum</i>	Abortion	*	*
Harada et al. (2008) ^[56]	Japan (30.80)	Case (45) Control (100) T (145)	<i>M. urealyticum</i>	Premature birth	3.30 (1.20–8.80)	*
Kafetzis et al. (2004) ^[57]	Greece (30)	Case (126) Control (125) **(251)	<i>M. urealyticum</i>	Premature birth	*	*
Farhadifar et al. (2016) ^[58]	Iran (29.60)	Case (109) Control (109) ** (218)	<i>M. hominis</i>	Abortion	0.49 (0.08–2.73)	*
Arnesen et al. (2015) ^[59]	America (*)	Case (1,461) Control (366,690) Total (368,151)	Syphilis	Stillbirth	1.88 (1.25–2.83)	Maternal risk factors
Dou et al. (2013) ^[60]	China (*)	*	Syphilis	Premature birth	3.70 (2.36–5.8)	Maternal age, residence location, education, and job
Geelhoed et al. (2015) ^[61]	Belgium (24.70)	Case (150) Control (300) Total (450)	Syphilis	Stillbirth	*	*
Ahmadi et al. (2018) ^[62]	Iran (*)	Case (109) Control (109) Total (218)	<i>T. Vaginalis</i>	Abortion	*	*
Buchmayer et al. (2003) ^[63]	Sweden (*)	*	<i>T. Vaginalis</i>	Premature birth	1.10 (0.70–1.70)	Maternal age and parity
Kamal et al. (2018) ^[64]	Egypt (*)		<i>T. Vaginalis</i>	Premature birth	*	*
Eleje et al. (2015) ^[65]	Nigeria (30.70)	Case (105) Control (105) Total (210)	<i>G. vaginalis</i>	Premature birth	12.17 (1.54–96.07)	*
Heumann et al. (2017) ^[66]	USA (*)	*	<i>N. Gonorrhoeae</i>	Premature birth	1.50 (1.20–1.90)	Marital status and smoking status
Nejad et al. (2008) ^[67]	Iran (*)	Case (80) Control (80) Total (160)	Bacterial vaginosis	Premature birth	2.63 (1.03–6.85)	Job, history of abortion, and educational level
Pereira et al. (2016) ^[68]	Brazil (*)	Case (109) Control (218) Total (327)	Bacterial vaginosis	Premature birth	1.44 (0.51–3.77)	*
Subtil et al. (2002) ^[69]	France (*)	Case (102) Control (102) Total (204)	Bacterial vaginosis	Premature birth	13.80 (7.70–22)	*
Svare et al. (2007) ^[70]	Denmark (NR)	Case (170) Control (3,092) Total (3,262)	Bacterial vaginosis	Premature birth	1.50 (1–2.10)	*
Ashshi et al. (2015) ^[71]	Saudi Arabia (*)	*	<i>C. trachomatis</i> and <i>M. genitalium</i>	Ectopic pregnancy	3.07 (1.30–12.30)	*
Burton et al. (2018) ^[72]	Australia (25.80)	Case (361) Control (372) Total (433)	<i>C. trachomatis</i> , <i>T. vaginalis</i> , and <i>N. Gonorrhoeae</i>	Premature birth	2.92 (1.07–7.97)	Previous preterm birth, smoking, frequency of antenatal care hypertensive

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Table 2: Contd...

Authors (Year) (Reference number)	Country (Age)	Sample size	Type of infection	Type of outcomes	Measurement of association	Controlled variables
Donders et al. (2009) ^[73]	Belgium (29)	*	Bacterial vaginosis and <i>M. hominis</i>	Premature birth	2.43 (1.10–4.70)	disease and antepartum hemorrhage, and remoteness and method of pregnancy dating *
Edwards et al. (2006) ^[74]	USA (25)	*	Bacterial vaginosis, <i>G. vaginalis</i> , <i>M. genitalium</i> , <i>M. urealyticum</i> , and <i>M. hominis</i>	Premature birth	0.90 (0.18–4.59)	*
Kataoka et al. (2006) ^[75]	Japan (29.60)	Case (21) Control (856) Total (877)	<i>M. genitalium</i> , <i>M. urealyticum</i> , and <i>M. hominis</i>	Premature birth	*	*
Kilpatrick et al. (2006) ^[76]	USA (26.30)	Case (102) Control (316) Total (418)	Bacterial vaginosis, <i>C. trachomatis</i> , and <i>N. Gonorrhoeae</i>	Premature birth	1.60 (0.70–3.60)	*
Nakubulwa et al. (2015) ^[77]	Uganda (*)	Case (87) Control (87) Total (174)	<i>T. Vaginalis</i>	Premature birth	1.15 (0.63–2.09)	*
Nyári et al. (2001) ^[78]	Hungary (*)	Case (148) Control (6,008) Total (6,156)	<i>C. trachomatis</i>	Stillbirth	1.80 (1.10–3.30)	*
Pientong et al. (2009) ^[79]	Thailand (*)	Case (32) Control (57) Total (89)	<i>C. trachomatis</i>	Ectopic pregnancy	5.04 (1.12–21.13)	*
Rantsi et al. (2016) ^[80]	Finland (*)	Case (243) Control (1,347) Total (1,590)	<i>C. trachomatis</i>	Premature birth, abortion, and ectopic pregnancy	1.00 (0.82–1.21)	*
Zhu et al. (2014) ^[81]	China (*)	Case (72) Control (146) Total (218)	<i>C. trachomatis</i>	Ectopic pregnancy	1.60 (0.67–3.83)	*
Povlsen et al. (2001) ^[82]	Denmark (*)	Case (84) Control (400) Total (484)	Bacterial vaginosis and <i>M. genitalium</i>	Premature birth	0.77 (0.33–1.60)	*
Schwab et al. (2016) ^[83]	Switzerland (26.70)	Case (23) Control (39) Total (62)	<i>M. urealyticum</i> and <i>M. hominis</i>	Premature birth	0.52 (0.15–1.57)	*
Silveira et al. (2009) ^[84]	USA (*)	*	Bacterial vaginosis, <i>C. trachomatis</i> , Syphilis, <i>T. vaginalis</i> , and <i>N. Gonorrhoeae</i>	Premature birth	1.00 (0.4–2.60)	Maternal age, maternal race, marital status, previous delivery, previous preterm birth, maternal alcohol use, maternal smoking, maternal drug use, hypertension, diabetes, thyroid dysfunction, and anemia
Ramazanzadeh et al. (2016) ^[85]	Iran (29.60)	Case (109) Control (109) Total (218)	<i>M. genitalium</i>	Abortion	*	*

Contd...

Table 2: Contd...

Authors (Year) (Reference number)	Country (Age)	Sample size	Type of infection	Type of outcomes	Measurement of association	Controlled variables
Romero et al. (2014) ^[86]	USA (21)	Case (18) Control (72) Total (90)	<i>G. vaginalis</i>	Premature birth	*	*

*Not Reported, **Treatment. Abbreviations: LAMP=Loop-mediated isothermal amplification, CT=Computed tomography

Table 3: Relationship between vaginal infections and preterm delivery, abortion, and ectopic pregnancy in pregnant women (in case-control studies) based on the type of colonization

Outcomes	Subgroups	Odds ratio (95% CI)	Between studies			Between subgroups		
			I square	Q	<i>P</i> _{heterogeneity}	Q	<i>P</i> _{heterogeneity}	
Preterm Birth	Colonization	Blood	1.17 (0.98–1.40)	81.02%	15.81	0.001	36.50	0.001
		Vaginal	1.98 (1.76–2.24)	95.07%	121.63	0.001		
		Cervix	1.23 (1.07–1.42)	55.04%	6.67	0.081		
		Uteri	1.65 (1.24–2.19)	90.34%	20.7	0.001		
	Type of vaginal infection	Bacterial vaginosis	1.54 (1.39–1.70)	86.81%	53.05	0.001	98.16	0.001
		Chlamydia trachomatis	1.03 (0.84–1.27)	75.02%	12.01	0.010		
		Mycoplasma genitalium	1.53 (1.25–1.88)	0.00%	0.06	0.810		
		Ureaplasma urealyticum	7.96 (5.50–11.51)	91.98%	12.47	0.001		
		Trichomonas vaginalis	1.18 (0.98–1.42)	96.09%	25.58	0.001		
		Culture	1.58 (1.46–1.71)	93.15%	175.24	0.001		
Diagnosis method	Serology	0.92 (0.70–1.21)	55.35%	10.72	0.090			
	Molecular	1.40 (1.11–1.76)	0.00%	5.00	0.610			
Abortion	Colonization	Blood	1.09 (0.96–1.24)	67.13%	3.04	0.082	3.43	0.060
		Cervix	1.37 (1.12–1.69)	43.84%	7.12	0.132		
	Diagnosis method	Culture	2.44 (1.16–5.11)	0.00%	0.34	0.555	5.95	0.050
		Serology	1.09 (0.96–1.24)	67.13%	3.04	0.089		
		Molecular	1.31 (1.05–1.62)	34.85%	4.60	0.200		
Ectopic pregnancy	Colonization	Blood	1.10 (1.03–1.19)	84.81%	32.92	0.001	0.37	0.54
		Cervix	1.16 (1.01–1.34)	0.00%	0.09	0.760		
	Type of vaginal infection	<i>Chlamydia trachomatis</i>	1.09 (1.02–1.17)	78.78%	0.001	28.28	5.10	-0.02
		<i>Mycoplasma genitalium</i>	1.44 (1.03–1.88)	-	-	-		
	Diagnosis method	Serology	1.11 (1.03–1.19)	81.85%	0.001	33.06	0.31	0.58
	Molecular	1.16 (1.00–1.34)	-	-	-			

studies were included in the meta-analysis. The results of merging case-control studies showed that pregnant women with bacterial infections (regardless of the type of infection) were 1.16 times more likely to have an abortion than pregnant women without infection (OR: 1.16; 95% CI, 1.04–1.29). The heterogeneity in this meta-analysis was low (55.36%), with a significance level of 0.030. The highest and lowest ORs in these six case-control studies corresponded to the studies of Ahmadi and Farhadifar, respectively [Figure 2].^[43,55,58,62] The results of publication bias are shown in Figure 3. In addition, the findings of Egger's test showed no publication bias in the effect of bacterial infections in abortion in pregnant women (coefficient, 1.10; SE, 0.552; $p = 0.341$).

In this study, the subgroup analysis was performed in case-control studies based on the type of colonization, the type of bacterial infection, and the type of bacterial infection detection method. For example, for the type of

colonization, the results suggest that based on blood and cervical samples, bacterial infections increase the odds of abortion in pregnant women by 1.09 (OR: 1.09; 95% CI, 0.96–1.24) and 1.37 (OR: 1.37; 95% CI, 1.12–1.69), respectively [Table 3]. The odds of abortion varies based on the diagnostic method, but according to the molecular method, it is estimated at 1.31 (OR: 1.31; 95% CI, 1.05–1.62; Table 3).

3) Ectopic pregnancy outcomes

Regarding bacterial infections and ectopic pregnancy in pregnant women, eight case-control studies were included in the meta-analysis. The results of merging case-control studies indicated that pregnant women with bacterial infections (regardless of the type of infection) were 1.12 times more likely to have an ectopic pregnancy than pregnant women without infections (OR: 1.12; 95% CI, 1.05–1.19). The degree of heterogeneity in this meta-analysis was low (79.03%) with a significance level

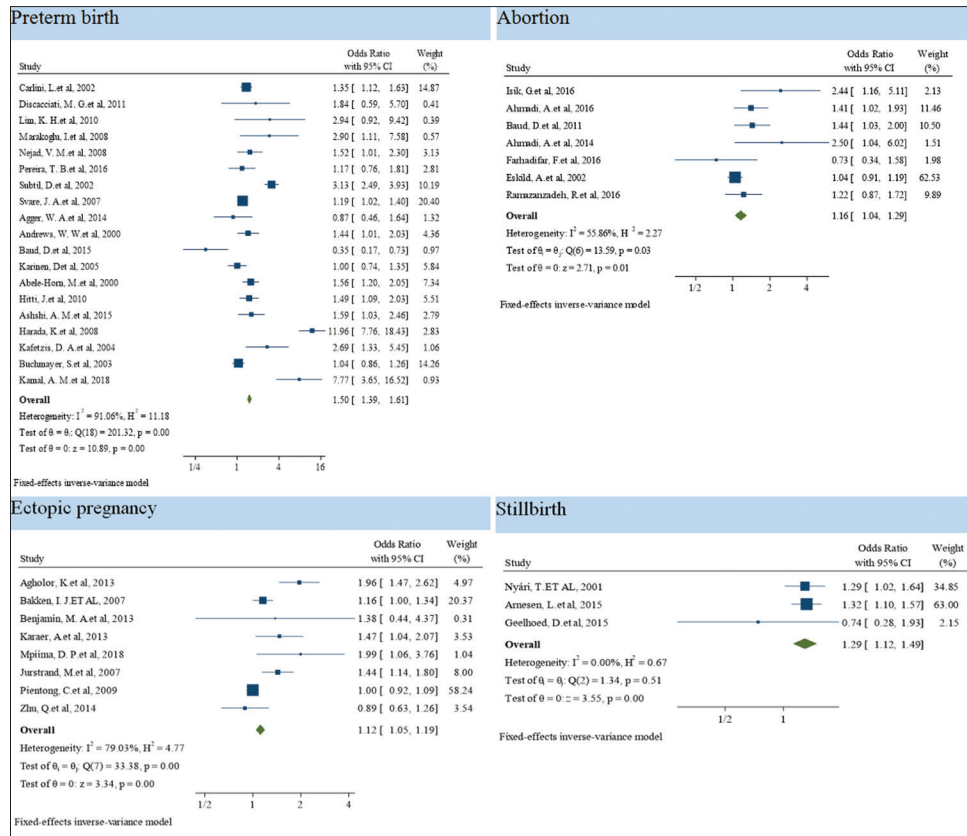


Figure 2: Cumulative as ratio of the effect of vaginal infections on preterm delivery and abortion in pregnant women based on case-control studies

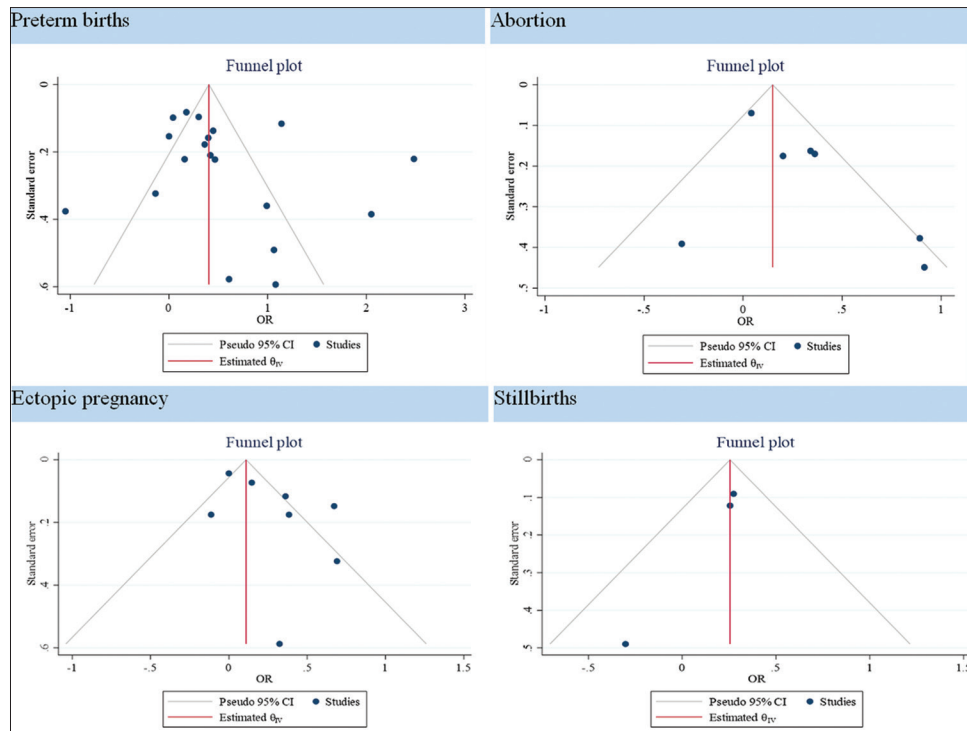


Figure 3: Publication bias of the cumulative effect of vaginal infections on preterm delivery and abortion in pregnant women based on case-control studies

of 0.001. The highest and lowest ORs in these eight case-control studies resembled those reported by Mpiima and Zhu, respectively [Figure 2].^[51,81] Publication bias was

also examined, and the results are presented in Figure 3. In addition, the results of Egger’s test showed no publication bias in the effect of bacterial infections in abortion in

pregnant women (coefficient, 1.00; SE, 0.341; $p = 0.098$). In this study, the subgroup analysis was performed in case-control studies based on the type of colonization, the type of bacterial infection, and the type of bacterial infection detection method. Based on blood and cervical samples, the type of colonization showed that bacterial infections increased the odds of ectopic pregnancy in pregnant women by 1.10 (OR, 1.10; 95% CI, 1.03–1.19) and 1.16 (OR, 1.16; 95% CI, 1.01–1.34), respectively. Based on the diagnostic method, the odds of ectopic pregnancy differed, but according to the molecular method, it was estimated at 1.16 (OR, 1.16; 95% CI, 1.00–1.34; Table 3).

4) Stillbirths outcomes

Regarding bacterial infections and stillbirth in pregnant mothers, three case studies were included in the meta-analysis. The lowest OR was reported by Geelhoed *et al.* (OR, 0.74; 95% CI, 0.28–1.93) and the highest by Arnesen *et al.* (OR, 1.32; 95% CI, 1.10–1.57).^[59,61] After merging control case studies, the overall OR was 1.29 (OR, 1.29; 95% CI, 1.12–1.49). The degree of heterogeneity was estimated at 0%, which was not statistically significant [Figure 2]. Due to the small number of studies, subgroup analysis was not performed to investigate this relationship. In addition, the results of Egger's test showed no publication bias in the effect of bacterial infections in stillbirth in pregnant women (coefficient, 1.10; SE, 0.221; $p = 0.260$; Figure 3).

Analysis of cohort studies

Screening articles for two outcomes of preterm delivery and abortion in pregnant women revealed the adequacy of data for meta-analysis. Accordingly, 14 cohort studies on preterm delivery and three cohort studies on abortion were included in the final analysis. After merging the results of these studies, the RR of preterm delivery in pregnant women with vaginal infections was calculated to be 1.57 (RR, 1.57; 95% CI, 1.46–1.67), whereas the RR of abortion was 2.02 (RR, 2.02; 95% CI, 1.72–2.38; Figures 4 and 5).

Table 3 shows the subgroup analysis based on colonization, infection type, diagnostic method, and study type to

determine the effect of bacterial infections on preterm labor and its outcomes. According to the results, RR was 1.70 (RR, 1.70; 95% CI, 1.56–1.85) in population-based studies and 1.70 (RR, 1.70; 95% CI, 1.56–1.85) in hospital-based studies [Table 4].

Discussion

This systematic review and meta-analysis investigated and analyzed studies on vaginal bacterial infections and pregnancy outcomes. In the subgroup analysis, the results of the present meta-analysis showed that regarding the relationship between vaginal infections and preterm birth, the main source of heterogeneity in general estimation was OR because heterogeneity in the diagnosis groups decreased compared to the general likelihood based on culture, serology, and molecular analysis. Furthermore, different diagnostic techniques and types of colonization are the primary sources of heterogeneity in studying the relationship between vaginal infections and abortion in pregnant women because the degree of heterogeneity declined in these groups. In analyzing and combining the results of cohort studies, the current meta-analysis was the only one with sufficient studies to estimate the association of vaginal infections with preterm birth. The subgroup results based on colonization showed that infections of the normal cervical floor had a greater effect than infections of the normal pelvic floor on inducing preterm birth in pregnant women. As for the agents of vaginal infections, the effect of *C. trachomatis* is greater than that of bacterial vaginosis on causing preterm birth in pregnant women. Since the degree of heterogeneity in these subgroups of analysis was not changed significantly, it could be concluded that the type of infection and colonization cannot be a source of heterogeneity in the overall estimation of the impact of bacterial infections on preterm birth after merging cohort studies. The results of combining population-based cohort studies revealed that the heterogeneity of RR was lower than the RR obtained from merging hospital-based cohort studies. In the study by Ahmadi *et al.*^[87] (2018), the prevalence of *C. trachomatis* infections was estimated based on preterm delivery using cross-sectional (OR, 0.16; 95% CI, 0.11–0.21) and case-control (OR, 0.13; 95% CI,

Table 4: Evaluation of the relationship between vaginal infections and preterm delivery in pregnant women (in cohort studies) based on the type of infection, type of colonization and type of infection diagnostic technique

Outcomes	Subgroups	RR (95% CI)	Between studies			Between subgroups		
			I square	Q	$P_{\text{heterogeneity}}$	Q	$P_{\text{heterogeneity}}$	
Preterm birth	Colonization	Vaginal	1.47 (1.37–1.58)	92.13%	117.08	0.001	29.40	0.001
		Cervix	2.67 (2.18–3.28)	6.95%	3.22	0.362		
	Type of vaginal infection	Bacterial vaginosis	1.54 (1.41–1.69)	94.97%	115.20	0.001	0.03	0.865
		<i>Chlamydia trachomatis</i>	1.57 (1.39–1.77)	66.44%	18.94	0.062		
	Methods of detection	Culture	1.55 (1.42–1.69)	93.12%	116.22	0.001	0.44	0.510
		Molecular	1.66 (1.38–1.99)	92.02%	25.07	0.001		
	Study population	Hospital-based	1.70 (1.56–1.85)	91.73%	120.98	0.001	1.66	0.200
		Population-based	1.54 (1.35–1.75)	66.50%	8.70	0.776		

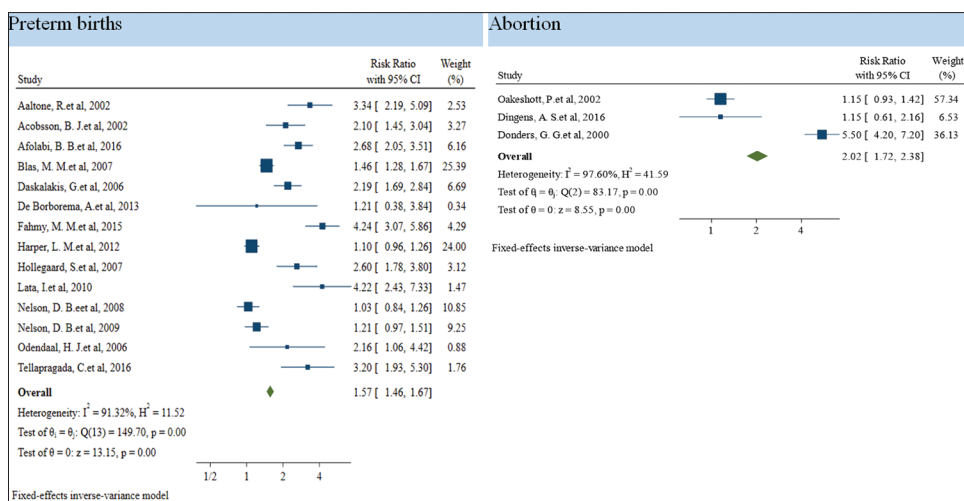


Figure 4: Cumulative RR of the effect of vaginal infections on preterm delivery and abortion in pregnant women based on cohort studies

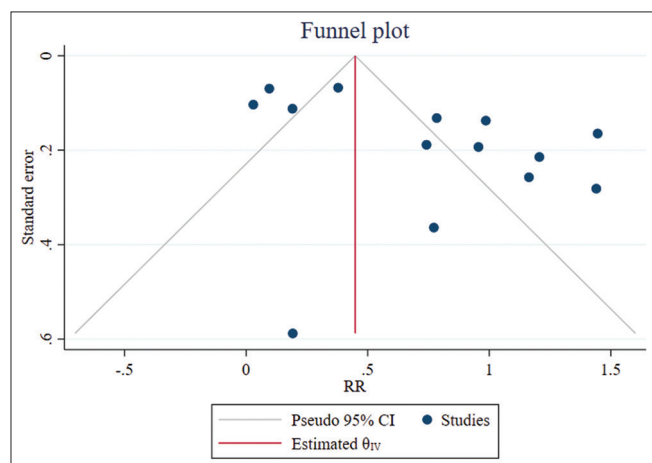


Figure 5: Publication bias of the cumulative effect of vaginal infections on preterm delivery in pregnant women based on cohort studies

0.08–0.17) methods. The prevalence of *C. trachomatis* infections in women was estimated based on preterm delivery using polymerase chain reaction (PCR; OR, 0.06; 95% CI, 0.04–0.09), serology (OR, 0.23; 95% CI, 0.10–0.35), and culture (OR, 0.17; 95% CI, 0.10–0.24) techniques. The overall prevalence of *C. trachomatis* infections in women based on preterm delivery was calculated to be 0.13% (95% CI, 0.11–0.16). In this study, an OR of 2.16 (95% CI, 1.3–3.57) was obtained. It can be concluded that women with *C. trachomatis* infection are 2.16 times more likely to give birth prematurely than healthy women. Harald et al.^[88] (2003) explored the relationship between bacterial vaginosis and preterm delivery in a meta-analysis. They reviewed 18 articles, finding that bacterial fibrosis increased the risk of preterm delivery (OR, 2.19; 95% CI, 1.54–3.12) and even spontaneous abortion (OR, 9.91; 95% CI, 1.99–49.34). These results are in line with those of case-control articles reviewed in the current paper. Weihua et al.^[89] investigated the association of *C. trachomatis* infection with pregnancy outcomes in a meta-analysis. In

their review of 50 articles, they reported that *C. trachomatis* infection increased the risk of preterm delivery in 30 articles (OR, 1.731; 95% CI, 1.343–2.230); also, the review of 18 studies showed a significant relationship between *C. trachomatis* and rupture of membranes (OR, 2.574; 95% CI, 1.213–5.464; $p = 0.014$). Also, in four studies, no relationship was found between chlamydia infection and neonatal stillbirth (OR, 0.993; 95% CI, 0.489–2.015; $p = 0.984$). In this paper, similar to our study, there were few studies on stillbirth outcomes. In general, the results of the present meta-analysis suggest that the ORs obtained from different subgroups after merging the case-control studies have a narrower CI, which is due to the larger number of studies compared to cohort studies examining the relationship between vaginal infection and pregnancy outcomes; however, the built-in bias should also be taken into account. The main strength of our study lies in the review of ample articles as case-control and cohort studies, as well as the comparison of the results obtained from these two types of studies in different subgroups. Another strength of our study is the analysis of literature based on sample type, infection type, and testing. This helps identify the sources of heterogeneity in the overall meta-analysis estimate. One of the limitations of the present meta-analysis is the small number of studies in some subgroups by the type of study. Also, to estimate all pregnancy outcomes, the number of studies was limited.

Conclusion

Based on the results of this meta-analysis, the presence of bacterial infections in pregnant women can lead to increase the risk of pregnancy outcomes, especially infant birth, preterm delivery, abortion, stillbirth, and ectopic pregnancy. So, it is necessary that the health policy makers develop new healthcare programs with an emphasis on the implementation of support programs to early detect bacterial infections in pregnant women. As well as it is recommended to conduct appropriate intervention studies

in order to evaluate the intervention programs formulated in different societies and to select the best intervention with the greatest effect to reduce these infections in the pregnant women.

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Conflicts of interest

Nothing to declare.

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Effectiveness of Community-based Obesity Intervention for Body Weight, Body Mass Index, and Waist Circumference: Meta-analysis

Abstract

Background: Obesity is a significant health problem worldwide and an alarming problem in the developed world including the United States of America and European populations. Subsequently, obesity can lead to different health problems, such as non-communicable diseases. However, it can be prevented through a healthy diet, exercise, and lifestyle modification. The study's purpose was to analyze the published literature on community-based obesity interventions and to present a comprehensive summary of how to reduce the body weight, Body Mass Index (BMI), and Waist Circumference (WC) among overweight and obese individuals in the community through health education and behavior interventions. **Material and Methods:** The meta-analysis was conducted in February–July 2021, searching CINAHL, Cochrane Library, Google Scholar, PubMed, and Science Direct databases. Studies published during the prior 12 years on community-based obesity intervention for weight, BMI, and WC were included in this review. Cochrane Revman software was used for meta-analysis. **Results:** Seventeen studies met the selection criteria for the review. A meta-analysis of the studies on health education and behavioral intervention studies resulted in a statistically significant reduction at 95% confidence intervals in the mean differences of BMI -1.19 (-1.77, -0.62) and WC -1.11 (-1.54, -0.68). **Conclusions:** Community-based obesity interventions through health education and behavior interventions effectively reduce the body weight, BMI, and WC. Implementing community-based health education and behavioral interventions effectively prevents and treats obesity in communities.

Keywords: Behavioral modification, body mass index, community-based, health education, obesity

Introduction

Obesity is the leading cause of chronic and non-communicable diseases, and it has now replaced infectious diseases as the leading cause of ill health.^[1] The abnormal or excessive fat accumulation in the human body is referred to as obesity or overweight and does present a health risk.^[2] Obesity is a complex, multi-factorial condition resulting from specific genotypes and environmental interaction.^[3] Several factors such as, but not limited to, social, behavioral, cultural, physiological, metabolic, and genetic factors all play a role. Obesity affects human health directly or indirectly in association with other problems like diabetes type 2, Coronary Artery Diseases (CADs), osteoarthritis, respiratory problems, and others.^[1] Moreover, obesity may lead to other adverse health outcomes including hyperlipidemia, stroke, gallbladder problems, and sleep apnea.^[4] Apart from

chronic and non-communicable diseases, it may also lead to problems related to mental health and impaired quality of life.^[5] Besides physiological and anatomical consequences in the human body, obesity also has behavioral and psychological implications. Persons who are overweight and obese tend to be stigmatized, leading to psychological challenges including disturbance in body image. Usually, a slim and physically active person is considered attractive as compared to an obese person.^[6] Furthermore, obesity is a significant health problem globally, and an estimated 37.70% of adults and 17% of children are obese in USA.^[7] According to WHO, over half of the European population is overweight, and 30% is obese.^[8] Pakistan is a developing country, and its population also suffers from the heavy burden of obesity. According to Tanzil and Jamali,^[9] 22% of men and 37% of women living in urban areas of the

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country are obese, whereas Zahid, Claussen, and Hussain^[10] reported that in rural areas of Pakistan, 26% of women and 18% of men are overweight and 20% of women and 8% of men are obese.

The three most commonly used measures of obesity are the Body Mass Index (BMI), Waist Circumference (WC), and waist-to-hip circumference ratio (WHR). BMI is the ratio of body weight and height. Normal BMI is 18.5–24.90 kg/m². A person is overweight if the BMI is between 25 and 29.90 kg/m² and obese if the BMI is ≥ 30 kg/m².^[8] WC is also essential as increased WC is a risk factor. Normal WC for men is ≥ 101.60 cm and ≥ 88.90 cm in women.^[8] Factors contributing to obesity include a family history of obesity, the biological makeup of the body, sociocultural beliefs and practices, eating customs and eating habits, level of education, and socio-economic background. The most common theory about obesity is the imbalance between foods consumed and utilized for energy output. A person becomes obese when the food intake exceeds the body's requirements.^[11]

However, obesity can be prevented and treated in the community through health education and behavior interventions for achieving and maintaining a healthy body weight.^[11] Community health nurses can play a vital role in preventing and treating obesity in the community through community participation. Awareness among people regarding lifestyle modification, diet, and food management may also play a vital role in the prevention and treatment of obesity. People's motivation for physical activities and exercise helps in burning extra calories. This systematic review and meta-analysis aimed to identify and analyze the available literature and present a comprehensive review of the effectiveness of interventions (health education and behavioral interventions) for reducing body weight, BMI, and WC in overweight and obese individuals in the community. The review's findings can be used as evidence for community-based obesity prevention and weight management programs in Pakistan.

Material and Methods

This meta-analysis was conducted in February–July 2021. The inclusion criteria for the selection of the studies were original articles with RCTs and quasi-experiments, articles on interventions that include health education and behavioral intervention sessions for obesity prevention and treatment, studies with the outcome measure of body weight and/or BMI and/or WC, and studies conducted in the community. Gao, Griffiths, and Chan conducted an earlier systematic review on children, adolescents, and adults but included studies up to 2007.^[12] For this reason, studies conducted between 2009 and 2020 were included in the review. Studies with a primary focus on conditions other than obesity and studies on obesity treated in clinics were excluded from the review. A comprehensive literature search was done for selecting the most relevant articles. The

databases used were CINAHL, Google Scholar, PubMed, and Science Direct. Only articles published in English were included. The first Boolean operator 'OR' was used for keywords treatment of obesity, weight reduction, reduction in BMI, obesity prevention, and obesity elimination. The second Boolean operator 'AND' was used to combine these terms with the second search term community-based intervention OR health education and behavior intervention, community-based intervention OR health education and behavioral intervention. The third Boolean operator 'NOT' was used to limit the review to the adult population by excluding the terms children, childhood, infant, adolescents, and teenagers. A total of 4096 articles were retrieved. From PubMed, 1789 were retrieved; Google Scholar, 353; Science Direct, 1 055; and CINAHL, 899. After applying different filters like age >18 years, English language, quasi-experimental or RCTs, nursing and Medline journals, articles published between 2009 and 2020, and studies on the human subject only, the number of retrieved articles was 270. The primary investigator Aurang Zeb (AZ) did the data search, and the relevance was confirmed by a second researcher, Muhammad Haroon (MH).

All the articles shortlisted were imported to Mendeley Reference Management Software to identify duplicate articles, and after removing 125 duplicate articles, 145 were shortlisted for first-level screening. This screening entailed reading the abstracts and titles of the citation, and 60 articles were shortlisted. Second-level screening consisted of reading the complete text of the remaining articles. In the end, 17 studies met the inclusion and exclusion criteria and were included in the review [Figure 1. PRISMA Flow chart]. Studies selected on second-level screening were assessed through full-text review. The Hong *et al.*^[13] tool was used to assess the quality of RCTs and quasi-experimental studies selected in the review. Of these reviews, 16 were RCTs and one was a quasi-experimental study. The tool assessed RCTs on five required components and quasi-experiments on another five components. Out of a total of 17 studies, seven had all five required components, whereas the remaining 11 had four out of five required components. An Excel sheet was used to record the study description for data extraction, including sample characteristics, the independent variable (health education and behavioral interventions), the dependent variable (body weight, BMI, and WC), results, and statistical methods.

MS Excel 2010 was used for the descriptive analysis of data. The total number of participants, percentage of men and women, the mean age of the participants, marital status, type of intervention (behavior intervention alone or a combination of education and behavioral interventions), and duration of the intervention (<6 months, 6 months to 1 year, 1 year and above) were measured. Means of mean differences in body weight, BMI, and WC between intervention and control groups were calculated. The meta-analysis used the Cochrane Review Manager

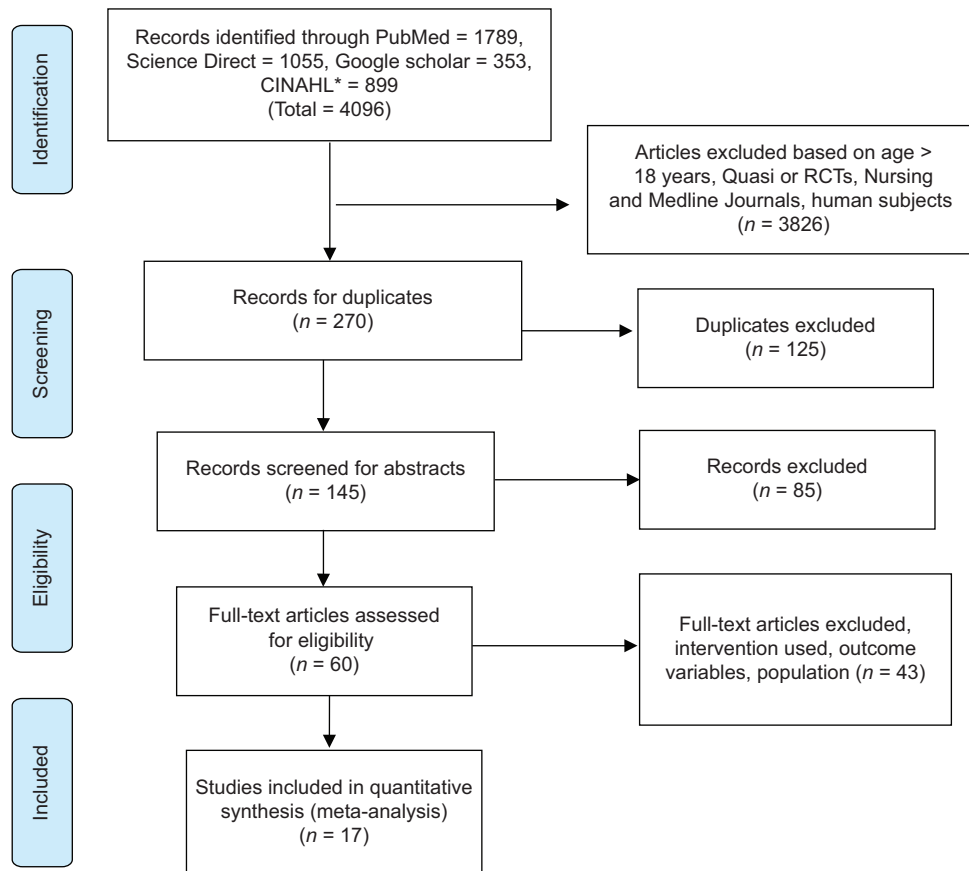


Figure 1: PRISMA Flow Diagram. *Cumulative Index to Nursing and Allied Health Literature

Software to calculate the 95% Confidence Interval (CI) of the mean, which was used to describe the probability for BMI and WC. CIs were used because they provide the variation around where the actual value of the mean lies. Therefore, the reviewer could state that they are 95% confident that the true population mean is within the given interval range. CI not only gave us the range within which the true population mean lies but also gave us the direction and the strength of the effect, which was essential for clinical decisions. As the CI does not contain NULL, the results can be interpreted as statistically significant between the intervention and control groups. Forest plots for BMI and WC were also generated.

Ethical consideration

An ethical review was granted by the ethics committee at Shifa Tamee-e-Millat University in March 2021. The ethical certificate was issued on October 14, 2021, with reference number IRB#351-21. The researchers avoided any form of plagiarism, and the data were analyzed with honesty without any fabrication, falsification, or manipulation of data for their benefit.

Results

All the 17 studies selected for this review are described in Table 1. The descriptive characteristics of the studies are

given in Table 2. The second table also shows the different studies and the durations for intervention; three studies used less than 6 months, eight studies used 6 months to 1 year, and the remaining seven studies used 1 year or more. Three studies in the review used behavioral interventions, while the rest used both health education and behavioral interventions. Studies with both education and behavioral interventions resulted in a significant reduction in BMI and WC when compared to studies with behavioral interventions alone. The analysis revealed that studies conducted for less than 6 months resulted in lower mean differences in body weight, BMI, and WC between control and intervention groups compared to the studies with a duration of 6 months or more.

The Forest plot with the CI for BMI is given in Figure 2. Nine studies were included in the meta-analysis for BMI. The CI of -1.19 (-1.77, -0.62) demonstrates a statistically significant difference between the experimental and control groups, favoring the experimental group. A meta-analysis of 10 studies was performed for WC. The Forest plot demonstrates that the intervention significantly contributed to a loss in WC with CI -1.11 (-1.54, -0.68) as displayed in Figure 3.

The funnel plots for the studies included in the meta-analysis for BMI and WC were constructed to

Table 1: Studies included in the review

Study	Study Characteristics	Mean Difference BMI* kg/m ² **	Mean Difference WC*** inches	Mean Difference Body weight Kg's****
[14]	66 participants were divided into equal control and intervention groups, 80.30% were females, 71.40% have < high education, and 82.40% were married. The study duration was 4 months. Both education and behavioral intervention were used.	-0.99	0.50	-0.73
[15]	A total of 90 participants including 38 in intervention and 52 in control groups, mean age was 49.65, and the study duration was 6 months. Both education and behavioral interventions.	---	---	-4.21
[16]	94 females in the intervention and 91 in a control group with a mean age of 35.40 years, 59.60 have < high schooling, the study duration was 1 year. Both education and behavioral interventions.	-0.60	---	-1.40
[17]	166 participants in the quasi-experimental of 3-month duration have a mean age of 41.50 years, 98% females, 85% married. Both education and behavior interventions.	-0.26	-3.80	-30
[18]	131 participants, equally divided in intervention and control groups with a mean age of 55.24 years and 70.20% have < high school education. The study duration was 6 months using behavioral intervention only	-0.47	-0.97	-3.63
[19]	300 participants were equally divided into intervention and control groups with a mean age of 49 years, 80% of females, 59.50 have < high schooling. The study duration was 6 months. Both education and behavioral interventions.	-3.90	-1.60	-4.20
[20]	495 participants divided into intervention 259 and control 233, all females with a mean age of 39.50 years, 57% have < high school education. The study duration was 6 months. Both education and behavioral interventions were used.	---	---	-0.48
[21]	239 participants with a mean age of 46.80 years, 83.30% of females with 70% have < high schooling. The study duration was 6 months. Both education and behavioral interventions.	---	---	-5.90
[22]	86 female participants in control and intervention groups each, with a mean age of 53.50 years, 52.50% have < high schooling, and the study duration was 6 months. Both education and behavioral interventions.	---	---	-0.96
[23]	333 participants in intervention and control groups each, with mean age of 53.70 years, 78% females. The study duration was 12 months. Both education and behavioral interventions.	---	---	-1.50
[24]	184 participants including 109 in intervention and the rest in control groups, mean age of 52.10 years, 50 have < high schooling, and 95% married. The study duration was 12 months. Both education and behavioral interventions.	-0.15	-0.17	-0.79
[25]	151 in intervention and 150 participants in control, 58% females, the study duration was 12 months. Both education and behavioral as interventions.	---	-4.80	---
[26]	351 participants were equally divided into two groups, the mean age is 50.70 years, 68% females, 49% married. The study duration was 6 months, and behavioral interventions only.	-1.40	-3.30	---
[27]	29 out of 97 in intervention and the rest in control groups, with a mean age of 56 years, 92% females. The study duration was 6 months. Both education and behavioral interventions.	---	---	-1.20
[28]	61 participants were divided into the intervention 29 and control 32, mean age of 49.50 years, 77% females, and the study duration was 8 months. Both education and behavioral interventions were used.	-4.49	-2.20	-1.82
[29]	480 participants were equally divided into intervention and control groups, mean age of 66.80 years, 53% females and 85.60% having < high school education, the study duration was 18 months. Both education and behavioral interventions were used.	---	-3.74	-3.19
[30]	74 participants were equally divided into intervention and control groups, the mean age of 61 years, 50% females, and the study duration was 12 months. Both education and behavioral interventions were used.	-2.60	---	---

*Body Mass Index. ***Kilogram Per Meter Square. ***Waist Circumference. ****Kilograms

identify publication bias. Both funnel plots are symmetric, in Figures 4 and 5. It is important to draw awareness that demonstrating a low likelihood of publication bias given there was significant heterogeneity among the included

Table 2: Demographic Characteristics of the Participants in the Studies

Category	No. of studies	Total participants	Women (n) %	Mean age (In years)	Mean (SD)* difference in weight (kgs)**	Mean (SD) difference in BMI*** (kgs/m ²)****	Mean (SD) difference In WC***** (inches)
General	17	4135	(3183) 77	51	-2.44 (1.74)	-1.68 (1.49)	-3.71 (2.68)
Duration of the study							
Less than 6 months	3	293	(161) 55.4	45.50	-1.85	-1.91	-1.833
6 months to 1 year	7	1694	(1338) 79.10	50.30	-1.94	-2.56	-2.02
1 year and above	7	1723	(1120) 64.60	53	-2.55	-2.11	-3.55

*Standard Deviation. **Kilograms. ***Body Mass Index. ****Kilograms Per Meter Square. *****Waist Circumference

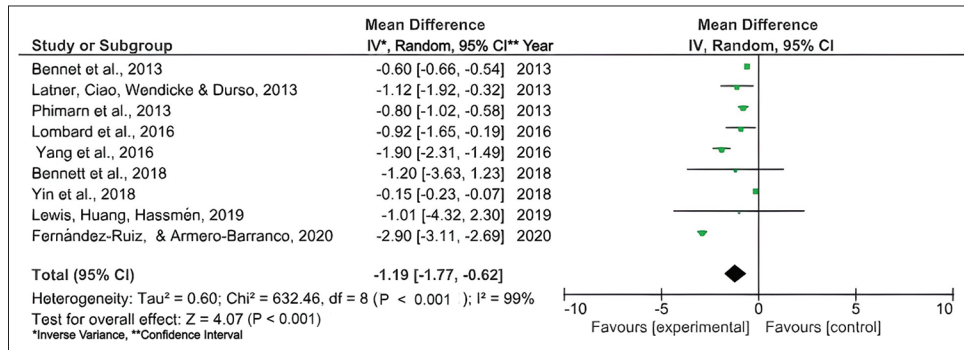


Figure 2: Forest Plot for BMI

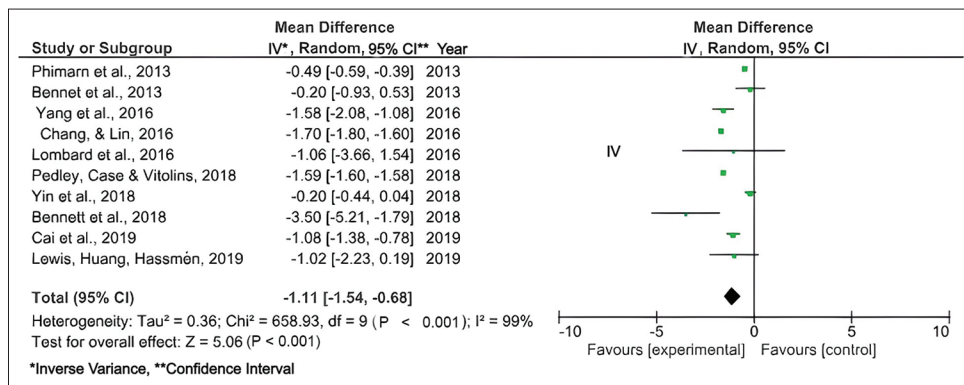


Figure 3: Forest Plot for WC

studies, with both having an I² of 99%, meaning there was considerable heterogeneity between the included articles.

Discussion

The current meta-analysis has been done on studies conducted during the last 12 years on obesity interventions including health education and behavioral interventions in the community to evaluate the effect thereof on BMI and WC. The findings of the study are compared with the literature. An earlier review on community-based obesity prevention in an adult population by Gao, Griffiths, and Chan^[12] included 20 studies. Their review concluded that community-based obesity interventions were effective in reducing weight and BMI. The present review confirmed these findings.

The review's strengths included the topic's importance and the literature available. Furthermore, the supervisory team's contribution and expertise were also strengths. The findings of the current meta-analysis supported the recommendation that obesity can be prevented and treated comparatively inexpensively in the community through health education and behavioral intervention. It is imperative that the government take the necessary action to initiate policies about obesity prevention and treatment services in the community. Media can be used to generate awareness among people about obesity and its associated morbidities and mortalities can reduce the epidemic of obesity.

This review has some limitations. The study included articles from Nursing and Medline Journals and lacked studies from gray literature like conference proceedings,

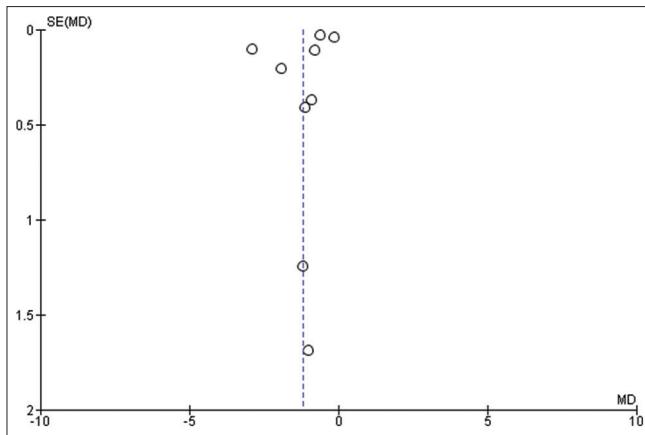


Figure 4: Funnel Plot for studies on BMI**. *Body Mass Index

doctoral desertions, and agency reports. The review was limited to the English language only. There might be studies done in languages other than English. Also, China, Taiwan, Singapore, and Japanese populations have different skeletal mass and body fat ratios as compared to the Western population.^[31] Studies published in local languages in these Asian countries may have helped in the current review. Studies included in this review have focused on health education and behavioral interventions only, so further research on other interventions like compliance to exercise and adherence to a healthy diet may be helpful strategies for obesity reduction in the community. The dependent variables measured in this review were limited to weight, BMI, and WC. Further studies can include other variables like waist and hip ratio, blood cholesterol level, and other physiological measures that may even produce valuable results.

Conclusion

This meta-analysis established that the implementation of health education and behavior interventions significantly reduces BMI (CI-1.19 (-1.77, -0.62)) and WC (CI -1.11 (-1.54, 0.68)). It is recommended that both strategies be implemented in a community-based obesity prevention and weight management program to alleviate obesity in the community. The support of comprehensive community health programs can provide health education about optimum weight, obesity, complications, and treatment.

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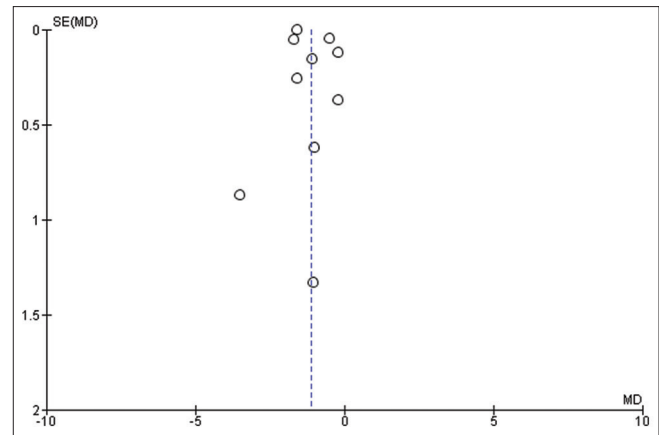


Figure 5: Funnel Plot for studies on WC*. *Waist Circumference

Conflicts of interest

Nothing to declare.

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Implementing the Verbal and Electronic Handover in General and Psychiatric Nursing Using the Introduction, Situation, Background, Assessment, and Recommendation Framework: A Systematic Review

Abstract

Background: Patient handover (handoff in America) is the transfer of information and accountability among nurses assigned to patient care. Introduction, Situation, Background, Assessment, and Recommendation (ISBAR) is currently the most popular framework for framing handovers. However, research shows that incomplete handovers and information transfers among healthcare providers and nurses exist and are responsible for adverse patient events. **Materials and Methods:** The current systematic review aims to view contemporary literature on handover, especially but not exclusively in psychiatric settings, and to extract current conditions from Electronic Patient Records (EPRs) using the ISBAR framework. A total of fifty-five scientific papers were selected to support the scoping review. Eligibility criteria included structured research to analyze outcomes, completed by reviewing policy papers and professional organization guidelines on I/SBAR handovers. **Results:** Our systematic review shows that the application of ISBAR increases interprofessional communication skills and confidence and the quality of the transfer of clinical information about patients, resulting in increased patient safety and quality of care. **Conclusions:** Implementing the knowledge and application of structured patient handover will respond to current recommendations for service improvement and quality of care. Furthermore, nurses who use ISBAR also reported its benefits as they feel they can deliver what is required for patient care information in a structured, fast, and efficient way. A further increase in the efficacy of handovers is reported by using EPR.

Keywords: *Medicine, nursing, patient handoff, patient handover, psychiatric nursing*

Introduction

A nursing handover occurs when one nurse transfers patient care to another; for example, each patient is discussed on average at the end of a nursing shift.^[1] There are several ways to carry out handovers in daily practice, including verbal handovers, reading from the patient's medical records, or a combination of both; some patients participate in handovers at their bedside to exchange information with their carers.^[1] It is reported that one of the most crucial steps in a patient's journey is the clinical handover, a core skill that must be taught to junior clinicians and health professions students.^[2] However, despite clear frameworks and guidelines for providing clinical handovers, these are frequently poorly performed, often with omitted necessary details and irrelevant points included.^[2] Instead, implementing a systematic, standardized

handover framework, such as Introduction, Situation, Background, Assessment, and Recommendation (ISBAR), may enhance patient care outcomes.^[2] A handover is a procedure for shifting accountability from a sender to a recipient via communication, information transmission, interaction for ambiguity resolution, and context-sensitive patient care management.^[3] Clinical handover, or "handoff" in North America, is when part or all of the professional responsibility and duty for caring for a patient or group of patients is temporarily or permanently given and communicated to another person or group of professionals.^[4] Clinical handover is also a direct transfer of information about patients, supporting the circulation of clinical accountability and responsibility among healthcare professionals to enable continuity of care for the patient and facilitate

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shared awareness of patients' conditions and planned management.^[5,6]

However, broken communication links between healthcare professionals and during verbal and written handovers about patients are responsible for 25% to 40% of adverse patient care events, 27% of cases of clinical misconduct, and over 70% of warning clinical incidents.^[7] An investigation of 23,000 medical malpractice lawsuits found that more than 7,000 were caused by communication breakdowns among caregivers during patient handovers, resulting in about 2,000 preventable deaths and 80% of serious medical errors.^[8] On the other hand, electronic health records in nursing have been suggested to reduce clinical mistakes, improve handoffs, and fill in information gaps by ensuring data flows smoothly and consistently between health providers.^[9] A series of National Health Service (NHS) in the UK white papers encourage implementing electronic patient handover, indicating that the goal is to make patients' clinical data available to any involved staff member, wherever they are.^[10]

We aimed to conduct a systematic review to provide a qualitative perspective on how and why structured patient handover/handoff are accomplished. We also aimed to offer a pathway to implementing a politic of inclusion in health care and a preferential instrument for communicating salient data about patients. Without proper patient handover/handoff, there is missing data in patient care, and challenges ensue in completing care plans. Our preliminary meta-analysis could not capture more naturalistic aspects of clinical handovers. Instead, the current systematic review follows our previous research, highlighting that interprofessional team performance bottlenecks are linked to communication impasses in handovers.^[11] The present review thus aimed to collect existing literature on clinical handovers to extract the outcomes of I/SBAR training and its application in clinical practice healthcare settings.

Materials and Methods

The current systematic review lasted from August 2022 to February 2023, and the publication date of the extracted issues was expanded to include historical findings when a theoretical and applicative argument was presented. During this period, our team collected evidence for a systematic review to condense the results of target journals and extract relevant similarities and topics for discussion.^[12] The study was part of a project sponsored by the local health authority and university. The current systematic review included peer-reviewed articles, dedicated websites on target topics, and books. The review also included government and policy websites, quantitative, qualitative and mixed-method research, professional guidelines, and white papers from nursing and medical organizations. A narrative analysis of a systematic review focuses on plausible truth and synthesizes topics studied by different research perspectives while interpreting findings that

transcend specific disciplinary boundaries.^[13] The aim is to make a compelling case based on expert knowledge that can win over a panel of peers; the author of a narrative analysis of a review is responsible for accurately portraying the supporting evidence (including original research) and how that information was used to arrive at the review's findings in the written output.^[14]

All the articles selected were in English or translated into English. Exclusion criteria were studies where I/SBAR was a marginal finding, and the investigation did not primarily focus on it. We included policy articles on I/SBAR in mental and medical settings to extend the review's meaning. Exclusion criteria were other systematic reviews. Articles not in English were also excluded. The keywords used in PubMed/Medline search were "ISBAR, SBAR, patient handover*, nursing, electronic handover, psychiatry*, mental health, patient handoff, electronic patient record*, electronic medical record*, communication, information, setting*, mental health, nursing, and policy." The same applied to the other search engines. The keywords were aggregated with the Boolean connectives AND, OR, and NOT. Database searches for electronic sources were conducted at the local University Online Library, Web of Science, Medline/Pubmed, Embase, ERIC, Scopus, and ProQuest.

PRISMA flowchart summarized the literature search outcomes [Figure 1]. Extracted data contained the outcomes of the individual studies.^[15] At least two researchers scrutinized the extracted literature and articles, one being the principal author (CL) while the other unauthored author supervised the review. All the extracted papers were reviewed manually. We used the Population, Intervention Outcome (PIO) framework as an extraction method.^[16] For the quality assessment, we employed Cochrane ROB-2 software to evaluate biases.^[17] CL and MR (unauthored) appraised all studies, and disagreements with the other unauthored researcher were discussed between the two. In the case of any dispute, the opinion of a more experienced person or a third person was considered. Study quality was not a factor in inclusion or exclusion criteria, as per the Arksey and O'Malley scoping review framework.^[18] This framework includes some recommendations such as stage one: clarifying and connecting the purpose and research question; stage two: balancing feasibility with the breadth and comprehensiveness of the scoping process; stage three: using an iterative team approach to selecting studies; stage four: incorporating a qualitative thematic analysis; stage five: including stakeholder interaction as a necessary knowledge translation component of the scoping research approach; and stage six: considering the implications of study findings to policy, practice, or research.^[19] A total of 50 documents were retained for the study after being screened for quality and relevance to the review topic. We extracted population, settings, interventions, and outcomes [Table 1]. The current review

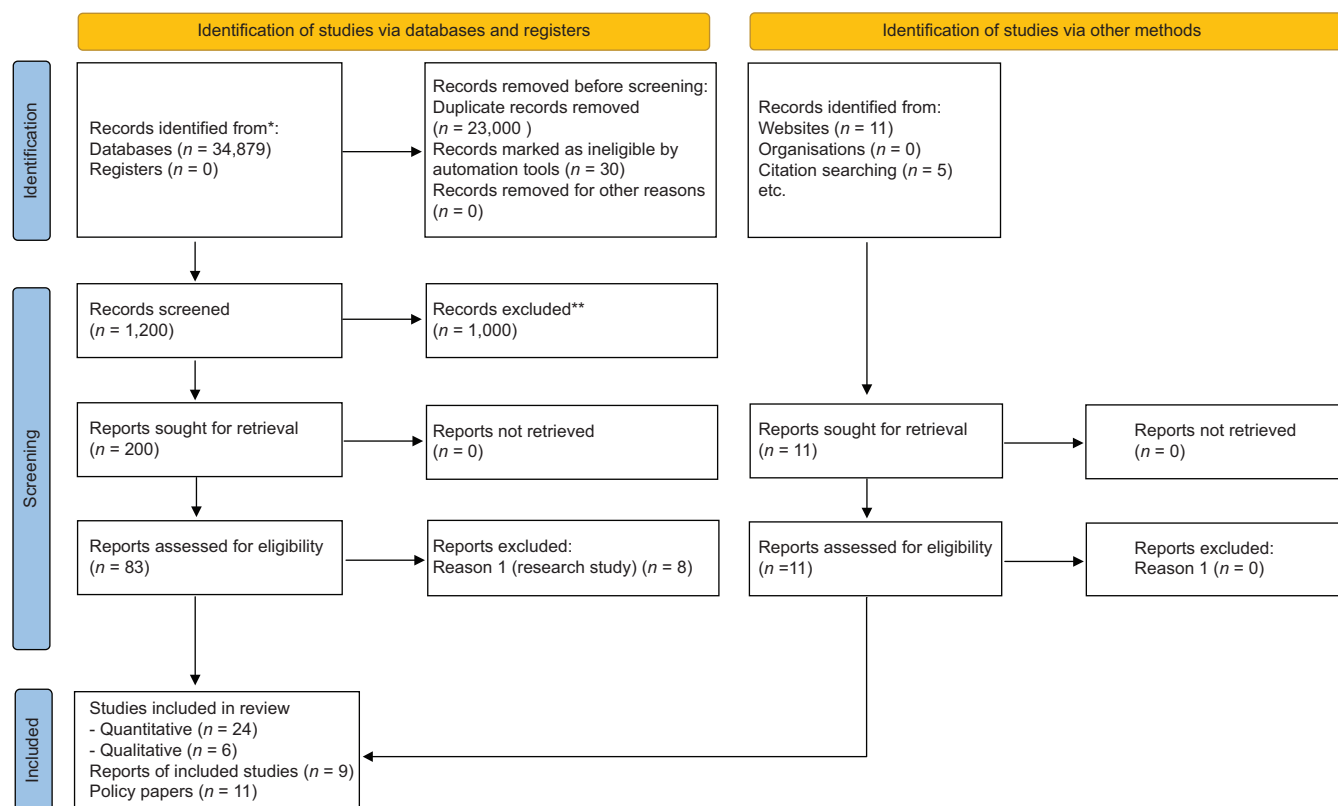


Figure 1: PRISMA flowchart. *Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers). **If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools. *From:* Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: <http://www.prisma-statement.org>

did not require ethical approval from local health and academic authorities.

Ethical considerations

The current study is a systematic review. It did not imply direct contact with a sample of people. The author did not have direct participation of human subjects or involvement in an experimental design. Data were collected from an online literature search and not from hospital depositories. No ethical approval was essential for the current study. According to the Declaration of Helsinki, facts were published with the authors endorsing and supervising the findings' comprehensiveness and correctness.

Results

ISBAR handover is a communication proficiency that the US Navy made to help submarines talk to each other clearly and accurately; the World Health Organization has backed ISBAR handover to provide a standard way of speaking that can be used in many clinical settings, such as shift changes, patient allocations for tests or appointments, inter-hospital transfers, and escalation of a patient who is getting worse.^[2] A structured clinical handover enhances patient safety and care by reducing communication mistakes within and across health carers while increasing the likelihood that crucial information

will be correctly conveyed and acted upon during the care transition.^[45] Additionally, electronic handover ensures quick interprofessional sharing of patient information and is easily reachable by all the healthcare providers involved with the same patient.^[46]

The Australian Commission on Safety and Quality in Health Care has created the following protocols for patient handover, often known as the transfer of care: (1) the event, such as patient admission, referral, or discharge during shift changes or patient movement within or between a hospital, unit, or services; (2) the handover approach, which can use face-to-face or telephone communication, written instructions, and electronic handover tools or systems; (3) a clinical handover location, such as at a patient's bedside in a shared staff area at a hospital or clinic reception, (4) who takes part in clinical handover, such as all health carers' working for the same organization, multidisciplinary teams of health carers from various organizations or agencies, a treating clinician, and a patient with their family or caretaker (e.g., ambulance officers and emergency workforce).^[47]

From the extracted studies, the primary outcomes deriving from the application and learning of I/ SBAR clustered around the following domains: (1) increased communication and handover skills and

Table 1: Summary of findings, outcomes, and quality assessment

Authors	Setting and population	Interventions	Rob-2 Quality Assessment ^{****,*****}						
			Outcomes ^{***}	D1	D2	D3	D4	D5	OA
Kostoff <i>et al.</i> , 2016 ^[20]	School of Pharmacy	Simulation-based on SBAR where pharmacy and nursing students were, respectively, sender and receiver	O1	⊕	⊕	⊕	⊖	⊕	⊕
Choi & Chang, 2023 ^[21]	Nursing home emergency	Interviews on SBAR application and network analysis on data from semi-structured, face-to-face interviews	O4	⊖	⊕	⊕	⊖	⊖	⊕
Hum 2019 ^[22]	Nursing school	Impact of SBAR on communication performance, perception, and practicum-related outcomes in senior-year nursing students.	O1	⊕	⊕	⊕	⊕	⊕	⊕
Lee & Kim, 2020 ^[23]	Nursing school	Team task performance was categorized into two phases: the initial team performance before a call to a mock doctor and the team task performance after receiving verbal instructions from a doctor via phone.	O3	⊖	⊕	⊕	⊖	⊕	⊕
Shrader <i>et al.</i> , 2015 ^[24]	PharmD fourth year	Simulation with standardized colleagues.	O3	⊖	⊕	⊕	⊕	⊖	⊕
Barnett <i>et al.</i> , 2017 ^[25]	PharmD students	Simulated interactions with healthcare providers.	O2	⊖	⊕	⊕	⊖	⊖	⊕
Acharya <i>et al.</i> , 2016 ^[26]	School of psychiatry	Three-hour sessions in simulation education.	O2	⊖	⊕	⊕	⊕	⊖	⊕
Brust-Sisti <i>et al.</i> , 2019 ^[27]	Pharmacy school	Simulated telephone intervention.	O1	⊖	⊕	⊕	⊕	⊖	⊕
Jeong and Kim, 2020 ^[28]	Nursing college	Handover skills.	O1	⊖	⊕	⊕	⊕	⊖	⊕
Noh & Park, 2022 ^[29]	Nursing college	Simulation with 200-minute sessions for 15 sessions.	O1, O2	⊖	⊕	⊕	⊕	⊖	⊕
Cooper <i>et al.</i> , 2019 ^[30]	PharmD and DPT* students	Educational intervention on SBAR and interprofessional education using an online audio-conferencing tool.	O2	⊖	⊕	⊕	⊕	⊖	⊕
Franko <i>et al.</i> , 2021 ^[31]	Nursing and medical school	Education in the use of SBAR.	O2	⊕	⊕	⊕	⊕	⊖	⊕
Chen <i>et al.</i> , 2020 ^[32]	Public hospital	The ISBAR** communication training impacts residents' interpersonal communication and teamwork in general practice standardized training.	O3	⊖	⊕	⊕	⊕	⊖	⊕
Yeh <i>et al.</i> , 2019 ^[33]	Nursing school	Communication performance.	O1, O2	⊖	⊕	⊕	⊕	⊖	⊕
Breen <i>et al.</i> , 2019 ^[34]	Nursing and medical school	Proficiency-based progression training approach to clinical communication in the context of clinically deteriorating patients.	O1	⊕	⊕	⊕	⊕	⊕	⊕
Marshall <i>et al.</i> , 2009 ^[35]	Medical school	Communication during telephone referral in a simulated clinical setting.	O1	⊕	⊕	⊕	⊕	⊕	⊕
Mutter <i>et al.</i> , 2021 ^[36]	Medicine and nursing school	Mock-paging interprofessional education.	O1	⊖	⊖	⊕	⊕	⊖	⊕
Janaway <i>et al.</i> , 2021 ^[37]	Mental-health settings	Survey about awareness of SBAR through its use and benefits.	O2	⊖	⊕	⊕	⊖	⊖	⊕
Abela-Dimech, 2018 ^[38]	Mental health settings	Impact of SBAR on 122 handovers.	O2	⊖	⊕	⊕	⊕	⊖	⊕
Lee & Jang, 2021 ^[39]	Mental health settings	SBAR simulation to improve communication skills.	O1	⊖	⊕	⊕	⊖	⊖	⊕
Ting <i>et al.</i> , 2017 ^[40]	Obstetric wards	One-hour session during monthly meetings.	O2, O5	⊖	⊕	⊕	⊕	⊕	⊕
Raurell-Torredà, <i>et al.</i> , 2021 ^[41]	Nursing school	The intervention group was trained in teamwork skills, role, and task assignment skills, and the use of the SBAR worksheet in a one-hour role-play training session.	O2	⊕	⊕	⊕	⊕	⊕	⊕
Spooner <i>et al.</i> , 2018 ^[42]	Public hospital	Checking if, after ISBAR training, there is an increase in completed core categories.	O1, O3	⊖	⊕	⊕	⊕	⊖	⊕

Contd...

Table 1: contd...

Kaltoft <i>et al.</i> , 2022 ^[43]	Post-anesthesia care unit	Nurses were interviewed about their satisfaction with the handover via an electronic survey.	O1	⊖	⊕	⊕	⊕	⊕	⊕
De Meester & Vespury, 2013 ^[44]	Public hospital	SBAR Training of Intensive Care Unit (ICU) nurses.	O1, O5	⊖	⊕	⊕	⊕	⊖	⊕

*doctor of physical therapy; **Introduction, Situation, Background, Assessment, and Recommendation, ***O1: increased communication and handover skills and quality; O2: increased confidence, preparedness, and self-efficacy; O3: increased interprofessional communication skills and confidence; O4: registered nurses are more frequent senders in communication exchanges; O5: increased patient safety. ****D1: Randomization process; D2: Deviations from the intended interventions; D3: Missing outcome data; D4: Measurement of the outcome; D5: Selection of the reported results; OA: Overall. *****Low risk: (+) ; Some Concerns: (!) ; High risk (-)

quality, (2) increased confidence, preparedness, and self-efficacy in those who applied the handover, (3) increased interprofessional communication skills and confidence, (4) registered nurses are more frequent senders in communication exchanges, and (5) increased patient safety. The quality analysis evidenced a limited number of randomized controlled trials, although the overall risk of bias was low for all studies. The settings where I/SBAR was promoted or trained included nursing schools, medical and pharmacy schools, general hospitals, or specific healthcare departments. Most stakeholders from I/SBAR training were nurses and other healthcare professionals in any area of specialization [Table 1].

The basic psychiatric assessment and handover in the UK is any information about a patient that is structured to include reasons for admission and how the referral occurred, the history of the current presentation, personal history, family history for psychiatric conditions, past psychiatric history, medical history, risk assessment, mental state (behavior, speech, mood, thought, perceptions, and cognition), diagnostic impression, treatment plan, capacity, and insight.^[48] Hence, a similarity exists between ISBAR and routine psychiatric handover.

From an initial systematic review of the literature, it was found that, at the current moment, there is no study about the use of ISBAR on electronic handover in psychiatry. Two extracted studies only report the use of electronic handover, but no mention is made of ISBAR. Studies on ISBAR were conducted in medical, nursing, or pharmacy schools but not in psychiatric settings, apart from the research by Koli and Filippidou.^[49] In summary, from the initial search, limited studies have been conducted on ISBAR as a template for electronic handover in psychiatry.

Other qualitative studies do not provide sufficient ground to make recommendations about the effect size of ISBAR in mental health settings.^[50,51] A paper in a psychiatric setting using verbal ISBAR showed that nurses scored highly in all sections of handover; at the same time, trainees and medical personnel mainly focused on the “assessment and recommendation” sections.^[49] A study regarding the application of SBAR (an ISBAR without an “Introduction”) was undertaken among mental health

professionals; the results indicate that mental health nurses expressed knowledge of the SBAR, ease of use, actual use, better efficacy in communication, and value in comprehending patients.^[37] In the second study, conducted in Canada, psychiatric nurses were audited with questions about handover; they reported an increase in confidence, preparedness, and self-efficacy in those who adopted SBAR or ISBAR handover.^[38] After scenario-based training in ISBAR with psychiatry nurse trainees, these last reported feeling more empowered when interacting with senior colleagues and a better understanding of the part of other professions in the handover process.^[26]

A uniform, standard method of communicating patient information increases compliance with and clarity of handover procedures; at the same time, pre-set forms rather than open text templates are advantageous, according to research into electronic handover within medical and surgical specialties.^[52] Furthermore, psychiatric handovers are often incomplete. It is hoped that electronic handovers in health care might fill information gaps while improving information sharing among all caregivers linked to a communal patient record.^[52] Information that might also go on EPR is (1) data related to the current illness; (2) diagnosis or previous diagnoses; (3) warning signs or significant symptoms; (4) work or other information related to private life; and (5) any information related to therapy, such as duration, steps to increase compliance, and other aspects of care.^[52] After patients with a mental or medical health condition are cleared from the hospital, they usually have EPRs readily available to the community team for the after-discharge follow-up.^[53]

To lessen the likelihood of misunderstanding or miscommunication between the nursing profession and the patient, handover communication protocols are intended to assist nursing staff in organizing their handover communication and presenting patients’ information logically and coherently.^[54] Therefore, a structured communication framework for nurse handover is beneficial in ensuring that clinicians cover every crucial piece of information.^[55] A handover also allows the giver and the recipient of the communication about the patient’s data to obtain clarification.^[7] Furthermore, a structured,

standardized clinical tool for handovers may help decrease technical mistakes and high-risk events by efficiently delivering correct and complete clinical information with fewer omissions.^[56] Moreover, a handover communication system facilitates collaboration among hospital staff members at various hierarchy levels and multidisciplinary clinical teams.^[57]

Our systematic review has confirmed the importance of endorsing routine ISBAR handover in all clinical practices. Handovers also improve interprofessional performance and reduce team communication bottlenecks if there is a lack of clear directives on sharing essential clinical information among team members. Furthermore, handover training and application reinforce nurses' self-esteem while reducing information gaps and the likelihood of adverse clinical effects in patient care. The global outcome is improved practice, improved quality of care and safety, and enhanced self-esteem in health carers who apply ISBAR and optimize data transfer within teams involved with the same patient's care. Evidence of these outcomes was extracted from current literature on the topic. However, despite the limited studies on long-term effects and randomized controlled trials of handoff training and application, preliminary data from different settings and studies confirm the applicability and usefulness of ISBAR handover on patient care.

Discussion

Several professional organizations in the UK are endorsing the need to implement SBAR/ISBAR handover. A patient SBAR handover is appropriate when it allows for planned out and moving patients between transferring and receiving teams, according to the National Institute for Health and Care Excellence, which guides and endorses good clinical practice in the UK.^[58] The Royal College of Nursing in the UK endorses studies reporting that poor communication is one of the leading causes of patients' dissatisfaction with health care; at the same time, there is strong evidence connecting team communication to treatment results.^[59,60] The Royal College of Physicians in the UK supports a study that suggests that providing safe patient care depends on effective communication; moreover, utilizing organized communication approaches, such as the SBAR handover, may increase patient safety.^[51] The NHS Institute for Innovation and Improvement in the UK encourages healthcare practitioners to understand the impact of SBAR handover on their communication interactions.^[61]

Traditional face-to-face interaction is increasingly being replaced (in the healthcare system) by a group of people collaborating across organizational, temporal, and spatial barriers using network connections and information technology.^[62] Through these last, the teams coordinate meetings and complete tasks; furthermore, dispersed team members may meet specified objectives without being constrained by distance or deadlines.^[63] A way forward is to incorporate the ISBAR template into EPR. The most

popular platform used by the NHS for EPR is RIO. This last is a comprehensive electronic system accessible to authorized healthcare providers, where each nurse and carer can provide their input regarding a patient according to their expertise; it is usually accessible in hospitals through validated intranet authorizations. In mental health practice, RIO handovers are the only documents practitioners can access for notes about patient presentation and progress. Around 20,000 mental healthcare professionals through six London mental health trusts routinely use RIO.^[63]

The RIO system has also brought about more extensive patient involvement with their care; all clinicians occupied in the care of a patient accrue into the same case record, which enables a care plan to be created, amended, and accessed more rapidly; clinicians assess the care plan with the patient and their carer on a flat panel screen—or even, in some multidisciplinary meetings, by projecting it onto a wall through a media projector—giving a new sense to patient involvement; this has been reflected in enhancements mentioned in a recent mental health service users' surveys, led by the Healthcare Commission.^[63,64] Before being granted access to RIO, all personnel in the NHS UK are officially trained. An electronic card allows access to RIO for authorized personnel only. EPRs have legal significance, and any event that occurs to patients is recorded on RIO. EPRs are accessible to all personnel linked to a patient. This electronic platform for handovers is a promising method of promoting quality in handover and reducing information loss, impacting the quality of care and patient safety. However, nurses might express fear and anxiety during handovers, sometimes likely to be due to their lack of handover training or hesitancy in being involved in it; however, because a handover is not an easy procedure and should be accurate, complete, specific, relevant, timely, up-to-date, subjective, and objective, such learning is required both during undergraduate educational programs and as part of in-service educational programs in clinical settings.^[65]

Yet, a two-fold increase in patients' mortality and duration of hospital stay is linked to poor communication between nurses and doctors.^[66] Furthermore, ineffective interprofessional communication can lead to patients' disappointment, errors in diagnosis or medication, deferred treatments, or even severe patient injuries.^[67,68] A systematic review of 11 studies found that mistakes in interprofessional communication can occur at any stage of communicating the ISBAR framework within a team, relating to the patient and consisting of (1) Introduction, where the presenter introduces herself, her role and where and why she is providing the handover inclusive of patient's biographical data such as gender, age, social, and living conditions, (2) Situation, where the communicator provides clarification on what is currently happening to a patient, (3) Background, is whatever has conducted to the current patient's situation, inclusive of previous hospital admissions, illnesses, and

contact with the healthcare services, (4) Assessment of the current clinical condition and (5) Recommendation for dealing with the current condition according to the carer's area of expertise.^[69] In research on 16,165 electronic records in Michigan, among the significant drawbacks in interprofessional communication were missing necessary communications, missing communication goals, skewed physical or temporal situations or contexts of the message, missing key participants, and unclear or missing information.^[70] On the other hand, note-taking throughout the handover procedure considerably reduces the quantity of lost information; if a printed handover sheet is used, 100% of the report is maintained, with just 1% of the information lost after five handovers; furthermore, the printed handover page is only helpful if the data on the written sheet is consistently updated.^[71]

The NHS UK policy is to implement EPRs and handovers to make patient information available to all staff, wherever they are.^[72] It is reported that illegible handwritten notes may happen as follows: (1) In clinics and hospitals, records may not be available because they have not been returned or are being used in another location; (2) paper records can only be in multiple locations simultaneously if they have been wholly photocopied; (3) paper records frequently lack important details or may not be available when a patient is seen; (4) records may be missing information due to a clerical mistake or a backlog in the filing room.^[73] On the other hand, electronic health records have been suggested to reduce clinical errors, improve handoffs, and eliminate information gaps by ensuring that information flows smoothly and consistently between health providers.^[64] More specifically, electronic handover is the transfer of information between healthcare providers involved with the same patient using different electronic platforms (e.g., computers, emails) where practitioners can share admission and discharge data and transfer information between shifts, teams, wards, health professionals, and services.^[64,73] Nonetheless, there may be a 100% loss of information after five handover reports if nurses rely solely on verbal modes of communication; in contrast, there is a greater chance of retention of information if nurses combine oral methods of contact with a typed handover sheet.^[74] Hence, structured clinical handovers have been found to enhance patient safety and care by reducing communication mistakes within and across health service organizations and increasing the likelihood that crucial information will be correctly conveyed and acted upon.^[45] In line with these findings, the current systematic review will extract salient points about the value of handover and its theoretical framework with applications in nursing practice.

Conclusion

The current review highlights the significance of relying upon a framework to structure handover in daily clinical

practice. The most popular handover nurses and health carers refer to is ISBAR. Most studies report that missing information and incomplete handover might cause clinical errors. On the other hand, structured handovers increase patients' safety and care. Using structured handovers boosts the feeling of self-efficacy in health carers while improving the clarity of their team communication. However, studies also indicate that handovers might be incomplete, and, in this case, there is misunderstanding and miscommunication between professionals, increasing the likelihood of medical errors. One way that is becoming prevalent is employing electronic handovers, which should solve many of the problems found in verbal and written handovers. The nursing policy should thus endorse the implementation of I/SBAR handover in all clinical and surgical specialties. Therefore, implementation research aims to comprehend and operate under real-world situations instead of attempting to account for or eliminate foreseeable circumstances as causative factors.^[75] The scientific study of strategies to encourage the systematic integration of clinical research findings and other evidence-based practices into daily practice, thereby enhancing the quality (effectiveness, reliability, safety, appropriateness, equity, and efficiency) of health care, is known as implementation research; it includes studies on factors influencing organizational behavior and the behavior of healthcare professionals.^[76] Efforts to improve handovers will be directed at this target. Yet, cautious conclusions should be made regarding the outcomes of the current review. The present study bears some limitations linked to the subjective methods of systematic reviews, which are informed by the author's instruments of selection and analysis of the extracted studies. Furthermore, the conclusions of a systematic review depend on the author's interpretations. Therefore, it was based on an interpretivism framework, which allows findings to be applied in different and similar settings and is subjective in generating theories yet under the bias of the researcher conducting the study and drawing the conclusions.^[77] Limitations of the current review are also linked to the reduced external generalisability of the study with threats; for instance, one limitation is the population of interest in a review.^[78] Other limitations are linked to the variety of settings and conditions that characterized the studies analyzed, accounting for the types of extracted outcomes. Although this review identified the nursing field as the population of interest, different settings, countries, and public or private practice might make a difference in the conclusions. Other limitations of the review reflect Rob-2 biases in the literature review about non-randomized studies, such as bias in the selection of participants (e.g., nurses from separate healthcare sectors), bias in the measurement of intervention (e.g., some studies used qualitative analyses, others quantitative ones), bias in the measurement outcome (e.g., the current review reports general effects on patient safety which are not measurable),

and bias in the description of the results (e.g., results linked to the risk of the poor handover were selected).^[79]

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Conflicts of interest

Nothing to declare.

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Knowledge and Practice of COVID-19 Preventive Strategies among Nurses

Abstract

Background: Knowledge of COVID-19 preventive measures, in addition to appropriate practices of such measures, remains a necessity for the prevention of contracting COVID-19 by nurses. This study assessed nurses' knowledge and practice of COVID-19 preventive strategies. It also determined the influence of sociodemographic variables on the knowledge of preventive measures for COVID-19 among nurses. **Materials and Methods:** The study adopted a descriptive cross-sectional survey design using multi-stage sampling to recruit 344 nurses. **Results:** The results showed that 92% of the nurses had adequate knowledge of COVID-19 preventive measures. The practice of COVID-19 preventive measures among nurses showed that 98.80% had sufficient knowledge of the infection preventive measures. Nurses with Registered Nurse/Registered Midwife (RN/RM-AOR 12.30; CI 4.79–31.63; $p = 0.001$) and Bachelor of science in nursing (BScN-AOR 37.60; CI 7.644–184.95; $p = 0.001$) were more knowledgeable about the COVID-19 preventive compared to other nurses with higher degree qualifications. **Conclusions:** The nurses in the study had good knowledge of the preventive measures for COVID-19 despite not being trained as frontline staff. It is essential to transform theory into practice by ensuring that the preventive measures they know are implemented to halt the spread of the disease in the face of minimal vaccine coverage.

Keywords: COVID-19, general practice, knowledge, nurses, prevention and control

Introduction

Coronavirus Disease 2019 (COVID-19) is a highly contagious and acute respiratory syndrome that has an enormous negative impact on people's health and well-being.^[1] It was first identified in Wuhan, China, and now spreads to almost all countries, including Nigeria. World Health Organization declared the virus a pandemic on March 11, 2020, and there are more than 296,496,809 confirmed cases of COVID-19, including 5,462,631 deaths globally. 246195 cases have been confirmed, 217509 patients have been discharged, and 3066 deaths have been recorded in 36 states and the Federal Capital Territory of Nigeria.^[2,3] The COVID-19 virus spreads through contact with infected persons' respiratory droplets in coughing or sneezing or by touching contaminated surfaces or objects and then touching their mouth, nose, or eyes^[4,5] of which practice of preventive measures as identified by World Health Organization (WHO) (2020) and Nigeria Centre for Disease Control (NCDC) (2020) required

health workers to be prepared and ready to respond to an outbreak, in particular, limit human-to-human transmission by way of implementing WHO recommended infection prevention and control interventions and identify, isolate, and report suspect and confirmed cases.^[5]

There have been a wide variety of studies globally on knowledge and practice for COVID-19 among healthcare workers and the general public.^[6-8] Studies have mostly focused on identifying which demographic and other variables are associated with different levels of knowledge and practice of COVID-19 preventive measures. Some of the studies include a study by Zhou *et al.*^[9] on healthcare workers' knowledge regarding COVID-19 preventive measures, which shows that healthcare workers across ten hospitals in Henan, China, 89% of HCWs had sufficient knowledge of COVID-19 preventive measures. Furthermore, other studies on knowledge and preventive practices for COVID-19 among Chinese women showed that most Chinese residents are knowledgeable about COVID-19, hold

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optimistic attitudes, and have appropriate practices toward COVID-19.^[10,11]

In Nigeria, however, the high infection and death rate of health workers due to COVID-19 and its related complications call for concern by various stakeholders in the health sector. Some studies have emerged on COVID-19 in Nigeria, including those by Olapegba *et al.*,^[12] Odikpo *et al.*,^[13] and a few others that were not specifically on COVID-19 knowledge practice preventive strategies for COVID-19 among nurses in Anambra State. Currently, preventive strategies are the critical intervention for controlling the spread in the face of limited vaccine coverage. Consequently, nurses are among the high-risk groups. They are to prevent the disease from spreading by carrying out basic measures while discharging their duties, such as hand hygiene, respiratory etiquette, social distancing, and proper Personal Protective Equipment (PPE).^[14] Therefore, understanding the need for change in behavior due to the current pandemic will go a long way in managing and controlling the spread of the disease. This study, therefore, assessed the knowledge and practice of preventive strategies for COVID-19 among nurses in Anambra State. It also determined the influence of sociodemographic data on knowledge and practice of preventative measures for COVID-19.

Materials and Methods

The study adopted a cross-sectional survey design. The study was conducted in Nnamdi Azikiwe University Teaching Hospital, Nnewi (NAUTH) and Chukwuemeka Odimegwu Ojukwu Teaching Hospital, Awka (COOUTH); these are the tertiary health institutions in Anambra State, Nigeria. The study was conducted in 2020, and the authors conducted data gathering between May 2020 and November 2020. Nurses were the target population. The sample size of 344 nurses for the study was determined using the Cochran (1977) formula^[15] for calculating categorical variables, $n_0 = (t)^2 \times (p)(q)/(d)^2$ where n_0 = required return sample size; t = value for the selected alpha level (type I error) which was set at 0.05. The t-value for alpha level of 0.05 is 1.96; p = maximum possible proportion is 0.5; $q = 1 - p$ (estimate of variance); d = acceptable margin of error for proportion being estimated = 0.05. This yielded a sample of 344 nurses; 121 from Chukwuemeka Odimegwu Ojukwu University Teaching Hospital, Awka, and 223 from Nnamdi Azikiwe University Teaching Hospital, Nnewi. The researchers adopted multi-stage sampling technique; in the first stage, proportionate sampling was used to allocate the number of nurses to be included in the study from various departments for proper representation. After that, a simple random sampling method was used by the researchers for the selection of respondents until each unit's required size was achieved. Researchers administered a questionnaire to the participants to obtain information on sociodemographic characteristics

such as age, sex, marital status, religion, qualification, cadre, and years of experience. Also, knowledge and practice of preventive measures for COVID-19 were assessed by the researchers among respondents using the researchers' questionnaire. Face and content validity of the instrument was done by research experts consisting of a microbiologist, health educationist, and medical statistician to evaluate the appropriateness of the content of the survey instrument. After the validation, the researchers used the validator's comments to adjust the tool before using it for data collection. For reliability, a pilot study was conducted using thirty randomly selected nurses at the University of Nigeria Teaching Hospital, Enugu, by the test-retest method to ascertain the instrument's reliability. The researchers subjected the data generated from the pilot study to the Cronbach alpha reliability test, and a reliability coefficient (r) of 0.87 was obtained. This result showed that the instrument is reliable. The questionnaire administered was completed in a self-report manner by the participants. Data were analyzed using Statistical Package for Social Sciences (SPSS) window version 25.0, manufactured by IBM software company at Stanford, Chicago. The data results were analyzed using mean and percentages and presented in tables and charts based on the research questions for straightforward interpretation.

Ethical considerations

The researchers obtained ethical approval for the study from Nnamdi Azikiwe University Teaching Hospital Research Ethics Committee with reference code NAUTH/CS/66/VOL. 13/VER 111/50/2020/035. The study participants were given adequate information on the study and only those who signed the consent forms participated. The study participants were assured of confidentiality, and the data set was anonymized to ensure privacy.

Results

The result of the demographic profile shows that majority of the respondents were within the age of 26–35 years 214 (62.20%), females 324 (94.20%), married 265 (77%), Christians 339 (98.50%), RN/RM double qualified 240 (69.70%), and senior nursing officers and nursing officer's 153 (44.50%) and 96 (26.70%). Years of experience for many nurses were 11–20 years 197 (57.30%). Result also shows that the majority of the nurses in the hospitals had no formal training on COVID-19 303 (88.10%).

Knowledge of nurses on preventive measures toward COVID-19 shows that they have the knowledge that COVID-19 can be spread through droplets and touching of contaminated surfaces 223 (64.80%), facemasks and goggles can be used to prevent COVID-19 207 (60.20%), and that appropriate disinfection and disposal of PPEs gown is a preventive measure to COVID-19 168 (48.80%). Also, following guidelines by WHO and NCDC could help one prevent COVID-19 202 (58.70%) and 245 (71.20%)

strongly agreed that COVID-19 could lead to pneumonia, respiratory failure, and possibly death [Table 1].

The majority of the nurses, 316 (92%), had adequate knowledge of COVID-19 preventive measures [Figure 1], and 163 (47.40%) were satisfied with the knowledge acquired so far on COVID-19, as depicted in Figure 2. Their sources of information on preventive measures for COVID-19 were mainly from health institutions (30.50%) [Figure 3].

On the practice of COVID-19 preventive measures among nurses [Table 2], the result shows that 340 nurses (98.80%) know all the infection preventive measures against coronavirus. A total of two hundred and twenty-four (65.10%) nurses maintained approximately 2 meters distance around an infected individual; hand washing was carried out mainly after any contact that resulted in hand contamination 335 (97.40%). Institutionally, availability of running water and soap for hand hygiene 308 (89.50%), availability of hand sanitizer 328 (95.30%), availability and use of surgical face mask when caring for patient 312 (90.70%), availability of isolation ward to admit confirmed COVID-19 cases 231 (67.20%), and use of privacy curtains between beds to prevent close contact 189 (46.20%) and also decontamination of patient wards, hospital environment, and high-touched areas were always done 62 (92.50%) as reported by the few that claimed to be involved in the decontamination process of their ward 67 (19.50).

The significantly associated variables were entered into a multivariate logistic regression model [Table 3], and analysis showed that nurses who had RN/RM (AOR12.30; CI 4.79–31.630; $p = 0.001$) and BScN (AOR 37.60; CI 7.644–184.95; $p = 0.001$) were more knowledgeable when compared to nurses with MSN/Ph.D. Similarly, senior nursing officers (SNO) had more knowledge than other cadres studied (AOR 36.20; CI 7.65–171.71; $p = 0.001$). Nurses with 11 to 20 years of experience had more

knowledge when compared to others (AOR 57.30 CI 7.65–428.60; $p = 0.001$).

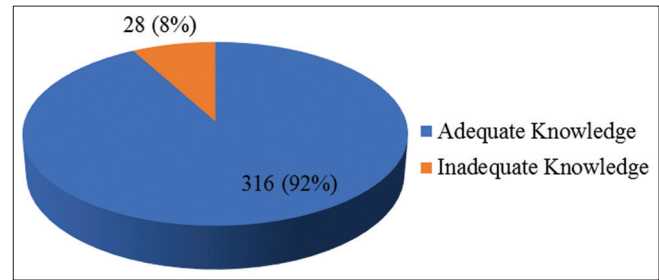


Figure 1: Knowledge status of the respondents on COVID-19 preventive measures

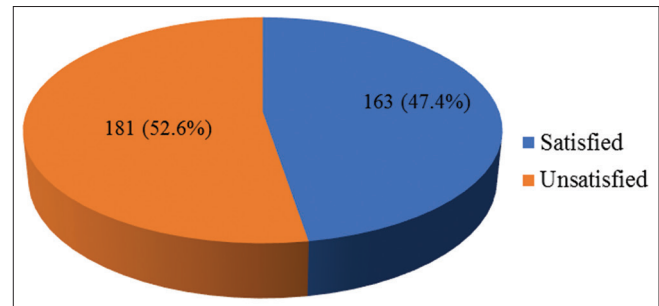


Figure 2: Satisfaction with knowledge acquired so far on COVID-19

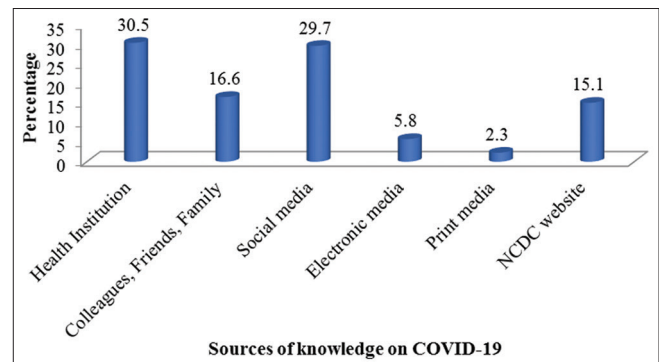


Figure 3: Sources of knowledge on preventive measures for COVID-19

Table 1: Knowledge of preventive measures for COVID-19 among the respondents

Questions	True		False	
	Agree	Strongly Agree	Disagree	Strongly disagree
	n (%)	n (%)	n (%)	n (%)
1. SAR COV-2 is the major cause of COVID-19	185 (53.80)	117 (34.00)	4 (1.20)	38 (11.00)
2. COVID-19 can be spread through droplets and touching contaminated surfaces	121 (35.20)	223 (64.80)	0 (0.00)	0 (0.00)
3. Facemasks and goggles can be used to prevent COVID-19	207 (60.20)	96 (27.90)	13 (3.80)	28 (8.10)
4. Wearing protective booths can be used to prevent COVID-19	201 (58.40)	68 (19.80)	37 (10.80)	38 (11.00)
5. Wearing a protective gown is a preventive measure against COVID-19	214 (62.20)	81 (23.50)	18 (5.20)	31 (9.00)
6. Appropriate disinfection and disposal of PPEs gown is a preventive measure against COVID-19	168 (48.80)	112 (32.60)	29 (8.40)	35 (10.20)
7. Following guidelines by WHO* and NCDC** can help one prevent COVID-19	202 (58.70)	142 (41.30)	0 (0.00)	0 (0.00)
8. Appropriate hand hygiene, physical distancing, and avoiding touching the face, eyes, and nose are preventive measures against COVID-19	175 (50.90)	169 (49.10)	0 (0.00)	0 (0.00)
9. COVID-19 can lead to pneumonia, respiratory failure, and possibly death and require to be prevented	99 (28.80)	245 (71.20)	0 (0.00)	0 (0.00)

Table 2: Practice of COVID-19 preventive measures among respondents

Questions	Yes n (%)	No n (%)
Know all the infection preventive measures against COVID	340 (98.80)	4 (1.20)
The distance that should be maintained around an infected individual		
Approximately 2 meters	224 (65.10)	-
Approximately 5 meters	21 (6.10)	-
Approximately 6 meters	70 (20.30)	-
All of the above	29 (8.40)	-
Washing of hands		
Before every episode of direct patient care	334 (97.10)	10 (2.90)
After any contact that results in to hand being contaminated	335 (97.40)	9 (2.60)
After removing of Proper Personal Protective Equipments (PPEs)	334 (97.10)	10 (2.90)
Any time	122 (35.50)	222 (64.50)
Availability of running water and soap for hand hygiene	308 (89.50)	36 (10.50)
Availability of hand sanitizers	328 (95.30)	16 (4.70)
Availability and use of face mask		
Availability of surgical face mask when needed	163 (47.40)	181 (52.60)
Use of surgical face mask when caring for a patient	312 (90.70)	32 (9.30)
Physical distancing in inpatient settings		
Availability of isolation wards in your unit to admit confirmed cases of COVID-19	231 (67.20)	113 (32.80)
Maintain recommended distance from patients	267 (77.60)	77 (22.40)
Use privacy curtains between beds to prevent close contact.	159 (46.20)	185 (53.80)
Environmental decontamination of highly touched surfaces		
Involvement in decontamination of the hospital	67 (19.50)	277 (80.50)
Decontamination of patient wards, hospital environment, and high-touched areas		
Always	62 (92.50)	-
Once a week	3 (4.50)	-
Once a month	0 (0.00)	-
Only when it's dirty	2 (3.00)	-
Linen		
All linen used in the direct care of patients with possible and confirmed cases of COVID-19 should be managed as "Infectious linen."	215 (62.50)	129 (37.50)
Linen must be handled, transported, and processed by following stipulated guidelines.	341 (99.10)	3 (0.90)
Disposable gloves and an apron should be worn when handling infectious linen.	337 (98.00)	7 (2.00)
A laundry receptacle should be readily available for the immediate disposal of linens.	344 (100.00)	0 (0.00)

*World Health Organization **Nigeria Centre for Disease Control

Discussion

The study assessed if the nurses were trained as frontline workers in the respective hospital before they started attending to patients as the outbreak became a global concern; the study revealed that the majority of the nurses in the hospitals had no formal training on COVID-19, which may increase the risk of transmitting the disease to their contacts. COVID-19 became an emergency in most countries, making them unprepared to face the pandemic; healthcare providers had to work with their fundamental knowledge on standard precautions. The disease nature and fatalities associated with COVID-19 would have motivated the nurses to seek knowledge through various media where information was readily available to protect themselves,

their patients, and communities while carrying out their duties. Studies have identified lapses in infection prevention and control in healthcare settings as significant drivers of uninterrupted transmission of certain diseases, especially infectious diseases like COVID-19.^[16,17] This could lead to failure to adhere to proper infection prevention practices as stipulated by WHO^[14] and may expose nurses to increased risk of contracting the disease, especially in Nigerian Hospitals where PPEs have been reported to be inadequate with little capacity to deal with the disease compared to other developed countries.^[18]

Findings from the study on the knowledge of nurses on preventive measures toward COVID-19 showed that nurses are knowledgeable about the means of contacting

Table 3: Sociodemographic characteristics influencing knowledge of COVID-19 preventive measures among the respondent

Variable	Knowledge		AOR*	Confidence interval	p
	Good n=316	Poor n=28			
Age category (years)					
16–25	38 (12.00)	10 (35.70)	-	-	-
26–35	200 (63.30)	14 (50.00)	3.80	1.56–9.09	0.003
36–45	58 (18.40)	3 (10.70)	5.10	1.31–19.70	0.018
46 and above	20 (6.40)	1 (3.60)	5.20	0.63–44.10	0.126
Gender					
Male	18 (5.70)	2 (7.10)	-	0.28–5.79	0.754
Female	298 (94.30)	26 (92.90)	1.30		
Qualification/level of education					
Registered Nurse/midwife	215 (68.00)	25 (89.30)	12.30	4.79–31.63	<0.001
Bachelor of science	94 (29.70)	2 (7.10)	37.60	7.64–184.95	<0.001
Masters of science/doctor of philosophy in nursing	7 (2.20)	1 (3.60)	5.60	0.60–52.00	0.130
Cadre					
Nursing officer 11	25 (7.90)	12 (42.90)	-	-	-
Nursing officer 1	80 (25.30)	12 (42.90)	3.20	1.28–8.01	0.013
Senior nursing officer	151 (47.80)	2 (7.10)	36.20	7.65–171.71	<0.001
Principal nursing officer	23 (7.30)	1 (3.60)	11.00	1.33–91.71	0.026
Assistant chief nursing officer-assistant director nursing services	37 (11.70)	1 (3.60)	17.80	2.17–145.34	0.007
Years of experience					
1–10	89 (28.20)	26 (92.90)	-	-	-
11–20	196 (62.00)	1 (3.60)	57.30	7.649–428.60	<0.001
21–30	31 (9.80)	1 (3.60)	3.40	1.179–69.56	0.034

*AOR: Adjusted odd ratio

the disease, they have the knowledge that COVID-19 can be spread through droplets and touching of contaminated surfaces, that facemasks and goggles can be used to prevent COVID-19, and that appropriate disinfection and disposal of PPEs gown is a preventive measure to COVID-19. Also, following the guidelines of WHO and NCDC could help one prevent COVID-19, and nurses strongly agree that COVID-19 could lead to pneumonia, respiratory failure, and possibly death. Most of the nurses had adequate knowledge of COVID-19 preventive measures and were satisfied with the knowledge acquired so far on COVID-19. These findings are comparable with Zhou *et al.*^[9] on the understanding of healthcare workers regarding COVID-19 preventive measures, which showed that healthcare workers had sufficient knowledge of COVID-19 preventive measures. In their study, Zhong *et al.*^[10] also observed that most Chinese residents of relatively high socioeconomic status, particularly women, were knowledgeable about COVID-19. In the same vein, Odikpo *et al.*,^[13] Giao *et al.*,^[11] and Farah *et al.*^[7] also discovered the majority of healthcare workers in a similar study had good knowledge of COVID-19 and its preventive measures. A good understanding of COVID-19 preventive measures was also reported by Ejeh *et al.*^[19] and Tsiga-Ahmed *et al.*^[20]; Maude *et al.*^[21]

On the sources of knowledge on preventive measures for COVID-19, the nurses reported having obtained COVID-19

knowledge primarily from health institutions. This finding is similar to that reported by Maude *et al.*,^[21] which showed information sources most used by health workers were the workplace, work colleagues, health workers, and television. Contradicting this report, Olapegba *et al.*^[12] reported in Nigeria that information about COVID-19 is mainly derived from traditional media, which was not the case in this study.

The practice of COVID-19 preventive measures among nurses showed that nurses are knowledgeable about all the infection preventive measures against coronavirus, which are necessary to prevent the disease.^[14] Most of the nurses maintained approximately 2 meters distance around an infected individual, and handwashing was carried out mainly after any contact that resulted in to hand being contaminated, which did not follow the moments of handwashing strictly as stipulated in other to prevent infections. The nurses also stated that their institution had an isolation ward to admit confirmed COVID-19 cases. Also, decontamination of patient wards, hospital environments, and high-touched areas was always done, as reported by the few who claimed to be involved in the decontamination process of their ward. COVID-19 is a global pandemic in which the primary means to protect themselves from being infected is the practice of preventive measures. The report shows that the nurses are acquainted with the appropriate

preventative measures and practice the same as in the study. The finding is similar to an account by Limbu *et al.*,^[8] where the health workers in their study had good preventive practices for COVID-19. WHO^[14] and Nigerian Center for Disease Control^[4] require health workers to be prepared and ready to respond to an outbreak, in particular, the one due to COVID-19, and should implement WHO recommended infection prevention and control interventions, including identifying, isolate and report suspect and confirmed cases.^[14] Similarly, Zhou *et al.*^[9] findings on preventive measures for COVID-19 revealed that nurses followed correct practices regarding COVID-19. Contrary to the finding in this report, Farah *et al.*^[7] study discovered overall good knowledge of COVID-19 but a relatively low level of practice. These contradictions found in some reports may be a result of environmental factors.

The sociodemographic characteristics influencing knowledge of COVID-19 preventive measures among the respondent showed that nurses who had RN/RM and BScN were more knowledgeable when compared to nurses with M.ScN/Ph.D. Similarly, Senior Nursing Officers (SNO) with 11 to 20 years of experience had more knowledge when compared to other cadres studied. This result revealed practically oriented educational qualifications and increased years of professional experience; there is a tendency to have more knowledge as events unfold, especially in the face of epidemics like COVID-19. This result is comparable with the findings of Wen *et al.*^[6] who discovered that nursing staff with working experience ≤ 10 years scored lower than those with working experience ≥ 20 years, with OR values of 0.490 (95% CI: 0.412–0.583) and 0.654 (95% CI: 0.551–0.775). Similar report was also found in another similar study with AOR values of 0.747 (95% CI: 0.629–0.886).^[22] Also, Tsiga-Ahmed *et al.*^[20] also identified that having a bachelor's or medical degree an influence on good knowledge of COVID-19 (aOR = 4.60, 95% CI: 1.3-16.50)

The study's primary limitation was the limited area and sample covered by the survey. The researchers could have covered more expansive areas and added other hospitals in the state but resorted to two tertiary institutions due to the COVID-19 restrictions placed by the government, including restrictions on movement; hence, the study result may need to be generalized to a broader population. Another area for improvement of the study was utilizing the researchers' developed tool as a standardized tool was not utilized for data collection by the researchers.

Conclusion

The nurses in the study had good knowledge of the preventive measures for COVID-19 despite not being trained as frontline staff; it is essential to transform theory into practice by making sure that the preventive measures they know are put into practice as a means to halt the spread of the disease in the face of minimal vaccine coverage.

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Conflicts of interest

Nothing to declare.

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Effects of Auriculotherapy on Gestational Hypertension: Randomized Controlled Trial Study

Abstract

Background: This study aims to observe how auriculotherapy acts as a nonpharmacological treatment for pregnant women's gestational hypertension. **Materials and Methods:** This study was a randomized controlled trial. Eighty patients were with gestational hypertension recruited and divided into control (n = 40) and intervention (n = 40) groups. The control group just received the usual perinatal care. The intervention group received one month of auriculotherapy in addition to the usual care. Blood pressure was measured before and 15 minutes after rest in both groups twice a week. The data were analyzed using descriptive statistics and inferential tests. **Results:** The mean systolic blood pressure, based on the Mann-Whitney test, was not statistically significant between the two groups before the intervention and in the first two weeks after the intervention ($p > 0.05$); however, after the third week of intervention, the mean systolic blood pressure in the intervention group was significantly lower than that in the control group ($p < 0.001$). As per the Mann-Whitney test, the mean diastolic blood pressure was not statistically significant between the two groups before the intervention and the first week after the intervention ($p < 0.05$). However, after the second week of intervention, the mean diastolic blood pressure in the intervention group was significantly lower than that in the control group, and this decrease was highest in the fourth week of the intervention ($p < 0.001$). **Conclusions:** This study demonstrated that auriculotherapy would reduce blood pressure in pregnant women suffering from hypertension.

Keywords: Auriculotherapy, hypertension pregnancy-induced, pregnancy

Introduction

Gestational hypertensive disorders are among the most common pregnancy complications that increase fetal and maternal mortality.^[1,2] These complications have a global prevalence of 5%-10%^[3] rising from 57.3 to 86.5 per thousand births in the hospital.^[4] The prevalence of this disorder in Iran has been reported at 6.5%.^[5] Today, many studies have shown a relation between gestational hypertension and chronic hypertension, cardiovascular disease, future metabolic disease, thromboembolism, and death.^[1,4,6] Despite the problem of hypertension in pregnancy and its numerous complications, no preventive action has been noticed.^[7] Applied standard therapies include pharmacological and nonpharmacological therapies, the most common of which are pharmacological therapies (such as hydralazine, labetalol, and nifedipine).^[8]

Common nonpharmacological treatments encompass absolute or partial bed rest, diet change, and limiting weight gain.^[2,7] The nonpharmacologic methods have the advantage of low price and availability and limited side effects, increasing the patients' activity and adaptability, reducing care costs, and the number of bed occupancy in hospitals.^[7,9] Nonpharmacological methods that have been considered in recent years include massage, music therapy, hypnosis, herbal medicines, aromatherapy, reflexology, and auricular therapy.^[10,11] Auriculotherapy is one of the complementary medicine methods.^[12] It is very similar to hand and foot reflexology and means stimulation of the orifice or outer ear. Auriculotherapy is a branch of acupuncture in traditional Chinese medicine^[13,14] performed in a variety of ways including electrical stimulation, the use of needles or granular labels including magnetic seeds, and plant

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seeds such as Vaccaria and hand pressure in the outer ear is stimulated.^[11,15] Recently, it has become common to use a seed to stimulate the outer ear, which is usually made of steel or Vaccaria beads, which are fixed with a little glue on the ear, which can stay on the ear for 3 to 6 days, and its essential advantage is not inflicting an injury to the skin of the ear.^[16]

It is believed that the outer part of the ear is identical to an inverted fetus and is a view of the internal organs and organs of the body so that with the help of the ear, one can reach all anatomical parts of the body and different parts of the brain, spinal cord, and central and peripheral nerves.^[17,18] In general, the three main meridians or energy channels that carry energy throughout the body pass through the ear, and by stimulating these points on the ear, one can produce and regulate the flow of energy throughout the body.^[9,14,17] This method creates balance in the body and increases the sense of health in humans. Numerous studies on the effect of acupressure on various components such as vital signs, pain, and anxiety have been performed separately.^[19-23] Considering the study conducted by Suen *et al.*,^[18] which aimed to evaluate the effect of auricular therapy with two different methods of using acupressure and magnetic beads on high blood pressure, the results showed that auricle therapy using magnetic beads had positive results on moderate blood pressure, but there was no significant difference between the two methods in reducing blood pressure.

As per the study carried out by Li *et al.*,^[19] auriculotherapy is effective in anxiety and quality of patients' lives, but again there was no difference in blood pressure. In the study of Ferreira *et al.*,^[21] auriculotherapy was not effective in heart rate and diastolic blood pressure before and after intervention, but it caused a significant decrease in systolic blood pressure after the intervention. Auricular therapy is a simple, inexpensive, and noninvasive procedure, but there are conflicting results in its effectiveness. Despite the importance of hypertension in pregnancy and considering the side effects of antihypertensive drugs and their inability to prevent preeclampsia, limited studies have been conducted on using acupressure or acupuncture to control blood pressure. Moreover, we did not find any researches that assessed the effects of acupressure on gestational hypertension. Therefore, considering acupressure's safety, we studied acupressure's impacts on gestational hypertension in pregnant women by referring to Kowsar Medical Center in Qazvin.

Materials and Methods

This study is a randomized controlled trial study (IRCT20190402043156N1) in the Obstetrics and Gynecology Center of Kowsar Hospital (Iran) in 2020. We obtained the informed written agreement of every single participant to observe the principles of ethics in

the research. Inclusion criteria included hypertension equal to 140/90 mm Hg after 20 weeks of gestation without any specific previous disease history and proteinuria, singleton pregnancy, literate, and not having external ear diseases. Exclusion criteria included pre-eclampsia, eclampsia, and Hemolysis, Elevated Liver Enzymes, and Low Platelets syndrome (HELLP syndrome), systolic blood pressure equal to or more than 160 mm Hg, diastolic blood pressure equal to or more than 110 mm Hg, having uterine contractions and vaginal bleeding, using psychotropic substances, cigarettes, and alcohol, and using other methods of complementary medicine concurrent with our study and premature delivery, dissatisfaction with the continuation of the study, and diagnosis of a new disease during the study. Available sampling was performed on all women with gestational hypertension referring to Kowsar Educational and Medical Center. To estimate the sample volume, considering the first type error, $\alpha = 0.05$, and the second type error, $\beta = 0.20$, and taking into account a 15% drop rate, we estimated 80 people sample size for random allocation, and a quadruple block method was used. There are six different modes for the quadruple block (AaaA, aaAA, AaAa, aAaA, AaaA, and aAAa). These modes were written on six cards and placed in a bag, and by selecting 20 blocks from the six possible blocks, the process of assigning 80 patients to two groups was obtained before the study began. The selected samples were randomly assigned to the intervention group "A" (ear acupressure) and the control group "B" (conventional care).

Before the intervention, the researcher underwent acupuncture medicine training and obtained a valid certificate. After the random allocation of samples to the intervention and control groups, the intervention was started. In the first step, a nurse, other than the researcher, with 15 years of nursing experience and holding a Master's Degree in nursing with established skill in avital signed measurement was selected to complete the study. She measured the blood pressure of the participants and was blind to which group they were in. Moreover, an ABN mercury sphygmomanometer, made in Germany, was used to measure blood pressure. To confirm the validity of the sphygmomanometer, blood pressure was taken twice with a 30-minute interval from several patients, and the constant numbers in these two times confirmed the validity of the tool. In group "A", in addition to routine care such as fetal health, fetal heart rate control, and fundal height measurement to determine fetal growth, mothers received acupressure for one month. In eight sessions (twice a week), the researcher installed a label containing six seeds on the hypertension line behind the ear to perform acupressure in this group. Mothers were asked to apply pressure on the seeds six times a day for at least 1 minute to reach the pain

threshold. Moreover, they were invited to attend the center twice a week to change the seed tags and control their blood pressure. Their blood pressure was measured and recorded at each visit to change the adhesive containing seeds after 15 minutes of rest.^[17] Mothers were told that if the seeds caused any unpleasantness such as pain, insomnia, and any change in the conditions following its use, they could remove the label containing the seeds and leave the study. Group B, like group A, visited the center twice a week for routine medical care such as fetal health, fetal heart rate control, and fundal height for fetal growth. At the same time, this group's blood pressure was measured and recorded twice a week after 15 minutes of rest.

Data were analyzed using SPSS software version 19 and descriptive statistics (mean, standard deviation, frequency, and percentage) and inferential tests (Shapiro, Chi-square, Mann-Whitney, and Friedman's tests) were conducted. To check the normality of systolic and diastolic blood pressure, Shapiro-Vick test was used. Due to the non-normality of the variables, the Mann-Whitney test was used to compare the averages in two groups, and Friedman's repeated measurement test was used to compare the averages before and after the intervention; and in each group, p value less than .05 ($p < 0.05$) was considered significant.

Ethical considerations

This study was approved by the Research Ethics Committee of Qazvin University of Medical Sciences, Iran (IR.QUMS.REC.1397.370). Before the intervention, oral and written consents were obtained from the participants; all participants were informed of the study goal, method, and the voluntary nature of the research; besides, all were assured of the confidentiality of their information.

Result

There were 80 pregnant women in our study. Unfortunately, five participants dropped out of our research. In the intervention group, three patients left the study due to dissatisfaction to continue and one patient left due to hypertension. In the control group, two patients left the study due to hypertension. The data of the 75 remaining cases (37 in the experimental group and 38 in the control group) were analyzed [Figure 1]. The results showed there was no significant difference between the two groups in terms of individual social and pregnancy variables [Table 1].

As per the obtained results, based on the Mann-Whitney test, the mean systolic blood pressure was not statistically significant between two groups before the intervention and in the first two weeks after that ($p < 0.05$). However, after the third week of the intervention, the mean systolic blood pressure in the intervention group was significantly lower than that in the control group ($p < 0.001$). Using Friedman's

statistical test, the mean diastolic blood pressure after the intervention in both groups showed a significant decrease ($p < 0.001$). As per the effects' size, the calculated difference in the two groups was an average effect size [Table 2].

As per the Mann-Whitney test, there was no statistically significant mean in diastolic blood pressure between the two groups before the intervention and the first week postintervention ($p < 0.05$). However, after the second week of intervention, the mean diastolic blood pressure in the intervention group was significantly lower than that in the control group, and this decrease reached its peak in the fourth week ($p < 0.001$). Using Friedman's

Table 1: Comparison of demographic information in control group and intervention

	n (%) / Mean (SD)		p*
	Intervention group "A*" (n=37)	Control group "B*" (n=38)	
Qualitative variables			
Women's education level			
Guidance school	21 (54.76)	25 (65.79)	0.340
High school	14 (37.84)	10 (26.32)	
Academic	2 (7.40)	3 (7.89)	
Women's job			
Unemployed	37 (100.00)	37 (97.40)	0.780
Employee	0 (0)	1 (2.60)	
Hypertension history			
Yes	1 (2.70)	3 (7.90)	0.285
No	36 (97.30)	35 (92.10)	
Diabetes history			
Yes	3 (8.10)	3 (7.90)	0.200
No	34 (91.90)	35 (92.10)	
Drug history (methyldopa)			
Yes	3 (8.10)	1 (2.63)	0.495
No	34 (91.90)	37 (97.37)	
Quantitative variables			
Women's age (year)	26.56 (4.91)	27.46 (5.03)	0.281
Gestational age (week)	26.21 (3.18)	25.56 (2.90)	0.204
Weight gain (Kg)	8.02 (1.67)	8.44 (1.70)	0.206

*Based on Chi-square or independent t -test, A: Intervention group; giving auriculotherapy, B: Control group; giving routine care

Table 2: Comparison of systolic blood pressure in two groups

	Intervention [Mean (SD)] "A"	Control [Mean (SD)] "B"	p	Cohen's effect size
Before intervention	143.24 (4.44)	142.24 (4.63)	0.545	
After 1 weeks	135.94 (5.24)	136.44 (6.86)	0.766	
After 2 weeks	133.91 (6.02)	135.38 (5.97)	0.095	
After 3 weeks	132.21 (2.73)	136.05 (6.27)	<0.001	0.37
After 4 weeks	130.81 (3.99)	136.31 (5.02)	<0.001	0.52
p	<0.001	<0.001		

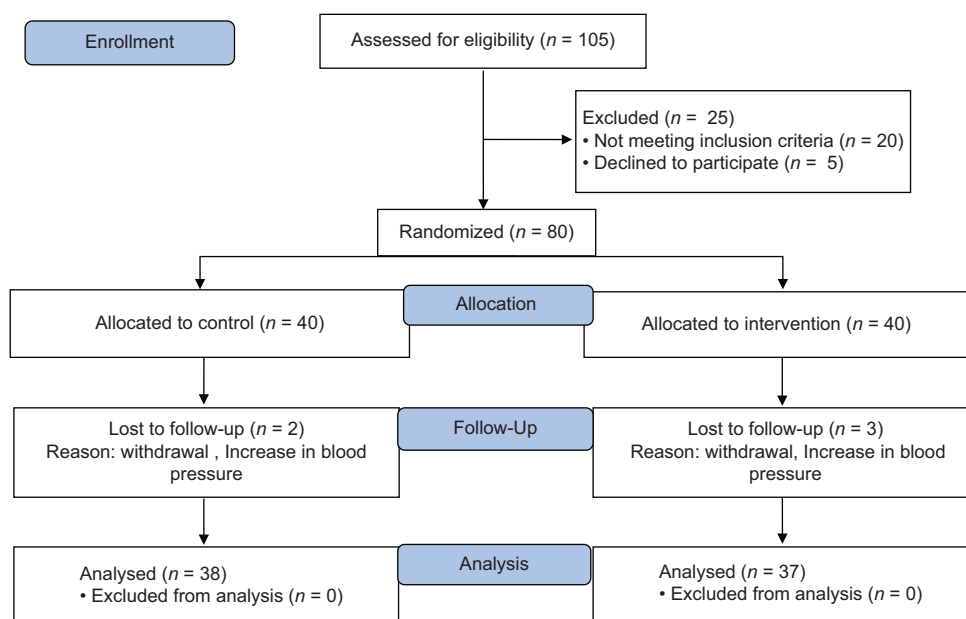


Figure 1: Consort diagram

statistical test, the mean diastolic blood pressure before and after the intervention in both groups showed a significant decrease ($p < 0.001$). Apart from that, as per the effects' size, the difference between the two groups with high effect size has been obtained [Table 3].

Discussion

This study aimed to evaluate the effect of ear acupressure on systolic and diastolic blood pressure in women with gestational hypertension. The results of this study showed that acupressure in the ear caused a significant reduction in blood pressure in the intervention group two weeks after the intervention.

Studies on the effectiveness of ear acupressure on gestational hypertension are restricted. Kocher and Hobbs^[24] conducted a similar study, and the effect of ear acupressure on lowering blood pressure in a pregnant woman with preeclampsia has been reported; a nulliparous pregnant woman with pre-eclampsia was treated with auriculotherapy for 5 weeks in this case study. The result of so-called study, similar to the present study, was a reduction in blood pressure. However, this study is a case report, and there are not a significant number of samples. Furthermore, the subject of the study has pre-eclampsia, which has a significant difference from the present study, and the findings are unreliable. As per Suen LK, the effect of ear acupressure caused a slight decrease in blood pressure in women with moderate hypertension. How long the blood pressure-lowering impact lasted was not noted.^[18] Patients were nonpregnant and included both sexes and received acupressure at 6 points and blood pressure medications, as per their findings, although the result is not statistically significant in this study. Kim *et al.*^[25] also evaluated ear

Table 3: Comparison of diastolic blood pressure in two groups

	Intervention [Mean (SD)] "A"	Control [Mean (SD)] "B"	<i>p</i>	Cohen's effect size
Before intervention	88.10 (6.16)	87.76 (6.22)	0.774	
After 1 weeks	82.16 (4.17)	83.15 (4.71)	0.333	
After 2 weeks	80.81 (2.20)	84.07 (4.91)	0.002	0.39
After 3 weeks	80.54 (1.57)	82.36 (4.14)	0.05	0.28
After 4 weeks	79.67 (1.17)	84.07 (4.91)	<0.001	0.74
<i>p</i>	<0.001	<0.001		

acupuncture to lower the first stage-hypertension and prehypertension. This finding is consistent with the present study, but our results cannot be interpreted in the same way as Kim's finding because in pregnant women the hypertension mechanism differs from other hypertensive cases.

In a meta-analysis of 44 studies, Gao *et al.*^[26] concluded that using ear acupressure combined with antihypertensive medications significantly reduced blood pressure and stabilized blood pressure compared to the time the medicines were just used. However, the role of ear acupressure alone in the persistent blood pressure reduction is still unknown. This study, too, did not analyze the same patients' setting, and further studies are necessary to prove the effectiveness of acupressure. Song *et al.*^[27] and Zhao *et al.*^[28] evaluated the effect of acupressure on lowering blood pressure, but its persistence is still questionable.

Similar to our research results, the findings of Suen *et al.*^[18] also revealed that auriculotherapy with magnetic beads

had positive effects on uncontrolled medium hypertension. In a research by Li *et al.*,^[19] they also found out that blood pressure decrease was considerably higher in the intervention group. However, the acupressure techniques employed by Yeh *et al.*^[20] could not reduce the blood pressure in patients with chronic hypertension. In this study, nonpregnant people underwent ear acupressure for 10 weeks and in terms of methodology, it is different from the present study and cannot be completed.

Ferreira *et al.*^[21] also found out that acupressure had no effect on heart rate nor on the diastolic pressure; nonetheless, there was a significant decline in systolic blood pressure after the intervention.

The results of the present study similar to those of other studies reveal that auriculotherapy can be an influential and effective method to control blood pressure, but further studies in pregnant women with hypertension are mandatory to prove this hypothesis strongly. One of the limitations of this study was the dissatisfaction of participants because some pregnant mothers were not sufficiently willing to use the labels due to the importance of hypertension in pregnancy. To solve this problem, the researcher talked to the patients and assured them that this intervention would not have a negative effect on them and convinced them to participate. Another limitation was the uncertainty of the correct use of the labels. Hence, the researcher was in regular contact with the participants during the study and ensured the correct use of the labels.

Conclusion

It is concluded in this study that as a nonpharmacological intervention, auriculotherapy reduced blood pressure in pregnant women's gestational hypertension.

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Conflicts of interest

Nothing to declare.

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The Effects of Peer Education on Treatment Adherence among Patients Receiving Hemodialysis: A Randomized Controlled Trial

Abstract

Background: Non-adherence to treatments increases the rates of hemodialysis complications, hospitalization, and mortality. One strategy for adherence improvement is peer education. This study aimed to investigate the effects of peer education on treatment adherence among patients receiving hemodialysis. **Materials and Methods:** This was a randomized controlled trial. Patients in the control group were provided just with routine care, and the intervention group received peer education. Treatment adherence was assessed both before and after the intervention via the End-Stage Renal Disease (ESRD) Adherence Questionnaire. Data analysis was conducted by the Chi-square, the Mann-Whitney U, the paired-sample *t*, and the independent-sample *t* tests. **Results:** There were no significant between-group differences in terms of the pre-test mean scores of Adherence to regular attendance at hemodialysis sessions ($t = 0.19, p = 0.85$), Adherence to the prescribed medications ($t = 0.46, p = 0.64$), and Adherence to fluid restrictions ($t = 0.24, p = 0.81$). The same finding was observed after the intervention, except for the mean score of the adherence to fluid restrictions dimension which was significantly greater in the intervention group ($t = 2.86, p = 0.006$). Moreover, no significant changes were observed in the mean scores of treatment adherence dimensions in the control group. However, in the intervention group, the mean scores of the adherence to regular attendance at hemodialysis sessions ($t = 3.79, p < 0.001$) and the adherence to fluid restrictions dimensions were significantly greater than their pre-test values ($t = 4.47, p < 0.001$). **Conclusions:** Education by peer groups improves the compliance of patients with regard to the consumption of fluids in the interval between two dialysis sessions.

Keywords: Adherence, peer, renal dialysis

Introduction

According to the World Health Organization, treatment adherence is the corresponding level of a person receiving medication, following a prescriptive diet, or implementing lifestyle changes due to healthcare providers' recommendations. Adherence to hemodialysis for patients is essential and leads to lifestyle changes such as the need to regularly go to a dialysis center, consistently take prescribed medications, and extensively modify their diets.^[1] Non-adherence to each of these self-management tasks has associated risks independently. For example, patients who are not limiting their fluids are at risk for fluid overload. Fluid overload can cause a number of adverse effects, including coughing, edema, congestive heart failure, chest pain, and shortness of breath. Further, there is a limit to the amount of fluid that

can be safely removed in one treatment. Removing higher volumes of fluid during treatment can put patients at risk of serious side effects, such as hypotension, cramping, nausea, headache, and cardiac complications or death.^[2]

Moreover, non-adherence to fluid restriction causes excessive weight gain between hemodialysis sessions and, therefore, necessitates greater fluid removal in each hemodialysis session. As the length of each hemodialysis session is about 3–4 hours, the removal of a larger amount of fluids in a session necessitates rapid fluid removal, which in turn is associated with hemodialysis complications such as hypotension, muscle cramps, headache, nausea, and vomiting.^[3] The occurrence of such complications may require premature hemodialysis termination. Such termination prevents patients from reaching the optimum dry weight and causes fluid accumulation

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in the body, hypertension, ventricular hypertrophy, chronic heart failure, reduced coronary blood flow, myocardial ischemia and necrosis, arrhythmias, reduced quality of life, and increased mortality rate. Therefore, close adherence to fluid restrictions and weight management are of critical importance to the health and well-being of hemodialysis patients.^[2]

Appropriate medication use is another significant factor behind treatment success among patients with chronic renal failure. End-Stage Renal Disease (ESRD) patients are estimated to take eight to twelve prescribed medications per day requiring an average of 17–25 doses per day. However, some people might take up to 15–20 drugs. Medications are taken for a wide range of conditions and depend on the individual patient but frequently include drugs for anemia, managing phosphorus levels, and treating bone disease, hypercholesterolemia, endocrine disorders, thrombosis, mental problems, sleep disorders, restless leg syndrome, gastrointestinal disorders, osteoporosis, itching, diabetes mellitus, hypertension, and frequent infections and calcifications. The management of co-morbid illnesses like diabetes and/or hypertension may also need the use of medication. Bone disease, anemia, cardiovascular problems, and hypertension are just a few of the ailments that can get worse if they don't follow the prescription regimen.^[4]

Studies show that most hemodialysis patients have limited adherence to their treatment and dietary regimens and hence are at increased risk for hemodialysis complications and death.^[5]

Patient education materials provided by dialysis organizations do not increase patient self-efficacy or engagement with self-management as these documents contain complex medical jargon and provide only general guidelines, not patient-specific instruction. A multi-dimensional program including novel, scalable strategies that can provide needed social support to improve patients' self-efficacy and self-management is critically needed.^[6]

Peer education is among the strategies for promoting treatment adherence among patients with chronic conditions. Social cognitive theory provides a framework for understanding how peer mentoring may be a successful intervention for self-management in chronic disease, specifically amongst patients receiving in-center hemodialysis treatments. Social cognitive theory is one of the most widely used models of health behavior and has been used in multiple settings, including the clinical setting for self-management of chronic disease. Social cognitive theory, an interpersonal level health behavior theory developed by Bandura, is both an explanatory and change theory in that it provides a means to understand the problem of chronic disease self-management (e.g., lack of self-efficacy) but also suggests strategies to address the problem (e.g. social support and role models).^[7]

Social cognitive theory suggests that learning occurs dynamically in the social context and is a result of the interaction of environmental factors, behavioral factors, and personal factors. The interaction between these factors is known as triadic reciprocal causation or reciprocal determinism. The environment, behavior (s), and personal factors interact and influence each other. Personal factors are the individual's ability to determine his actions based on self-determination or self-regulation and analysis of experience. Self-efficacy and knowledge influence personal factors. Environmental factors can support or discourage health behaviors and may be real or perceived. Environmental influences include observational learning or role-modeling and social support. Behavioral factors are those things that affect health directly, either by promoting health or compromising it. Knowledge and skills, also referred to as behavioral capability, influence behavior. Social cognitive theory posits that these factors are dynamically linked and that changes in any one influence and change the others.^[8]

Based on Heisler's model as well as social cognitive theory, it is hypothesized that peer mentoring will increase perceived social support and knowledge, thereby increasing self-efficacy and improving self-management behaviors and health-related quality of life.^[9]

In peer education, a group of patients with a certain health status share their lived experiences with other patients with the same condition and emotionally support each other. Some studies reported the effectiveness of peer education in promoting treatment adherence among patients with acquired immunodeficiency syndrome,^[10-12] depression,^[13] schizophrenia,^[14] and bipolar disorders.^[15,16] However, some other studies showed the insignificant effects of peer education on patient outcomes.^[17,18] Moreover, there is a paucity of studies on the effectiveness of peer education on hemodialysis patients' treatment adherence. This study aimed to investigate the effects of peer education on treatment adherence among patients receiving hemodialysis.

Materials and Methods

This study was part of a Ph.D. dissertation in nursing in Isfahan University of Medical Sciences. This part was a randomized controlled trial. This trial has been registered with the code IRCT20171212037847N1 in the Iranian Clinical Trials System. The study setting was Noor and Hazrat-e Ali Asghar teaching hospital, Isfahan, Iran. The population of the study consisted of all 130 patients with chronic renal failure who regularly attended to receive hemodialysis. The sampling was done from July to September 2020 with a confidence level of 95% and a power of 80%; the sample estimation showed that at least 32 patients were needed for each group. The sample size estimation formula was $n = [(Z_1 + Z_2)^2 (2S^2)] / d^2$, where Z_1 was the z-score of a confidence level of 95% (=1.96), Z_2 was the z-score of a power of 80% (=0.84), S was the

standard deviation of treatment adherence in each group, and d was the minimum significant difference between the groups in terms of treatment adherence which was set at 0.7 of S in this study. As some patients might withdraw from the study, we increased the sample size to 38.

Patients were included in the study if they were receiving hemodialysis for at least 3 months and had no cognitive problems or memory impairments participation in peer education programs.^[19] Exclusion criteria were voluntary withdrawal from the study, incomplete answer to study data collection tools, or hospitalization or kidney transplantation during the study. Among all 130 patients who were referred to the setting for hemodialysis, 27 did not meet inclusion criteria and 18 refused participation. Therefore, 85 patients were eligible for the study; from them, a random sample of 76 patients was selected. In the present study, the socio-economic level of the patients in different hemodialysis centers of Isfahan was different, and this variable was evaluated as confounding. Thus, the patients of the intervention and control groups were selected from one center (Hemodialysis Center of Noor and Hazrat Ali Asghar Hospital (Khorshid)). In order to prevent the dissemination of information, the patients of both the groups were selected from the list of even and odd day patients. The patients undergoing hemodialysis go to the hemodialysis unit 3 times a week. Some patients underwent hemodialysis on even days (Saturday, Monday, and Wednesday) and some others on odd days (Sunday, Tuesday, and Thursday). Therefore, the patients were not in contact with each other, and no information was transferred between them.

The patients of even and odd days were allocated to the intervention and control groups using a coin toss. Thus, a person who was not part of the research team tossed a coin; if heads were up, the patients of the even days would be placed in the intervention group, and if tails were up, the patients of the odd days would be placed in the intervention group. After coin tossing, heads were up and, thus, the patients undergoing hemodialysis on even days (Saturday, Monday, and Wednesday) were included in the intervention group and the patients undergoing hemodialysis on odd days (Sunday, Tuesday, and Thursday) were included in the control group.

Then, a list of even and odd day patients was prepared and the patients of these groups were randomly selected by a person who was not part of the research team by shuffling the cards. In order to randomly select the patients, the names of the patients were written on the cards; then, the cards were mixed with each other and one card was taken out and its allocation was recorded and that card was returned to the other cards. The cards were mixed again and another card was taken out. This process continued until reaching a random sequence according to the sample size (38 subjects in each).

Blinding and concealment of random allocation were not applicable in this study. In order to prevent information dissemination, the patients of the intervention and control groups were selected from the list of even and odd day patients. The patients undergoing hemodialysis go to the hemodialysis unit 3 times a week. Some patients underwent hemodialysis on even days (Saturday, Monday, and Wednesday) and some others on odd days (Sunday, Tuesday, and Thursday). Therefore, the patients were not in contact with each other, and no information was transferred between them.

Patients in the control group were provided with just routine care measures, while their counterparts in the intervention group also received peer education. Several patients were initially selected as mentors to provide peer education to other patients in the intervention group. Selection criteria for mentors were close treatment adherence and good self-management as determined by the head nurse, staff nurses, and nephrologists in the study setting. The peer mentors were trained by the researcher according to the educational needs of dialysis patients, based on a review of the literature.

Before the heads of the groups began to train other patients, educational workshops were held for them by the research team (corresponding author) Khurshid in Hospital to improve their knowledge and information. The group heads received 8 sessions (12 hours) of training. Training sessions of the group heads were held three times a week (each session lasted for 1.5 hours) in the morning after the dialysis of them. In order to consolidate the information, training packages (including training manuals and workshop CDs) were provided to the group heads.

The contents of the educational materials that were taught to the group leaders were as follows: the first session, familiarizing the group leaders with their duties and how to encourage other patients to self-manage and share their information and experiences; the second session, how to communicate effectively; the third session, the diet of patients undergoing hemodialysis treatment; the fourth session, vascular access care; the fifth session, self-care in kidney transplant; the sixth session, self-care in the use of drugs; the seventh session, stress management techniques; and the eighth session, strategies for improving adaptation skills. The titles of the topics that were taught in this workshop, were in order to prepare the heads of groups, for the support of peers. Upon successful completion of the training, each peer mentor receives a certificate as a certified mentor. Recognizing the importance of continuing education following the initial training, refresher courses were conducted on a quarterly basis. These sessions featured discussions among mentors about their current experiences and a focused review of communication skills.

After patients in the intervention group were grouped to form five six-person and two four-person small groups. Each

mentor was allocated to one group to hold group discussions among group members and provide them with education about dietary regimens, medications, vascular access routes for hemodialysis, care measures before and after kidney transplant, and coping strategies [Table 1]. Mentors supervised groups and encouraged group members to participate in group discussions and share their information and experiences. All members of each group, including its mentor, were almost homogenous in terms of their gender, age, marital status, income level, educational level, hemodialysis protocol, and hemodialysis day. Peer education sessions were held twice weekly for 8 weeks, resulting in 16 sessions in total. Each session lasted around 2 hours.

The primary outcome in this study was treatment adherence, which was assessed both before and after the intervention via the End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ). This questionnaire was developed in 2009 by Kim *et al.* The first section pursues general information about patients' ESRD and RRT-related history (5 items), and the remaining four sections ask about treatment adherence to HD treatment (14 items), medications (9 items), fluid restrictions (10 items), and diet recommendations (8 items). These four final sections directly measure adherence behaviors (14, 17, 18, 26, 31, and 46) and patients' knowledge and perceptions about treatment (11, 12, 22, 23, 32, 33, 41, and 42). Responses to the ESRD-AQ utilize a combination of Likert scales and multiple choice as well as a 'yes/no answer format [Table 2].

Most items are scored on a five-point Likert-type scale, and some items are weighed according to their clinical

importance.^[20] Kim *et al.* reported great validity and reliability for the questionnaire with test-retest intra-class correlation coefficients of 0.83^[21] Borji *et al.*^[22] also reported the acceptable validity and reliability of the Persian translation of the questionnaire with a test-retest correlation coefficient of 85%.

Data analysis in this study was conducted using the SPSS software (v. 16.0). The groups were compared with each other respecting marital and employment status via the Chi-square test and respecting educational status and income level via the Mann-Whitney U test. Moreover, within- and between-group comparisons respecting treatment adherence mean scores were done via the paired- and independent-sample tests, respectively. *p* values were considered statistically significant if they were less than 0.05.

Ethical considerations

This article is extracted from the nursing doctoral thesis. In this study, a sequential exploratory mixed approach (qualitative-quantitative) was used. The qualitative phase of the study was conducted from 2015 to 2017. In the first phase of the research, a descriptive qualitative study was conducted in which semi-structured in-depth interviews were conducted with 35 patients undergoing hemodialysis treatment, patient family members, and health team members. One of the parts of the intervention program proposed by the panel of experts in quantitative phase was the training of patients by peer groups, which was registered on the IRCT system in 2017, and due to the conditions of the covid, it was not possible to implement and implement the work in 2019-2020. Our participants could voluntarily participate in or withdraw from the study. Written informed consent was obtained from each patient who agreed to participate in the study.

Results

Thirty-eight patients were recruited for each study group. During the study, four patients from the control group voluntarily withdrew from the study and one was hospitalized. In addition, three patients from the intervention group voluntarily withdrew from the study, one patient received a kidney transplant, and two patients incompletely filled out the study questionnaire. Thus, five patients from the control group and six from the intervention group were excluded. Finally, 33 patients in the control group and 32 in the intervention group completed the study [Figure 1].

Patients in both groups were mostly married and unemployed and had a below-diploma education. Statistical analyses indicated no significant differences between the groups in terms of patients' demographic characteristics. An independent *t*-test was used to confirm the similarity of quantitative demographic characteristics (age and duration of hemodialysis treatment) in the two groups. The Chi-score test was used for qualitative variables (gender,

Table 1: The topics that were taught to the team members by the group leaders

Description of the meeting	The topic of the meeting
The diet of patients undergoing hemodialysis treatment	Appropriate diet for kidney failure patients
Vascular access care	Discussion about the care of fistula, graft, and PC* , how to take care of vascular access
Self-care in kidney transplantation	Pre- and post-transplant care Suitable diet for kidney transplant patients How to prevent transplant rejection
Self-care in the use of drugs	Medicines used by kidney transplant patients for self-care in fifth kidney transplant Self-care in the use of drugs used by patients (Venofer, Eprex, Rena Gel, and blood pressure control drugs)
Stress management techniques	The stress management techniques
Improving adaptation skills	How to adapt to the disease

Pc: Permcath

Table 2: Scoring of end-Stage Renal Disease Adherence Questionnaire (ESRD-AQ)

Section Name	Question Numbers	Targeted Area in the Item	To Recorded Value of (Points)
Section 1: General Information (5 items)	1, 2, and 3	Fact related to previous Renal Replacement Therapy (RRT) history	No value
	4 and 5	Fact related to transportation situation to get HD	No value
Section 2: HD* Treatment (14 items)	6 and 7	act related to HD schedule	No value
	8	Perception of patients on HD schedule	No value
	9 and 10	Information about counseling on HD	No value
		11	Perception on importance of HD adherence
	12	Understanding level on importance of HD	Analyze responses using descriptive statistics
			No value
	13	Perception of patients on HD	Analyze responses using descriptive statistics
			No value
	14	Frequency of missing HD during last month	Response category 1→300
			Response category 2→200
Response category 3→100			
Response category 4→50			
Response category 5→0			
15	Reason for missing HD	No value (Note: If patients missed HD due to medical reasons (if the answer is 4, 6, or 7), adjust scores from question number 14 and give a full credit (300 points)	
16	Supplementary question for Question 15 (psychophysical symptoms)	No value	
17	Frequency of shortening HD during last month	Response category 1→200	
		Response category 2→150	
		Response category 3→100	
		Response category 4→50	
		Response category 5→0	
18	Duration of shortening HD during last month	Response category 1→100	
		Response category 2→75	
		Response category 3→50	
		Response category 4→25	
		Response category 5→0	
19	Reason for shortening HD treatment	No value (Note: If patients shortened HD due to medical reasons (if the answer is 2, 5, 6 or 11), adjust scores from question number 17 & 18 and give a full credit (200 and 100 points)	
Section 3: Medication (9 items)	20 and 21	Information about counseling on medication	No value
	22	Perception on importance of medication adherence	No value
			Analyze responses using descriptive statistics
	23	Understanding level on importance of medication	No value
			Analyze responses using descriptive statistics
	24 and 25	Fact related to difficulty with taking medicines	No value
	26	Frequency of missing medication during last month	Response category 1→200
			Response category 2→150
Response category 3→100			
Response category 4→50			
Response category 5→0			
27	Reason for missing medication	No value (Note: If patients missed medication due to medical reasons (if the answer is 6 or 7) adjust scores from the question number 26 and give a full credit (200 points).	
28	Supplementary question for Question 27 (psychophysical symptoms)	No value	

Contd...

Table 2: Contd...

Section Name	Question Numbers	Targeted Area in the Item	To Recorded Value of (Points)	
Section 4: Fluid Restriction (10 items)	29 and 30	Information about counseling on fluid restriction	No value	
	31	Fluid restriction: Self-monitoring (Frequency)	Response category 1→200 Response category 2→150 Response category 3→100 Response category 4→50 Response category 5→0	
	32	Perception on importance of fluid restriction	No value Analyze responses using descriptive statistics	
	33	Understanding level on importance of fluid restriction	No value Analyze responses using descriptive statistics	
	34 and 35	Fact related difficulty with limiting fluid intake	No value	
	36	Types of difficulty following fluid restriction (additional question to #35)	No value	
	37 and 38	Information on weighing at home (not mandatory requirements for all ESRD** patients)	No value	
	Section 5: Dietary Restriction (8 items)	39 and 40	Information about counseling on dietary recommendations	No value
		41	Perception on importance of dietary recommendations	No value Analyze responses using descriptive statistics
		42	Understanding level on importance of dietary recommendations	No value Analyze responses using descriptive statistics
43 and 44		Fact related to difficulty with following dietary recommendations	No value	
45		Types of difficulty following fluid Restriction (Additional question to #44)	No value	
46		Dietary restriction: Self-monitoring (Frequency)	Response category 1→200 Response category 2→150 Response category 3→100 Response category 4→50 Response category 5→0	

*HD: Hemodialysis. **ESRD: End-Stage Renal Disease

education level, and income). In order to compare the mean treatment compliance score of patients before and after the intervention in the intervention group, paired *t*-test was used. To compare the mean compliance score of the patients before and after the intervention in the control group, a paired *t*-test was used. An independent *t*-test was used to compare the average score of treatment adherence of patients in the control and intervention groups before the intervention. An independent *t*-test was used to compare the average score of treatment adherence of patients in the control and intervention groups after the intervention ($p > 0.05$; Table 3).

There were no significant between-group differences in terms of the pre-test mean scores of Adherence to regular attendance at hemodialysis sessions ($t = 0.19$, $p = 0.85$), Adherence to the prescribed medications ($t = 0.46$, $p = 0.64$), Adherence to fluid restrictions ($t = 0.24$, $p = 0.81$). The same finding was observed after the intervention, except for the mean

score of the adherence to fluid restrictions dimension which was significantly greater in the intervention group ($t = 2.86$, $p = 0.006$). Moreover, no significant changes were observed in the mean scores of treatment adherence dimensions in the control group. However, in the intervention group, the mean scores of the adherence to regular attendance at hemodialysis sessions ($t = 3.79$, $p < 0.001$) and the adherence to fluid restrictions dimensions were significantly greater than their pre-test values ($t = 4.47$, $p < 0.001$) [Table 4].

Discussion

This clinical trial aimed to investigate the effects of peer education on treatment adherence among patients receiving hemodialysis. The results of the study illustrated that peer education significantly improved adherence to regular attendance at hemodialysis sessions and adherence to fluid restrictions but had no significant effects on adherence to the prescribed medications and adherence to dietary restrictions. Adherence to regular attendance at

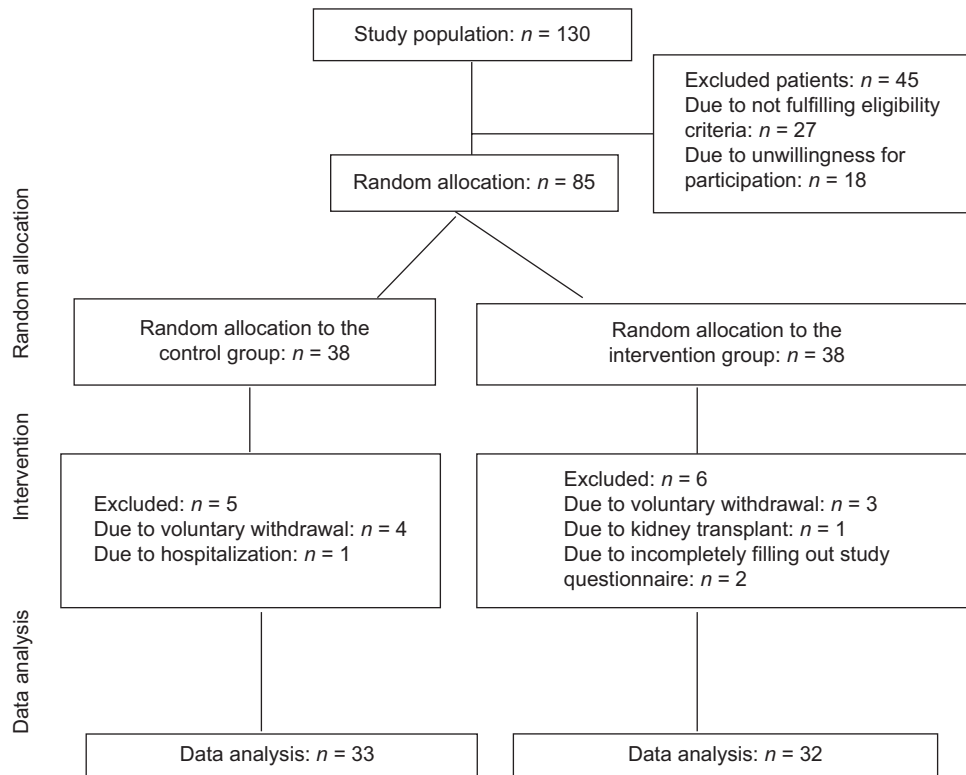


Figure 1: The flow of participants in the study

Table 3: Participants’ demographic characteristics

Group Characteristics		Intervention	Control	χ^2	<i>p</i>
Marital status	Single	4 (12.50%)	6 (18.18%)	2.13*	0.55
	Married	25 (78.10%)	25 (75.75%)		
	Widowed	1 (3.10%)	1 (3.03%)		
	Divorced	2 (6.30%)	1 (3.03%)		
Employment status	Employed	4 (12.50%)	7 (21.21%)	1.06*	0.79
	Unemployed	17 (53.10%)	16 (48.48%)		
	Disabled	6 (18.80%)	6 (18.18%)		
	Retired	5 (15.60%)	4 (12.21%)		
Educational status	Illiterate	4 (12.50%)	6 (18.18%)	0.009**	0.99
	Below diploma	25 (78.10%)	22 (66.66%)		
	Associate and bachelor’s	3 (9.40%)	4 (12.21%)		
Income level	Master’s and higher	0 (0%)	1 (3.03%)	0**	1
	Adequate	16 (50%)	17 (51.51%)		
	Inadequate	16 (50%)	16 (48.48%)		

* Chi square, **Mann-Whitney U

hemodialysis sessions and adherence to fluid restrictions are dimensions on which patients have greater control and hence, can significantly be improved through enhancing their knowledge, perceived social support, and self-efficacy. However, adherence to dietary restrictions and adherence to prescribed medications are more complicated and are determined not only by patients’ personal characteristics but also by family members; therefore, their improvement may need long-term multi-component interventions which actively involve family members in patient care.

According to Bandura’s Social Learning Theory, learning is the result of interactions among people, the environment, and society.^[23] Self-efficacy is the most important factor behind chronically ill patients’ self-management. It is defined as individuals’ beliefs in their own abilities to control their actions, functions, and life events.^[24] Bandura’s theory holds that people can learn how to modify their lifestyle by observing the behaviors of a role model. They usually model themselves on individuals who are similar to them in age, gender, race, ethnicity, and socioeconomic

Table 4: Within- and between-group comparisons regarding the mean (SD) scores of treatment adherence dimensions

Group Dimensions		Intervention Mean (SD)	Control Mean (SD)	Independent-sample <i>t</i> test	<i>p</i> **
Adherence to regular attendance at hemodialysis sessions	Before	66.14 (17.10)	66.94 (15.44)	0.19	0.85
	After	71.91 (16.01)	66.94 (16.05)	1.23	0.22
	paired-sample <i>t</i> test	3.79	1.36		
	<i>p</i> *	0.001	1	0.46	0.64
Adherence to the prescribed medications	Before	45.99 (8.93)	46.78 (3.58)	0.47	0.64
	After	46.72 (8.59)	45.94 (3.78)		
	paired-sample <i>t</i> test	0.61	1.81		
	<i>p</i> *	0.55	0.08		
Adherence to fluid restrictions	Before	47 (10.78)	47.55 (6.81)	0.24	0.81
	After	51.90 (8.88)	46.65 (5.31)	2.86	0.006
	paired-sample <i>t</i> test	4.47	1.35		
	<i>p</i> *	0.001	0.19		
Adherence to dietary restrictions	Before	47.91 (9.31)	47.35 (1.91)	0.32	0.75
	After	47.88 (6.96)	46.44 (2.71)	1.82	0.08
	paired-sample <i>t</i> test	0.22	1.68		
	<i>p</i> *	0.83	0.10		

*Paired-sample *t* test. **Independent-sample *t* test

status. This modeling helps them accept that they can do a certain activity because a person like them is doing that. Such acceptance improves their self-efficacy. Accordingly, when patients see that another patient with the same conditions can do self-care activities, they may feel greater self-efficacy in doing the same activities and, therefore, may show closer adherence to treatments.^[19] Consistent with our findings, a study shows that self-efficacy training based on Bandura's Self-Efficacy Theory significantly improved adherence to fluid restrictions among hemodialysis patients.^[25]

Perceived social support is another factor behind treatment adherence. Studies show that inadequate perceived social support is among the most significant predictors of poor treatment adherence.^[26] Perceived social support has significant roles in diminishing the negative effects and psychological strains associated with diseases. It is also a facilitator of patients' engagement in health-related behaviors and self-care activities.^[27] Accordingly, peers' emotional support for each other reduces their sense of social isolation, strengthens their perceived social support, and thereby, improves their self-efficacy and self-management.^[19]

The results of this study also showed that peer education had no significant effects on hemodialysis patients' adherence to dietary restrictions. An explanation for this result may be the fact that adherence to dietary restrictions necessitates family members' collaboration with hemodialysis patients on making proper diet foods. Previous studies also reported the significant role of family support in hemodialysis patients' adherence to dietary regimens.^[28] Yet, most hemodialysis patients are concerned about their family members' inadequate support.

The family members of these patients usually suffer from different tensions due to the long-term course of chronic renal failure, hemodialysis-related complications, and the need for major lifestyle modifications. Therefore, they may gradually become unable to support their ill members. The resultant lack of family support can negatively affect hemodialysis patients' treatment adherence.^[29,30]

Another result of this study was the insignificant effect of peer education on hemodialysis patients' adherence to the prescribed medications. Similarly, Kosse *et al.* found the ineffectiveness of MP3 messaging and peer support on adherence to corticosteroid therapy among patients with asthma. They noted that peer support would have no significant effects on self-efficacy when patients are experiencing denial or invulnerability. Therefore, these patients initially need behavioral therapy.^[31] Another study also reported the insignificant effects of peer monitoring on self-efficacy and satisfaction with perceived social support. Of course, the results of that study should be used cautiously due to its small sample size.^[31] It is noteworthy that treatment adherence is a multifactorial phenomenon which is affected by numerous factors such as lack of knowledge, forgetfulness in taking medications^[32] healthcare providers' interactions with patients,^[33] stress, anxiety, depression,^[34] side effects of medications, and the taste of medications.^[35,36] However, in contradiction to our results, most previous studies reported that peer support significantly improved medication adherence among patients with acquired immunodeficiency syndrome,^[37] tuberculosis,^[38] and schizophrenia.^[14] This contradiction may be due to the more complex treatment regimens of chronic renal failure compared with acquired immunodeficiency syndrome, tuberculosis, and schizophrenia. Patients with chronic renal failure use a wide range of medications for the management

of diabetes mellitus, hypertension, hypercholesterolemia, and hemodialysis-related complications. More than 25% of these patients need to take at least 25 medications each day. Such polypharmacy can considerably affect their adherence to medications.^[26] Another factor behind the ineffectiveness of our intervention in improving medication adherence may be low family support. A study showed that peer education was effective in improving medication adherence only among those patients who had adequate family support.^[39]

The lack of long-term follow-up of the study in the form of longitudinal studies was the limitation of the study. Given time limitations, the effect of peer education on treatment compliance was examined 8 weeks after the intervention; however, a long-term study of these variables over a longer period of time could have provided researchers with more accurate information.

Currently, many hemodialysis patients have fluid overload and do not follow the fluid intake restrictions, which increases their complications during dialysis (hypotension during dialysis, muscle cramps, cardiac arrest), hypertension, left ventricular hypertrophy, heart failure, and increased mortality of patients. Peer group training can improve the adherence of patients to treatment.

Conclusion

The results of this study demonstrate that peer education can significantly improve hemodialysis patients' adherence to attendance at hemodialysis sessions and adherence to fluid restrictions. Peer education is a simple and inexpensive experience-based approach and, therefore, is recommended to improve treatment adherence among patients with chronic illnesses.

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Conflicts of interest

Nothing to declare.

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Risk Factors of Recurrent Diabetic Foot Ulcers Based on the Delphi Method

Abstract

Background: The risk factors for recurrence are poorly understood. The purpose of study is to investigate the risk factors that contribute to the recurrence of diabetic foot ulcers. **Materials and Methods:** This is a cross-sectional study, and the two-phase Delphi method was used. A category was developed to investigate the risk factors of recurrent diabetic foot ulcers by experts. The recurrent items with risk factors were analyzed. Furthermore, the risk factor variables were clinically tested for inter-rater reliability agreement. Fourteen experts and two patients were included from February 15 to September 28, 2020, Indonesia. **Results:** There were 13 risk factors for recurrent diabetic foot ulcers. The mean authority coefficient was 0.71. The positive coefficients were 100% and 78%, respectively. The Kendall coordination coefficient was statistically significant ($p < 0.01$), and inter-rater reliability agreement was perfect (1.00). **Conclusions:** This study found some risk variables related with recurrent diabetic foot ulcers, which might serve as guidance to prevent future recurrences.

Keywords: Diabetic foot, recurrence, risk factors

Introduction

According to the International Diabetes Federation, the prevalence of diabetes patients in Indonesia would rise from 7.3 million in 2011 to 19.5 million by 2021. This report ranks Indonesia as the second in Western Pacific, indicating a steady increase in diabetes patients.^[1] Furthermore, diabetic foot ulcers are commonly observed among diabetes patients, with varying prevalence in different countries.^[2] In Indonesia, this disease is known to be predominant in 7.3–9.1% of individuals.^[3,4] A complication that often occurs in diabetes patients is amputation. According to a study, 80% of amputations are caused by diabetic foot ulcer.^[5] Meanwhile, the incidence of amputation in Indonesia is around 37.5%.^[6]

This disease has the risk of recurring or developing a new ulcer and also serious implications for Quality Of Life (QOL); hence, its prevention is necessary. Furthermore, recurrence can occur at the same location or a new site. Clarifying the risk factors associated with this disease is essential to inhibit a new development. These risk factors for the onset of diabetic

foot ulcers have been clarified;^[7] however, the determinants for its recurrence are yet to be elucidated. Thus, it is very important to be known and understood, which can ultimately prevent complication. In addition, the development of risk factors including patients is still little. Therefore, this study aims at investigating the risk factors associated with recurrence.

Materials and Methods

The study was conducted from February 15 to September 28, 2020. The Delphi method was used in this study.^[8] The sample size for experts in this study was 14. The size of the panel members varies from 10 to 1000 (usually between 10 and 100) in published research depending on complexity of the problem, homogeneity (or heterogeneity) of the panel, and availability of the resources.^[9] Meanwhile, the sample size for patients was two people; the alpha and power were 0.05 and 80%, respectively. According to the literature, a sample size of Cohen's kappa test of at least 2 is allowed for inter-rater agreement.^[10] Furthermore, the inclusion criteria are experts and patients as participants. Experts with more than

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10 years' experience in a hospital or clinic, a bachelor's or higher degree, and wound training or certificate were included. Subsequently, the patients with diabetic foot ulcers had to be ≥ 21 years of age, should have recurrence (the same or another location), and should have received a diagnosis of type 2 Diabetes Mellitus (DM) according to the American Diabetes Association 2013 guidelines. This diagnosis consists of glycated hemoglobin $\geq 6.5\%$ and fasting blood glucose ≥ 126 mg/dl (7.0 mmol/l) or 2-hour plasma glucose ≥ 200 mg/dl (11.1 mmol/l) during an oral glucose tolerance test.^[11] Patients who did not fulfill these criteria were not permitted to participate in the study. Also, informed consent was obtained from the participants and their family members. In the first phase, the questionnaire-based literature review and reference were developed using the google form application to obtain information from experts about recurrence risk factors. These questionnaires were sent by e-mail and contained the following: 1) instructions of the research background, time returned, contact information, and acknowledgment and 2) the suggestion from experts about "risk factors associated with the recurrence of diabetic foot ulcers". Moreover, this phase took place between February 15 and March 25, 2020. Based on input from experts, the questionnaires in the second phase were also developed through the google form application. These experts were obtained using previously identified variables to collect risk factors associated with recurrence. Furthermore, this instrument was structured similar to phase 1, where the risk factors' evaluation form on diabetic foot ulcer recurrence was the only difference, with a score ranging from 1 to 4 (1 = strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree). All questionnaires were sent via e-mail and between August 31 and September 28, 2020. Subsequently, two patients were used as raters to investigate the reliability agreement in a clinical setting. The questionnaires from the variable risk factors of recurrence in the second phase yielded a mean authority coefficient of 0.71. These variables included the following: 1) feet check, 2) knowledge, 3) diet pattern, 4) activity pattern, 5) foot care, 6) DM duration, 7) blood sugar value, 8) neuropathy status, 9) monofilament test check, 10) ankle-brachial pressure index examination, 11) ultrasonography assessment, 12) skin temperature, and 13) previous amputation. The questionnaire scoring included the following: 1 = strongly disagree, 2 = disagree, 3 = agree, and 4 = strongly agree. Moreover, data analysis was conducted with the IBM SPSS software (version 26.0., IBM Corp., Armonk, NY, USA). Each item was described using descriptive statistics, such as mean and standard deviation, while the Delphi method's reliability and validity were examined using expert opinion consensus and calculation of the positive predicative value. The authority coefficients (Cr) were determined by two factors, namely, the familiarity with the field (Cs) and criteria (Ca). Consequently, Cs used a value between 0.0 and 0.9^[12] to determine the five degrees of familiarity, namely, very,

more, generally, less, and not familiar.^[13] The terms practical experience (0.5, 0.4, and 0.3), theoretical analysis (0.3, 0.2, and 0.1), domestic and foreign references (0.1, 0.1, and 0.1), and subjective judgement (0.1, 0.1, and 0.1) were used to divide Ca into more, medium, and less. In addition, the degree of expert authority was expressed by $Cr:Cr = (Ca + Cs)/2$, while coordination was altered based on the variable and coordination coefficients.^[8] We used two indicators to evaluate the degree of coordination among expert opinions: the Coefficient of Variation (CV) and the coordination coefficient (Kendall's W). To calculate Kendall's coefficient, a value between 0 and 1 was used, where a higher denomination indicates better coordination. Furthermore, Cohen's Kappa was used to analyze the patient's inter-rater reliability agreement. The level of significance was set at $p < 0.05$.

Ethical considerations

This study was approved by the Ethics Review Committee of STIK Muhammadiyah Pontianak, West Kalimantan Province (Ethical Approval Number: 62/II.IAU/KET. ETIK/II/2020, and Date: February 2nd, 2020). Also, participation was voluntary, anonymous, and confidential. All participants received the consent document through the google form application and were requested to respond with a fill and return, indicating their readiness to participate in the study.

Results

In this study, the mean(SD) age of experts and the total working time were 39.40 (1.40) and 10.90 (1.60) years, respectively, with five having worked for >10 years. Furthermore, among these experts, one had a Ph.D. in medical surgery, three had a doctorate, two had a masters, and three possessed a bachelor's degree. Five of these individuals were from the wound clinic in West Kalimantan, two from the Middle Java's wound clinic, and one each from the wound clinics in Jakarta, Aceh, West Sulawesi, and East Kalimantan. The mean working time and age of the second Delphi experts were 11.20 (1.70) and 39.20 (1.50) years, respectively. Also, one expert had a surgeon's medical doctorate, three had a doctorate, and two and five had a master's and bachelor's degree. The positive coefficient was 100% (14 experts) in the first phase and 78% in the second. Table 1 shows that the mean authority coefficient in the second phase was 0.71, while Table 2 illustrates that the mean variable coefficient was 0.41. Subsequently, the coordination coefficient in the second phase was 0.177 ($\chi^2 = 25.359$, $df = 13$, $p = 0.02$) with a perfect inter-rater reliability agreement of 1.00.

Discussion

This is the first study that aims to investigate the risk factors associated with recurrence using experts' opinion and their experience. Moreover, recurrence patients were

Table 1: Coefficient expert of authority of variables

Variables	Ca*	Cs**	Cr***
Check feet every day	0.58	0.87	0.72
Check using monofilament test	0.57	0.85	0.71
Check ankle-brachial pressure index	0.60	0.85	0.72
Check using ultrasonography	0.55	0.85	0.70
Amputation previous	0.62	0.82	0.72
Knowledge wound healing	0.62	0.85	0.73
Diet pattern	0.61	0.81	0.71
Activity pattern	0.61	0.77	0.69
Footcare	0.64	0.75	0.69
Duration of DM****	0.63	0.79	0.71
Blood sugar	0.62	0.83	0.73
Neuropathy status	0.62	0.75	0.69
Skin temperature	0.61	0.84	0.73
Mean	0.61	0.82	0.71

*Criteria, **Familiarity with the field, ***Authority coefficients, ****Diabetes mellitus

Table 2: Coefficients and significance of variables

Variables	Mean (SD)*	CV**
Check feet every day	7.00 (4.00)	0.57
Check using monofilament test	8.00 (3.00)	0.38
Check ankle-brachial pressure index	8.00 (3.00)	0.38
Check ultrasonography	7.00 (4.00)	0.57
Knowledge wound healing	8.00 (3.00)	0.38
Diet pattern	7.00 (4.00)	0.57
Activity pattern	6.50 (4.50)	0.69
Footcare	7.50 (3.50)	0.47
Duration of Diabetes Mellitus (DM)	9.00 (2.00)	0.22
Blood sugar	9.00 (2.00)	0.22
Skin temperature	6.50 (4.50)	0.69
Amputation previous	7.50 (3.50)	0.47
Neuropathy status	9.00 (2.00)	0.22
Mean	7.80 (3.10)	0.41

*Standard deviation, **Coefficient of variation

used as participants, with different variables between the first and second phases, as indicated by the experts based on their experiences. The variables were also consistent with the patient's opinions. Experts with a bachelor's or higher degree and >10 years working experience in a hospital or clinic were questioned. These individuals were familiar with the study content and had in-depth knowledge of diabetic foot ulcers. The representation of experts was acceptable, and the participants included diabetes patients.

In reliability, the present study demonstrated positive coefficients indicating that experts were interested and optimistic about the study, with a high positive response. The literature indicated that a response rate of 60% or above was high positive response.^[12] Interestingly, our

study demonstrated that the authority coefficient was high. In line of the literature, if a coefficient is >0.7, the result of the inquiry was scientific and representative.^[14] Furthermore, the coefficient of variance was <3 and the mean values were ≥ 4 and ≤ 15 , respectively, thus indicating that better coordination and a high index could be maintained.^[15] Finally, the coordination coefficient in the second phase was consistent with good coordination. As a result, selecting qualified experts from various specialties and geographical distributions was critical to the success of the Delphi approach.^[9]

Our study demonstrated that there were some recurrent diabetic foot ulcer risk factors including neuropathy status, blood sugar, previous amputation, monofilament test, Ankle Brachial-Pressure Index (ABPI), foot care, duration of diabetes, activity and dietary pattern, wound healing knowledge, skin temperature, and assessment using ultrasonography.

Neuropathy status, blood sugar, and previous amputation were risk factors of recurrent diabetic foot ulcer, thus similar with previous studies.^[7,16] A previous study reported that the duration of diabetes increased with the risk of diabetic foot ulcer recurrence.^[7] Education about pre-ulcerative signs and foot care play an important role in the prevention of diabetic foot ulcers.^[17] Screening such as monofilament test ABPI and ultrasound are important to early detection peripheral arterial ischemia in diabetic foot ulcer.^[17] Checking the skin temperature, which is a feasible procedure, aids the prevention of recurrence.^[18] The last variables are activity and dietary pattern. The American Diabetes Association recommended physical activity and management of food on diabetes to prevent complication, particularly diabetic foot ulcer.^[19]

Generally, all variables were consistent with previous studies. Hence, they can be used to investigate risk factors associated with the recurrence of diabetic foot ulcers by health care professionals (clinicians, nurses, and others). The recurrence of diabetic foot ulcers was related to several risk factors that could be prevented by involving the patients and their families. Consequently, the patient's QOL is improved.

The limitation of the current study was that the number of participants in the inter-rater reliability agreement test was relatively small. Thus, generalizability may be limited. Future research is needed to evaluate these risk factors to recurrent diabetic foot ulcer patients with larger samples in clinical setting.

Conclusion

This study demonstrated that there are several risk factors associated with recurrent diabetic foot ulcers including neuropathy status, blood sugar, previous amputation, monofilament test, ABPI, foot care, duration of diabetes, activity and dietary pattern, wound healing knowledge, skin temperature, and assessment using ultrasonography. These

variables could serve as guidelines to prevent recurrence in the future that will improve quality of nursing of diabetic foot ulcer patients.

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Conflicts of interest

Nothing to declare.

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A Comparison of the Effects of Chlorhexidine and Sodium Bicarbonate Mouthwashes on COVID-19–Related Symptoms

Abstract

Background: Some studies have reported that mouthwashes can decrease the viral load in the mouth, but there is not much information about the effectiveness of mouthwashes on coronavirus disease 2019 (COVID-19). This study was conducted to compare the impact of using two types of mouthwash, chlorhexidine and sodium bicarbonate, on COVID-19 symptoms and infection. **Materials and Methods:** The present three-group, double-blind clinical trial examined 116 operating room nurses and anesthesia personnel of certain hospitals of Isfahan University of Medical Sciences, Isfahan, Iran. The participants were randomly assigned to three groups: intervention group 1 (chlorhexidine mouthwash), intervention group 2 (sodium bicarbonate mouthwash), and the control group (placebo). Mouthwash was used twice a day (morning and night) for 2 weeks. The participants were monitored in terms of COVID-19–related symptoms for 4 weeks, from the first day of mouthwash use. **Results:** Fisher’s exact test indicated a significant difference between the chlorhexidine and control groups in terms of the onset of COVID-19–related symptoms ($p = 0.02$). There was no significant difference in the symptoms of COVID-19 between the groups, but the groups were significantly different in terms of all symptoms at a 4-week interval ($p = 0.04$). Furthermore, headache was less observed in the chlorhexidine ($p = 0.007$) and sodium bicarbonate ($p = 0.03$) groups compared to the control group. **Conclusions:** The use of 0.2% chlorhexidine mouthwash can decrease the onset of COVID-19–related symptoms in health-care workers. In addition, this mouthwash can partially reduce the symptoms of this disease in comparison to the control and sodium bicarbonate groups.

Keywords: Chlorhexidine, COVID-19, medicine, mouthwashes, nursing, operating room, Persian, sodium bicarbonate

Introduction

In all countries, coronavirus disease 2019 (COVID-19) has caused a crisis and severe damage.^[1] The World Health Organization (WHO) declared COVID-19 a pandemic on March 12, 2020. High mortality rates, high hospitalization costs, and the ineffectiveness and dangerous complications of some proposed drugs for treating COVID-19 indicate the need for safe treatment and prevention.^[2] The transmission of this disease occurs primarily through aerosol, saliva, coughing, sneezing, and inhalation of virus-infected droplets.^[3] A healthy lifestyle, boosting the immune system, observing hand and face hygiene, wearing a mask, and social distancing protect individuals against the damages caused by COVID-19.^[2,4] Due to the presence of coronavirus (severe

acute respiratory syndrome coronavirus 2 [SARS-CoV-2]) in individuals’ saliva and contamination by aerosol, the oral cavity has been introduced as a potential reservoir for the transmission of COVID-19. Angiotensin-converting enzyme 2 (ACE2) has been identified as a coronavirus receptor. ACE2 levels are high in the lungs, heart, saliva, end part of the small intestine, kidney, and bladder;^[5,6] the number of positive cases of COVID-19 can reach 91.7% in the saliva samples, and live virus grows in saliva.^[7]

The best way to prevent this disease is to reduce its prevalence in society. Vaccines are the most reliable way to manage COVID-19 and can decrease the mortality rate caused by this virus. According to previous studies, vaccination cannot guarantee the prevention of coronavirus,

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but can minimize its complications and mortality.^[8,9] Using mouthwash is an effective and recommended method to reduce the viral load in the mouth. According to some studies, the virus may be destroyed in the early stages of the disease in the upper respiratory system, but the safety and effectiveness of mouthwashes on COVID-19 are unclear.^[10] Mouthwashes prevent coronavirus transmission through reduction of virus accumulation in the mouth by washing and removing the virus. They also inhibit virus attachment to the receptor, exhibit virucidal and virostatic properties, and make the biological environment of the oral cavity unsuitable for viruses.^[11,12]

Chlorhexidine is a biguanide antimicrobial that is effective against gram-positive and gram-negative bacteria, obligate anaerobes, aerobes, and yeast. It deactivates viruses at some specific concentrations and can be used as a mouthwash and a posterior pharyngeal spray. The results of the study by Jain *et al.*^[13] indicate that chlorhexidine digluconate at a concentration of 0.2% kills more than 99.9% of SARS-CoV-2 in the shortest possible time, and it seems to be a reliable and effective virus inactivator. The side effects of chlorhexidine include the possibility of tooth discoloration, supragingival mass formation, and changes in taste perception.^[14] Sodium bicarbonate, with the formula of NaHCO_3 , is a sodium salt in combination with carbonic acid. As a common household substance (e.g., 7.5%–8.4%), in Persian medicine, sodium bicarbonate solution has become a suitable mouthwash, which is easily accessible, has minimal abrasiveness, is safe, and has antibacterial properties and almost no side effects as a mouthwash.^[15-17] Studies have reported the different effects of sodium bicarbonate on COVID-19, and most of them have investigated sodium bicarbonate fumigation.^[17,18] Health-care workers are the main groups at risk of infection during the present COVID-19 outbreak. One study reported that the risk of infection with COVID-19 among health-care workers was 10 times higher than that in the general population.^[19] Since the operating room nurses and anesthesia personnel are in close contact with patients, they may be infected even after vaccination. According to a study that investigated the prevalence of COVID-19 in health-care workers after vaccination, even though vaccination can be very effective, this infection can still occur and may be asymptomatic and dangerous for the vulnerable population.^[20]

Considering the susceptibility of the oral cavity to COVID-19 infection and based on the results of some articles, which indicated that no vaccine provided complete immunity,^[21,22] preventive measures must also be taken in addition to vaccine injection. As there were few studies on the impact of mouthwashes on the prevention and treatment of COVID-19, the present study was conducted with the aim to compare the impact of mouth washing with chlorhexidine and sodium bicarbonate mouthwashes on COVID-19-related symptoms in operating room nurses

and anesthesia personnel in the operating rooms of certain hospitals of Isfahan University of Medical Sciences in the year 2022.

Materials and Methods

The present study was a three-group, double-blind clinical trial, including two intervention groups, which received chlorhexidine and sodium bicarbonate mouthwashes, and a control group that received a placebo. It was conducted on operating room nurses and anesthesia personnel in the operating rooms of certain hospitals of Isfahan University of Medical Sciences, Isfahan, Iran, from July to October 2022. This trial was registered in the Iranian Registry of Clinical Trial (IRCT) with the registration code of IRCT20220328054364N1.

Receiving at least two doses of vaccine, being under 60 years of age, not having been infected with COVID-19 in the last 2 months,^[23] having no symptoms of systemic infection, not receiving immunosuppressive drugs, having no history of allergy to mouthwash solutions, observing the minimum 2 weeks after the injection of the second dose,^[24] not being pregnant, and not breastfeeding were the inclusion criteria. The exclusion criteria included unwillingness to continue participating in the research, not using the mouthwash solution properly for any reason, and using the mouthwash for less than 7 days.

Operating room nurses and anesthesia personnel were enrolled in the study using convenience sampling and according to the study inclusion criteria and were then randomly allocated to three groups. For randomization, first, we allocated a number to each sample, and then, using the table of random numbers, registered samples into three groups. Considering a 95% confidence interval, $z_1 = 1.96$, $z_2 = 0.84$, and $d = 1$, and taking into account a 10% loss of samples, a sample size of 120 individuals was obtained. A number was assigned to each eligible person. The individuals were placed in an intervention group with chlorhexidine solution, an intervention group with sodium bicarbonate solution, and a control group using the random numbers table. Sampling continued until the required number of samples had been collected. Finally, the data related to 116 eligible individuals (36 individuals in the chlorhexidine mouthwash group, 40 individuals in the sodium bicarbonate mouthwash group, and 40 individuals in the control group) were analyzed. Figure 1 shows the CONSORT diagram.

The research data were collected at the seventh peak of COVID-19. Checklists 1 and 2 were used for data collection. Checklist 1 consisted of three parts. The first was a demographic characteristics form, including questions on gender, age, education level, body mass index (BMI), type of injected vaccine, history of taking complementary medicines and vitamin D in the last month, history of underlying diseases, history of respiratory failure, history

of smoking, hospital name, date of receiving mouthwash, and contact number, the second was the type of mouthwash solution, and the third included the COVID-19-related symptoms, including runny nose, lethargy, fever, body aches, headache, dizziness, wheezing, weakness, fatigue, ear inflammation and infection, loss of appetite, tears, sneezing, cough, dyspnea, sore throat, diarrhea, vomiting, skin rash, red and irritated eyes, and lower senses of smell and taste.^[25,26] The researcher completed the first and second parts of this checklist by questioning the participants according to the mouthwash they used. The third part was completed by collecting checklist 2 during the self-reporting of COVID-19 symptoms. Checklist 2 was prepared to record symptoms and the course of daily use of mouthwash. It included all COVID-19-related symptoms and was completed at 1-week intervals. Furthermore, a table was designed for recording the use of mouthwash, and the staff recorded their mouthwash use twice a day, in the morning and at night. Mouthwash use and symptoms were completed through self-report in this checklist.

Given that chlorhexidine compounds are effective against lipid-coated viruses, they were used as a mouthwash in this research. Some studies indicate that if cells are in an alkaline state (i.e., pH >7), the entry of the virus into the cell is reduced, but the viral load is increased in the host cell in acidic conditions (i.e., pH <7). Sodium bicarbonate increases the pH, it was used during the Spanish flu pandemic, and it is an available and safe option; hence, sodium bicarbonate was the second mouthwash used in this study.^[27,28]

Initially, the researcher explained the research objectives to the participants and obtained written informed consent forms from them. For blinding, uniform dark-colored medicine glass bottles were prepared and filled with sodium bicarbonate, chlorhexidine, and drinking water. After coding the solutions, the bottles were given to personnel along with a medicinal scale and a symptom registration sheet. The type of solution provided to each staff member and their characteristics were recorded in checklist 1. The mouthwash use method and other pertinent information were written on the bottles and also explained verbally. Each participant received two 250-ml dark glass bottles containing mouthwash solution; the first bottle of medicine was used in the first week and the second bottle was given to the staff at the end of the first week for use in the second week.

Ready and colorless 0.2% chlorhexidine solution (Vi-One, Tehran, Iran) was the standard concentration of this mouthwash. It was obtained from a pharmacy and poured into bottles prepared by the researcher. The sodium bicarbonate powder (production of Sabzkooh Iran company) was obtained from a sales unit. A 7.5% mouthwash solution was prepared by the researcher^[28] using a precise scale and graduated glass. Thus, 7.50 g of sodium bicarbonate was weighed after setting the scale to zero and was diluted with water to make 100 ml of solution. After dissolution, it was poured into glass bottles.

Placebo was the third mouthwash. Drinking water was used for placebo due to its use in the preparation of sodium bicarbonate solution. The colors of all three

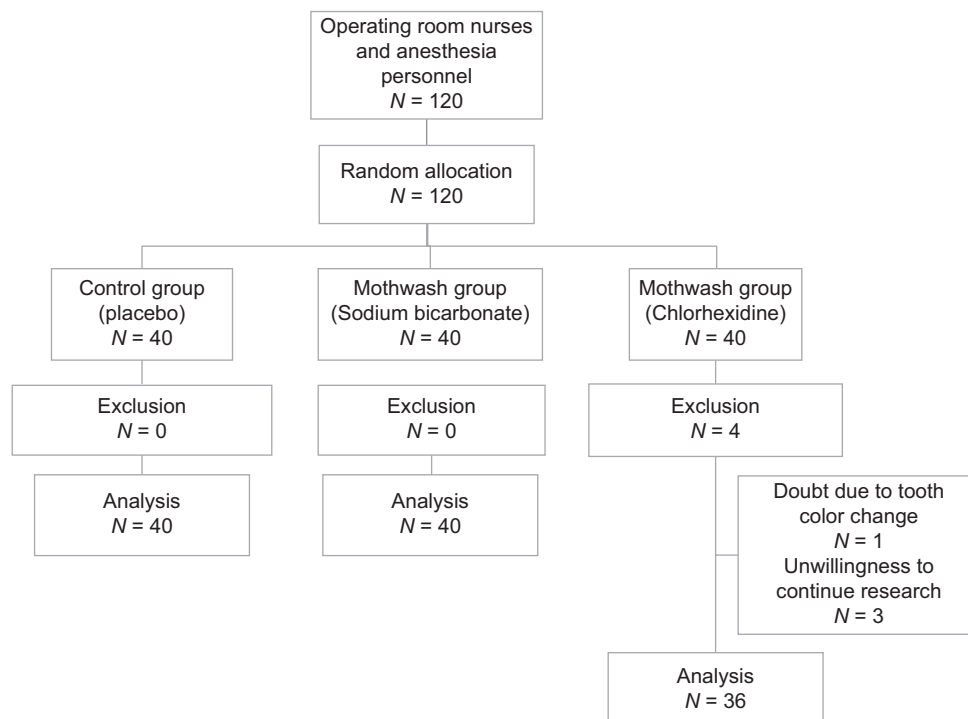


Figure 1: CONSORT diagram of participants

solutions were similar according to the rules of placebo and the double-blind nature of the research, but essential oils were not added owing to their potential effect on the antimicrobial properties of the solutions. According to the instructions on the chlorhexidine mouthwash bottle and a previous study, the method of use was 15 ml once in the morning and once at night for 1 min and over a 2-week period.^[29] The instructions included the following: avoid eating and drinking for at least half an hour after using the mouthwash, keep it at room temperature and away from direct sunlight, avoid continuous use for more than 3 weeks, brush your teeth before use, and the mouthwash solution is not edible. Given the antimicrobial properties of some types of toothpaste, the researcher provided the participants with simple toothpaste. After using the mouthwash, its use was stopped for 2 weeks, and the participants were followed for 4 weeks to examine the onset of symptoms of COVID-19 from the first day of using mouthwash (because the effects of mouthwash might be transient)^[13] as well as COVID-19-related symptoms in them. In this study, the emergence of at least two of the above-mentioned symptoms was considered an infection with COVID-19.^[25]

During the 4 weeks of monitoring the participants, they recorded and reported their symptoms once a week on the Symptom Recording Checklist (checklist 2). In the case of any suspicious symptoms, they wrote them in the checklist rather than symptom recording at 1-week intervals. Moreover, three virtual groups were created by the researcher based on the specific type of mouthwash solution used by the participants to remind them to use mouthwash every day. Furthermore, at the same intervals,

all three groups received a short clip with mouthwash usage instructions. The participants were asked to report any suspected symptoms of COVID-19 to be recorded by the researcher. The data were analyzed using the Statistical Package for the Social Sciences (SPSS) software (version 22; IBM Corp., Armonk, NY, USA) at a significance level of < 0.05 .

Ethical considerations

The present research was conducted after obtaining an ethical code (IR.MUI.NUREMA.REC.1401.044) from the ethics committee of Isfahan University of Medical Sciences, a letter of recommendation from the research deputy of the School of Nursing and Midwifery of the same university, and approval of the officials of each hospital. The researcher explained the research objectives to the participants and obtained written informed consent forms from them. Moreover, all of the participants were free to withdraw from the study whenever they wanted.

Results

According to the results of the Chi-square test, Kruskal–Wallis, and one-way analysis of variance (ANOVA), there was no significant difference between the groups in terms of gender, education level, age, and BMI. All participants were vaccinated at least twice. The Kruskal–Wallis test did not indicate any significant difference between the groups in terms of the numbers of vaccinations received. Table 1 summarizes the demographic information of the participants.

Cochran's test indicated no significant changes in symptoms in the groups over time, but the headache symptom was

Table 1: Demographic variables in the research groups

Variables	Group <i>n</i> (%)			Statistic (χ^2 */H**)	<i>p</i>
	Chlorhexidine	Sodium bicarbonate	Control		
Gender					
Male	6 (16.70)	2 (5.00)	3 (7.50)	3.28*	0.19
Female	30 (83.30)	38 (95.00)	37 (92.50)		
Age (years)					
20–30	12 (33.30)	13 (32.50)	14 (35.00)	0.020*	0.98
30–40	18 (50.00)	21 (52.50)	18 (45.00)		
40–50	5 (13.90)	3 (7.50)	6 (15.00)		
50–60	1 (2.80)	3 (7.50)	2 (5.00)		
Education level					
Associate degree	2 (5.60)	5 (12.50)	7 (17.50)	3.59*	0.16
Bachelor's	31 (86.10)	33 (82.50)	32 (80.00)		
Master's	2 (5.60)	2 (5.00)	1 (2.50)		
Ph.D.	1 (2.80)	0 (0)	0 (0)		
BMI*					
Weight loss	4 (11.10)	1 (2.50)	3 (7.50)	4.55**	0.10
Normal weight	18 (50.00)	23 (57.50)	29 (72.50)		
Overweight	12 (33.30)	13 (32.50)	8 (20.00)		
Obesity	2 (5.60)	3 (7.50)	0 (0)		

*Chi-square test. **Kruskal–Wallis test. ***BMI=body mass index

less observed and there was a significant change in this symptom in the chlorhexidine ($p = 0.007$) and sodium bicarbonate ($p = 0.03$) groups.

According to the Kruskal–Wallis test, there was no significant difference between the groups at different times, but there was a significant difference between the groups in terms of the total number of symptoms at a 4-week interval ($H = 6.30$, $p = 0.04$). Table 2 summarizes the relevant data.

A comparison of the chlorhexidine and control groups using the Mann–Whitney test indicated a significant difference between the two groups in the first week ($Z = -2.20$, $p = 0.02$) and the fourth week ($Z = -1.96$, $p = 0.04$). As can be seen in Table 3, a significant difference was also observed between the two groups in terms of symptoms ($Z = -2.29$, $p = 0.02$).

A comparison of the sodium bicarbonate and control groups using the Mann–Whitney test indicated no significant difference at any time ($p > 0.05$), but a P value of 0.06 was obtained in the third week for the mean total of symptoms, which was close to the significance level.

A comparison of the chlorhexidine and sodium bicarbonate groups using the Mann–Whitney test revealed no significant difference at any time ($p > 0.05$).

A total of seven (19.40%) participants in the chlorhexidine group, 18 (45%) in the control group, and 11 (27.50%) in the sodium bicarbonate group were infected with COVID-19.

The Chi-square test indicated a significant difference between the groups in terms of the onset of COVID-19-related symptoms ($\chi^2 (2) = 6.13$, $p = 0.04$). A pairwise group comparison was performed to accurately examine the difference between the groups. Fisher's exact test indicated a significant difference between the chlorhexidine and control groups in terms of the onset of COVID-19-related symptoms ($p = 0.02$), but no significant difference was seen between the control and sodium bicarbonate groups. Fisher's test indicated no significant difference between the chlorhexidine and sodium bicarbonate intervention groups in this regard [Table 4].

Discussion

The results of the present study indicated a significant difference in the onset of COVID-19-related symptoms between the chlorhexidine and control groups ($p = 0.02$). This study confirmed the results of a study by Huang and Huang (2021), indicating that chlorhexidine mouthwash is a simple and safe additive to current guidelines for the prevention of COVID-19 with significant effects on outbreak control. When chlorhexidine is used along with vaccination, appropriate social distancing, wearing a mask, and hand washing, it may help prevent the disease effectively.^[8]

The present study indicated that 18 (45%) participants in the control group and seven (19.40%) participants in the chlorhexidine group were infected with COVID-19 in 4 weeks, showing a significant difference between

Table 2: A comparison of the mean total of symptoms in different groups

Time/group	Chlorhexidine	Control	Sodium bicarbonate	H*	p
First week					
Mean (SD)	0.22 (1.17)	1.22 (3.14)	0.70 (1.84)	5.29	0.07
Minimum	0	0	0		
Maximum	7	17	8		
Second week					
Mean (SD)	0.66 (2.05)	1.50 (2.63)	0.87 (2.26)	2.48	0.28
Minimum	0	0	0		
Maximum	10	10	12		
Third week					
Mean (SD)	0.86 (2.66)	0.97 (2.16)	0.20 (0.72)	3.67	0.16
Minimum	0	0	0		
Maximum	11	10	4		
Fourth week					
Mean (SD)	0.05 (0.23)	0.92 (2.58)	0.75 (2.43)	3.82	0.14
Minimum	0	0	0		
Maximum	1	14	13		
Total					
Mean (SD)	1.80 (3.67)	4.62 (7.37)	2.52 (4.99)	6.30	0.04
Minimum	0	0	0		
Maximum	13	31	18		

*Kruskal–Wallis statistic

Table 3: A comparison of the mean amounts of symptoms in chlorhexidine and control groups

Time/group	Chlorhexidine	Control	Z*	p
Time/group				
Mean (SD)	0.22 (1.17)	1.22 (3.14)	-2.20	0.02
Minimum	0	0		
Maximum	7	17		
Second week				
Mean (SD)	0.66 (2.05)	1.50 (2.63)	-1.51	0.13
Minimum	0	0		
Maximum	10	10		
Third week				
Mean (SD)	0.86 (2.66)	0.97 (2.16)	-1.09	0.27
Minimum	0	0		
Maximum	11	10		
Fourth week				
Mean (SD)	0.05 (0.23)	0.92 (2.58)	-1.96	0.04
Minimum	0	0		
Maximum	1	14		
Total				
Mean (SD)	1.80 (3.67)	4.62 (7.37)	-2.29	0.02
Minimum	0	0		
Maximum	13	31		

*Mann-Whitney test. SD=Standard deviation

Table 4: Comparison of the onset of COVID-19-related symptoms (infection) in the research groups

Group	Number (%)	χ^*	df	p
Chlorhexidine	7 (19.40)	6.13	2	0.04
Control	18 (45.00)			
Sodium bicarbonate	11 (27.50)			

*Chi-square. COVID-19=coronavirus disease 2019, df=degrees of freedom

these two groups ($p = 0.02$), while a research^[30] indicated that COVID-19 was an enveloped virus and 0.12% chlorhexidine gluconate had little or no effect on viruses compared to other mouthwashes. This significant difference between these two studies might be due to the difference in the concentration of chlorhexidine mouthwash. The present study was consistent with a study by Moosavi *et al.*,^[11] which indicated that chlorhexidine mouthwash had a wide range of antimicrobial effects, and antiviral mouthwashes played important roles in decreasing the viral load of saliva.

The results of a study by De Paula Eduardo *et al.*^[31] on SARS-CoV-2 load reduction in saliva using mouthwash indicated that chlorhexidine mouthwash caused a significant reduction in viral SARS-CoV-2 load in saliva up to 60 min after washing, but its effect was transient. Therefore, it appears that chlorhexidine solution decreased infection by reducing the salivary viral load, which is consistent with the present study.

Huang and Huang conducted a study in 2021 on the effect of chlorhexidine mouthwash and posterior oral

oropharyngeal spray use on the prevention of COVID-19 among medical staff in Los Angeles and California.^[8] The results indicated that there were no cases of SARS-CoV-2 infection in the intervention group. Furthermore, the infection rate of COVID-19 in the control group was close to 50% in the same period. The results of this study were consistent with those of our research.

A comparison of the sodium bicarbonate and control groups indicated no significant difference in symptoms and infection of COVID-19 at any time ($p > 0.05$). The results of a study by Kumar *et al.*^[28] indicated that gargling with 7.5% sodium bicarbonate solution might be ineffective in achieving initial SARS-CoV-2 clearance in mild COVID-19 patients, and thus, its results were consistent with our study.

Zamani *et al.*^[17] indicated that inhalation of sodium bicarbonate could have a significant positive effect on respiratory complications caused by the coronavirus. This finding was inconsistent with the present study. The difference in these two studies might be due to the difference in the way sodium bicarbonate was used; mouthwash was used in the present study, but Zamani *et al.*^[17] used a nebulized form of sodium bicarbonate. Another reason for inconsistency in these two studies could be the difference in disease severity. The current study used sodium bicarbonate to prevent the mild form of the disease, whereas Zamani *et al.*^[17] used it to prevent the severe form of the disease and those who required tracheal intubation.

A comparison of the sodium bicarbonate and control groups indicated no significant difference in the symptoms and infection of COVID-19 at any time ($p > 0.05$). Siahpoosh *et al.*^[18] conducted a study on the effectiveness of inhalation of baking soda (sodium bicarbonate) on improving respiratory symptoms in COVID-19 patients. They reported that inhaling the nebulized form of sodium bicarbonate decreased the severity of respiratory system inflammation by increasing the airway blood flow and decreasing sputum stickiness. However, sodium bicarbonate molecules were not emitted from the evaporation of sodium bicarbonate solution during home fumigation, and its fumigation worked like hot water fumigation. Sodium bicarbonate fumigation was theoretically unsuitable for inflammation and COVID-19 infection. Furthermore, the nebulized form of sodium bicarbonate might increase the transmission rate of infectious aerosol in patients with COVID-19. The findings of Siahpoosh *et al.* are in line with the present study in that sodium bicarbonate solution has no effect when used as a home fumigant, and doubts remain about its effectiveness when used in the nebulized form.

Mir *et al.*^[16] conducted a study titled "Lysosomotropic properties of sodium bicarbonate and COVID-19" and showed that the entry of the novel coronavirus into host cells depends on pH. Sodium bicarbonate plays a role in neutralizing the acidic state and can be considered a safe

and available option for possible preventive and therapeutic interventions against the proliferation of SARS-CoV-2. However, comparison of the sodium bicarbonate and control groups in the present study indicated no significant difference in symptoms and infection of COVID-19 at any time ($p > 0.05$). The difference in the results of these two studies might be due to their methods and the fact that the study by Mir *et al.*^[16] was a laboratory study.

As a limitation of the study, despite daily and constant reminders to participants in a virtual group, there was the possibility of forgetting, and the researcher could not observe all points. This is due to the fact that it was impossible to follow the participants for each use. In addition, that why sodium bicarbonate not provided the desired result was probably due to its number of uses per day or its concentration, which could be increased to achieve the desired result.

Conclusion

Although the separate comparison of symptoms in the groups at different times did not show any significant differences, 0.2% chlorhexidine mouthwash decreased the symptoms. In the present study, 0.2% chlorhexidine mouthwash was more effective than sodium bicarbonate mouthwash and placebo. The symptoms and complications of COVID-19 are considered a serious challenge for health-care workers. The use of chlorhexidine mouthwash is recommended as a way to reduce the salivary viral load, reduce infection, and ultimately reduce the occurrence of disease symptoms. It is suggested that larger-scale research with more samples be conducted in multiple care centers. It is also recommended that these two solutions be compared at different concentrations.

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Conflicts of interest

Nothing to declare.

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Evaluation of Pregnant Woman's Perception of COVID-19 Based on the Health Belief Model in Isfahan

Abstract

Background: Coronavirus Disease (COVID-19) is a viral disease that has become an international public health concern. Thus, the present study aimed to evaluate pregnant women's perception of COVID-19 based on the health belief model in Isfahan. **Materials and Methods:** This cross-sectional study includes 100 pregnant women selected by random sampling. Data were collected using an online questionnaire on the Porsline website. This questionnaire examines the knowledge and structures of the health belief model, including perceived susceptibility and severity, perceived barriers and benefits, and self-efficacy regarding the prevention of COVID-19. Data were analyzed using analytical tests such as independent *t*-test and Pearson's correlation coefficient. The significance level was considered to be <0.05 . **Results:** The results showed that the knowledge of COVID-19 and preventative methods was at a reasonable level among most women (77%). Also, there was a significant correlation between education and self-efficacy. Based on the findings, the mean score of knowledge ($F_{1,99} = 0.116$, $p = 0.04$) and the mean score of perceived susceptibility ($F_{1,99} = 0.02$, $p < 0.001$) of mothers who were pregnant for the first time were significantly higher than mothers who were pregnant for the second time or more. **Conclusions:** The perceived severity and susceptibility scores were higher than other constructs, indicating women's proper understanding of the risks of COVID-19. However, half of them stated that they do not go to receive services, and this issue can have adverse consequences. The researchers recommend planning to improve other model constructs, such as self-efficacy, for improving women's performance in receiving care.

Keywords: COVID-19, health belief model, knowledge, pregnancy

Introduction

In January 2020, the World Health Organization (WHO) declared that the Coronavirus Disease (COVID-19) is a public international health concern.^[1] Since then, many problems have arisen about women expecting to have a baby and the possible effects of this issue on catastrophic outcomes in many nations.^[2] Pregnant women may be more susceptible to COVID-19 due to their greater vulnerability to respiratory infections.^[3] Some research on pregnant women infected with COVID-19 showed that they were all infected in the third trimester and had similar clinical findings to those of non-pregnant adults. Also, there were some cases of fetal distress and pre-term delivery among these individuals.^[4] Pregnant women are highly nervous about the prevalence of COVID-19 and its effects on their health.^[5] Many pregnant women do not see their physicians due to their concerns

about coronavirus exposure. Also, due to stress and anxiety, they are intended to give birth earlier than a cesarean section. Many pregnant mothers constantly use detergents to prevent the virus, which may lead to poisoning.^[6] In another study, more than four-fifths (82%) of the women believed that COVID-19 is real, and the majority had adequate knowledge of COVID-19.^[7]

The Health Belief Model (HBM) predicts behaviors based on perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy.^[8,9] Therefore, in the first stage, it is essential to study the level of knowledge, susceptibility, and perceived severity of pregnant women and their self-efficacy to go through the course of the disease. HBM is an exploratory model focusing on the changes in personal beliefs. In other words, the HBM emphasizes how people's perception creates motivation and

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eventually changes behaviors. Currently, limited evidence base exists to assess the knowledge of pregnant women about COVID-19. Therefore, the present study aimed to evaluate the knowledge of pregnant women about COVID-19 and perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy about the prevention of COVID-19 in Isfahan.

Materials and Methods

This cross-sectional study (from July 2020 to October 2020) was conducted on pregnant women aged 18–49 years covered by health centers in Isfahan via WhatsApp. The statistical population in this study included all pregnant mothers in Isfahan who were interested in cooperating in this study, referred to one of the health centers, and had a health record. In this study, the participants were chosen based on random sampling. Samples were selected from four health centers in four directions (i.e. south, north, east, and west) of Isfahan. Inclusion criteria were pregnant women living in Isfahan who had access to smartphones, WhatsApp applications, and Internet access and were literate and willing to participate in the study. The exclusion criteria were incomplete responses to the questionnaire.

After obtaining the code of ethics and the letter of introduction from Isfahan University of Medical Sciences, the project's executors referred to Isfahan Health Centers, selected randomly. The healthcare workers selected pregnant women from the list by random sampling, contacted pregnant mothers who were eligible to study, and encouraged them to participate. Also, before starting the study, the objectives and necessity of the study were explained to them over the telephone by the midwifery healthcare staff of health centers. Afterward, they completed the online informed consent form. The link for this questionnaire was sent via the WhatsApp application. The questionnaire was self-made and consisted of several sections, including demographic information and questions related to Health Belief Model constructs such as knowledge (9 items), perceived susceptibility (22 items), perceived severity (7 items), perceived benefits (5 items), perceived barriers (10 things), cue to action (9 items), and self-efficacy (15 items) measured on a Likert scale. The items of this scale included “very agree” (=5), “agree” (=4), “no idea” (=3), “disagree” (=2), and “strongly disagree” (=1). The total time spent completing the questionnaire was 20 min. Ten health experts evaluated the tool's validity. Also, its Content Validity Index (CVI) and Content Validity Ratio (CVR) were estimated to be 0.80 and 0.74, respectively. The internal consistency method was used to assess the scale's reliability, which was confirmed to be 0.76 in Cronbach's alpha.

Data were entered into SPSS (version 16.00; SPSS Inc., Chicago, IL, USA) and analyzed using descriptive and analytical tests such as the Shapiro–Wilk test, independent *t*-test, and Pearson's correlation coefficient. The significance level in the present study was less than 0.05.

Ethical considerations

Participants' informed consent was obtained to participate in the study. The student research committee approved this project. Ethical considerations such as information confidentiality about pregnant women were observed. Also, the ethics code was received from the ethics committee of Isfahan University of Medical Sciences with the number IR.MUI.RESEARCH.REC.1399.350.

Results

In total, 100 pregnant mothers with a mean (Standard Deviation [SD]) of the age of 28.19 (4.38) years participated in the present study. Based on the findings, the educational status of 10% of the participants was related to medical sciences [Table 1]. Table 2 presents the mean score and SD of the structures of the HBM among pregnant mothers. The mean (SD) of perceived susceptibility and severity, knowledge, and self-efficacy was 71.73 (16.23), 26.50 (2.80), 6.90 (1.35), and 63.99 (8.57), respectively.

Table 3 shows the relationship between demographic characteristics and HBM constructs. Accordingly, having higher education levels increases the mean self-efficacy score among pregnant mothers. Based on the findings, the mean score of knowledge and the mean score of perceived susceptibility of first-time-pregnant mothers were significantly higher than those of mothers who were pregnant for the second time or more ($F_{1,99} = 0.116$, $p = 0.04$., $F_{2,99} = 0.02$, $p < 0.001$). However, no significant relationship was observed between other demographic variables and HBM components.

Table 1: Demographic characteristics of pregnant mothers

Variable	Number (percentages)
Field of study	
Medical sciences	10 (10%)
Other fields	90 (90%)
Education level	
High school diploma	17 (17%)
Diploma	40 (40%)
Above diploma	13 (13%)
Bachelor's degree and higher	30 (30%)
Job	
Housewife	89 (89%)
Student	4 (4%)
Employed	7 (7%)
Frequency of pregnancy	
First	50 (50%)
Second	28 (28%)
Third	18 (18%)
Fourth and more	4 (4%)
Underlying disease	
Yes	11 (11%)
No	89 (89%)

The findings showed that 70% of pregnant women wore masks when leaving their houses. Given that pregnant women are at high risk, and the best way to prevent COVID-19 is to follow health tips, this rate may seem unacceptable. Also, only 51% of pregnant women regularly visited health centers for routine prenatal care.

Discussion

This study aimed to evaluate pregnant women's perception of COVID-19 based on the health belief model in Isfahan.

Table 2: Mean score and standard deviation of the health belief model constructs and knowledge

The health belief model constructs	Mean (SD)	Min	Max
Knowledge	6.90 (1.35)	2	9
Perceived susceptibility	71.73 (16.23)	12	107
Perceived severity	26.51 (2.84)	14	38
Perceived benefits	22.48 (3.11)	11	35
Perceived barriers	23.31 (5.05)	12	33
Self-efficacy	63.99 (8.57)	43	79

According to the result, there is a positive correlation between demographic characteristics and HBM constructs. The mean score of self-efficacy among pregnant mothers increases remarkably by education level. However, no statistically significant relationship was observed between other demographic variables and Health Belief Model components. This rate may seem unacceptable, but only 51% of pregnant women regularly visited health centers for routine prenatal care.

The results showed that the knowledge of COVID-19 and preventative methods was at a good level among most women in 77% of pregnant women. Consistent with this result, Wolf *et al.* and Alahdal *et al.* reported that more than 90% of women knew how the coronavirus is transmitted.^[10,11] In a similar study, Hernández-Padilla *et al.*^[12] noted that the mean score of self-efficacy was consistent with the present study's findings.

In our study, the mean self-efficacy score increased due to an increase in their education levels. Several methods for increasing self-efficacy, such as verbal persuasion and increasing people's knowledge of their abilities, could be

Table 3: Determining the relationship between the demographic characteristics of pregnant mothers with health belief model and knowledge

Variable	Knowledge Mean(SD)	Perceived sensitivity Mean(SD)	Severely perceived Mean(SD)	Perceived benefits Mean(SD)	Perceived barriers Mean(SD)	Self-efficacy Mean(SD)
Field of study*						
Medical sciences	6.64 (1.54)	68.73 (16.92)	27.41 (2.63)	23.95 (2.01)	22 (5.52)	65.50 (6.43)
Other fields	6.92 (1.30)	72.06 (16.27)	26.44 (2.97)	22.32 (3.22)	23.43 (5.02)	63.83 (8.70)
<i>p</i>	0.50	0.40	0.60	0.30	0.30	0.09
Education**						
Under diploma	6.51 (1.06)	81.24 (22.61)	26.70 (3.62)	22.20 (3.43)	25.28 (6.80)	58.55 (12.86)
Diploma	6.95 (1.47)	70.15 (14.62)	26.71 (2.44)	21.92 (3.59)	23.27 (4.44)	63.99 (6.93)
Above diploma	6.68 (1.33)	68.51 (17.02)	26.74 (3.83)	23.63 (2.58)	22.86 (5.96)	66.94 (6.40)
Bachelor's degree and higher	7.31 (1.34)	69.76 (11.93)	25.93 (2.52)	22.83 (2.57)	22.51 (4.19)	65.86 (7.11)
<i>p</i>	0.20	0.07	0.80	0.30	0.10	0.02
Job**						
Housewife	6.81 (1.37)	71.44 (16.93)	26.67 (2.92)	22.54 (3.26)	23.30 (5.23)	63.87 (8.82)
Student	7.22 (0.95)	79.00 (6.62)	26.24 (3.20)	21.77 (2.30)	23.57 (3.86)	65.00 (8.16)
Employed	7.41 (2.07)	70.73 (9.05)	25.12 (1.96)	22.56 (2.31)	22.43 (3.27)	65.23 (4.17)
<i>p</i>	0.20	0.70	0.30	0.60	0.50	0.40
Frequency of pregnancy**						
First	7.20 (1.20)	71.71 (14.34)	26.04 (2.60)	22.55 (2.95)	23.00 (4.53)	65.27 (6.64)
Second	6.97 (1.23)	71.46 (16.05)	27.22 (2.65)	22.10 (3.64)	22.07 (4.61)	64.30 (8.61)
Third	6.14 (1.69)	66.93 (14.42)	26.64 (3.08)	22.54 (3.10)	26.16 (5.62)	61.54 (7.87)
Fourth and more	6.77 (1.57)	93.47 (31.53)	26.7 (5.52)	23.57 (1.93)	23 (7.84)	56.72 (5.07)
<i>p</i>	0.04	0.001	0.50	0.70	0.60	0.20
Underlying disease*						
Yes	6.70 (1.33)	65.10 (11.79)	26.13 (2.47)	22.93 (2.14)	28.73 (3.55)	62.65 (8.56)
No	6.90 (1.37)	72.53 (16.58)	26.54 (2.96)	22.44 (3.29)	22.67 (4.87)	64.18 (8.57)
<i>p</i>	0.60	0.07	0.60	0.40	0.03	0.3

*An independent *t*-test was used to compare the data. **Analysis of variance was used to compare the data. A significance level of <0.05 was considered

used to promote preventive behaviors against COVID-19.^[13] In this study, the mean score of perceived susceptibility was good. Findings reported by similar studies are consistent with the present study. For example, Shahnaz revealed that most respondents had relatively high perceived exposure.^[14]

Nasirzadeh's study in Qom (Iran) also confirmed the present study's findings.^[15] In addition, another study showed that 80% of pregnant women felt vulnerable and were predominantly concerned about getting infected with coronavirus even when following the health tips.^[16] In contrast, Lee *et al.* showed that 46% of pregnant women were unsure whether their infection may lead to abortion or getting into pre-term delivery. High perceived susceptibility in our participants was due to exposure to various media, including television.^[17] Furthermore, the mean score of perceived susceptibility among pregnant women indicated that pregnant mothers considered themselves more susceptible to the disease. Hosseintalaei *et al.*^[18] also reported this result in their study.

The high mean score of a person's perception of the susceptibility and severity of health risks significantly impacts a person's behavior to prevent the occurrence of that risk.^[19] However, in Walrave *et al.*^[20] study, there was no significant relationship between the intention related to perceived sensitivity and severity. Pregnant women with the underlying disease were noticeably higher than mothers without the underlying disease. According to these results, in addition to pregnant mothers, more attention should be paid to pregnant mothers who suffer from the underlying disease to prevent deteriorating diseases such as COVID-19.

People who perceive more barriers are less likely to show appropriate behaviors. For instance, Gorman found that pregnant mothers who perceived more barriers to influenza vaccination were less likely to be vaccinated.^[21] Concerning the inverse relationship between perceived barriers and self-efficacy in this study, the greater the perceived barriers are, the less competent the pregnant mothers are in preventing the disease through self-efficacy. Therefore, by trying to eliminate these barriers, an effective step could be taken to increase the self-efficacy of pregnant mothers.

Due to COVID-19, many pregnant women did not visit healthcare centers, so we had to use online programs to fill out questionnaires. In this case, only those who had WhatsApp and internet access could complete the questionnaires.

Conclusion

Most pregnant women had sufficient knowledge about COVID-19 and used masks. Also, the perceived severity and susceptibility scores were higher than other model constructs, indicating women's proper understanding of the risks of COVID-19. However, half of these women have stated that they do not go to receive services, and this issue can have adverse consequences. Therefore,

researchers plan to improve other structures of the model, such as self-efficacy, which effectively improves women's performance in receiving care, especially in women with a lower level of education.

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Conflicts of interest

Nothing to declare.

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Comparison of the Percentage of Umbilical Cord Nucleated Red Blood Cells in Preterm Neonates during Vaginal Delivery and Emergency Cesarean Section

Abstract

Background: There are insufficient and contradictory reports regarding the effect of delivery method on the rate of umbilical cord Nucleated Red Blood Cell (NRBC). Therefore, the present study aimed to compare the percentages of umbilical cord NRBC in vaginal delivery and emergency cesarean section (C-section) in preterm neonates. **Materials and Methods:** The present cross-sectional study was performed on mothers with vaginal delivery and C-section, from 2020 to 2021. The samples (n = 221) were preterm neonates selected using the convenience sampling method. The percentages of NRBC in neonates born by natural childbirth and by emergency C-section were measured and compared in this research. A researcher-made checklist, which included maternal and neonatal characteristics and laboratory evaluation, was used as a data collection tool. **Results:** The statistical population of this research included 93 (42.10%) and 128 (57.90%) neonates born by vaginal delivery and by C-section, respectively. The mean (SD) score of gestational ages at birth was 30.75 (2.81) weeks. The mean (SD) score of umbilical cord NRBC level were estimated at 8.01 (5.93) and 25.64 (22.61) for the neonates born by natural childbirth and by emergency C-section, respectively ($t=-8.43$, $df = 150$, $p<0.001$). Statistically significant differences were observed in the gestational age ($t=-3.36$, $df = 218$, $p = 0.001$), fifth-minute Apgar score ($t=-2.32$, $df = 200$, $p = 0.021$), umbilical cord NRBC ($t=-8.43$, $df = 160$, $p<0.001$), and short-term prognosis ($p = 0.032$) between the two groups. It was also revealed that the number of NRBCs in the dead neonates was about 1.5 times higher than that in the discharged neonates. **Conclusions:** Based on the results of the present study, emergency C-section increased the mean of umbilical cord NRBC by three times, compared to that of normal delivery. Since an increase in the NRBC raises the risk of infant death, it is advisable to take steps to maintain the health of children by identifying high-risk neonates through umbilical cord NRBC measurement immediately after delivery and special care.

Keywords: Cesarean section, mothers, natural childbirth, neonate, nucleated erythrocytes, umbilical cord

Introduction

Natural childbirth is the healthiest for extrauterine life. Hematological changes, many aspects of which are still unknown, occur in the newborn during childbirth.^[1] NRBC, as the primary prerequisite for erythrocytes, is naturally found in fetal and neonatal circulation during the first week of life and is associated with gestational age and health status.^[2] It is an erythropoietic progenitor cell not found in the peripheral blood of healthy neonates.^[3] Numerous acute and chronic stimuli increase the number of NRBCs in circulation due to the enhanced activity of erythropoietic or the sudden

release of bone marrow reserves. In healthy neonates, the number of NRBCs is less than 10/100 WBC and decreases rapidly after birth, so that NRBCs are not usually observed on the fourth day. However, in premature infants, NRBC levels are usually higher and are seen in the peripheral blood up to a week after birth. The reason for elevated NRBCs is often attributed to prematurity, fetal anemia or neonatal hemolytic disease, cyanotic heart disease, intrauterine growth retardation, maternal diabetes, preeclampsia, smoking, intrauterine infections, acute or chronic chorioamnionitis or asphyxia, necrotizing enterocolitis, severe Intraventricular

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Hemorrhage (IVH), retinopathy of prematurity, and infections or death.^[4,5]

The increase of nucleated red blood cells in the peripheral blood occurs because of stillbirths, hypoxic conditions and antenatal stress,^[6] erythroblastosis fetalis, maternal diabetes mellitus, acute fetal distress, intrauterine growth restriction, premature rupture of membranes, and chorioamnionitis. During pregnancy, fetal NRBCs are found in maternal blood circulation.^[7] Anxiety about childbirth and the secretion of cortisol and catecholamines may prolong labor and cause the mother's blood vessels to constrict during labor, reduce placental blood flow, and reduce fetal oxygenation, leading to fetal hypoxia. Hypoxia, in turn, leads to an increase in the number of NRBCs in cord blood.^[8,9] In Bedrick's study, an elevated NRBC count after childbirth indicated utero hypoxemia that likely occurred before delivery.^[10] According to the results of a study performed by Boskabadi, absolute NRBC amounts and NRBC percentages could be used as markers for predicting the neonatal morbidity and mortality rate.^[11] The results of research conducted by McCarthy showed that delivery in low-risk pregnant women, in the absence of an abnormal fetal heartbeat, had no effect on umbilical cord NRBC levels.^[7] Due to the contradictory results of previous studies; the uncertain effect of the type of delivery on the number of umbilical cord NRBCs, especially in premature neonates; and the importance of identifying high-risk preterm infants based on NRBCs, the present study was performed to compare the percentages of umbilical cord NRBC in vaginal delivery and in emergency cesarean section.

Materials and Methods

This cross-sectional study was performed on 221 premature neonates born in the maternity ward of Hospital, from 2020 to 2021. The premature neonates born by vaginal delivery or emergency C-section were selected through the convenience sampling method. A sample containing 1.5 cc of whole blood from the neonate's umbilical cord, which is usually thrown away, was collected to evaluate the NRBC level. The samples were gathered in ethylenediaminetetraacetic acid anticoagulant tubes. Peripheral blood samples were prepared, and a Leishman stain was performed on them. In this study, the number of NRBCs per 100 white blood cells and the absolute number of NRBCs per cubic millimeter in the blood

were calculated. The exclusion criteria were neonates with diabetic mothers, preeclampsia, hemolytic jaundice, positive Coombs test, infections, and acute and chronic hypoxia, as well as neonates born by elective cesarean section.

By using the test of two averages related to a quantitative trait in two communities and with alpha of 1% and beta of 1% (power of 99%), 92 premature births were obtained in each group of 92 babies.

The required data were collected using a researcher-made questionnaire, which contained information about maternal characteristics (e.g., maternal age, type of delivery, and parity), neonatal characteristics (e.g., gestational age, first-minute Apgar score, fifth-minute Apgar score, birthweight, gender, need for resuscitation, short-term prognosis) and neonatal laboratory specifications (e.g., umbilical cord NRBC). The gathered data were analyzed in SPSS software (version 26, IBM SPSS Statistics 26.0 IF006). Initially, statistical tables and graphs were used to describe the results. Next, the Chi-square and *t*-test tests were applied to compare the NRBC levels in newborns born by the two delivery methods. The significance level was considered $p \leq 0.05$ in all cases.

Ethical considerations

The parents' consents were obtained before entering the study. The approval to conduct this study was provided by the ethics committee of Mashhad University of Medical Sciences (IR.MUMS.MEDICAL.REC.1399.702).

Results

In this research, 300 mothers were entered into the study; however, 30 neonates with asphyxia, 26 newborns with preeclampsia mothers, 19 cases with diabetic mothers, 1 case with hemolytic jaundice, and 4 cases with infection were excluded from the study. Finally, 93 (42.10%) neonates born by vaginal delivery and 128 (57.90%) ones by C-section were studied. In this study, the mean (SD) scores of gestational ages at birth, umbilical cord NRBC, and neonatal weight were estimated at 30.75 (2.81) weeks, 18.22 (19.65) per 100 white blood cells (WBCs), and 1428.84 (494.66) g, respectively. Based on the findings of

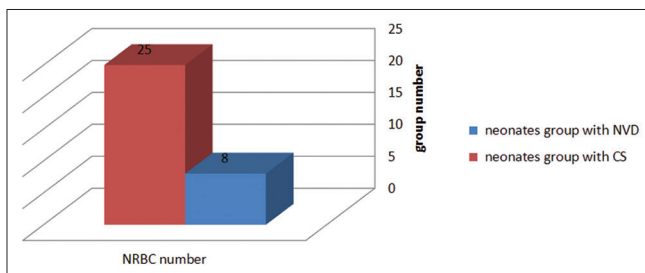


Figure 1: Comparison of nucleated red blood cell in two groups of neonates born by vaginal delivery and emergency cesarean section

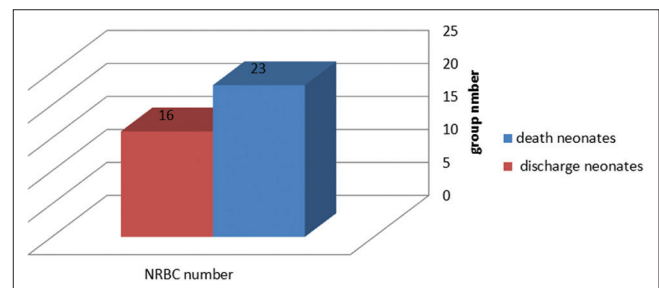


Figure 2: Comparison of nucleated red blood cell in two groups of dead neonates and discharged neonates

the present study, the first-minute Apgar score ($p = 0.207$), birthweight ($p = 0.083$), maternal age ($p = 0.164$), and parity ($p = 0.232$) were not significantly different between the two groups. Nevertheless, the difference between the two groups was statistically significant regarding the gestational age ($p = 0.001$), fifth-minute Apgar score ($p = 0.021$), and umbilical cord NRBC ($p < 0.000$), with the values being lower in the group of neonates born by natural childbirth [Table 1].

Also, another statistically significant difference was found regarding the short-term prognosis ($p = 0.032$), meaning that the mortality rate was about 1.5 times higher in the group of neonates born by C-section than in their counterparts born by vaginal delivery (36% vs. 21%). It was also revealed that discharges were more in the group of neonates born by natural childbirth than in the group of neonates born by cesarean delivery (78% vs. 63%). Nevertheless, no statistically significant difference was observed between the two groups in terms of neonatal gender ($p = 0.354$).

The number of NRBCs was more than three times higher in the group of neonates born by emergency C-section than in the group of their counterparts born by vaginal delivery [Figure 1]. According to the results of the multivariate logistic regression model, variables NRBC/100WBC and gestational age had a significant effect on the response variable. After adjusting for confounding factors such as gestational age and fifth-minute APGAR score, again the number of NRBCs in the emergency cesarean section was significantly higher than in normal delivery ($p = 0.022$).

Furthermore, the number of NRBCs was found to be about 1.5 times higher in the group of dead neonates than in the discharged ones [Figure 2].

Discussion

Based on the results of the present study, the umbilical cord NRBC/100WBC was more than 3 times higher in neonates born by emergency cesarean delivery than in neonates born by vaginal delivery. It was also found that

the levels of umbilical cord NRBC varied according to the type of delivery in different studies. After controlling for confounding factors such as gestational age with multivariate regression analysis, NRBC levels in neonates born by emergency cesarean delivery were still significantly higher than in neonates born by vaginal delivery. In a study performed by Mital, the NRBC levels were significantly lower in the vaginal delivery group than in the cesarean delivery group 9.25(7.29) vs. 14.25 (6.51).^[12] In another research carried out by McCarthy, the mean scores of NRBC/100WBC were calculated at 7.80 (7.40) and 9.3 (10.5) in the neonates born by elective C-section and natural childbirth groups, respectively, which was not significantly different.^[7] According to the results of a study performed by Mansour Ghanaie, the mean umbilical cord NRBC count of neonates born by elective C/S was less than those delivered by natural childbirth, although this difference was not significant.^[13]

In our study, since clear cases of asphyxia were excluded, mechanisms other than hypoxia might have been effective in increasing NRBC. Numerous mechanisms have been suggested to increase NRBC during labor among term newborns, most of which have been attributed to justifying the increase in NRBC following hypoxia during labor or pregnancy. There was also the possibility that mild hypoxia failing to result in birth asphyxia led to increased NRBC. Elevated NRBC has also been reported in important neonatal diseases, such as infections, retinopathy of prematurity, and IVH, which complicates the justification of the mechanism of changes. On the other hand, based on the findings of studies, NRBC can be a predictor of neonatal morbidity and mortality.^[5]

In this study, the mean scores of gestational ages at birth and umbilical cord NRBC were estimated 30.75 (2.81) weeks and 18.22 (19.65) per 100 White Blood Cells (WBCs), respectively. It has been reported that the NRBC count at birth is higher in more premature neonates.^[14] In premature newborns, erythropoiesis increases; therefore, a significant number of NRBCs can be observed for a longer period after birth. The increased number of NRBCs

Table 1: Comparison of the mean (SD) of some maternal and neonatal variables in the two groups of neonates born by natural childbirth and emergency cesarean section

Variables	Neonates born by natural childbirth 93 (42.10%) cases Mean (SD)	Neonates born by emergency cesarean delivery 128 (57.90%) cases Mean (SD)	<i>p</i>
Gestational age (weeks)	30.02 (3.00)	31.28 (2.54)	0.001
First-minute Apgar score	5.94 (2.32)	6.35 (2.26)	0.207
Fifth-minute Apgar score	7.48 (1.59)	8.01 (1.61)	0.021
Birthweight (g)	1360.77 (510.76)	1478.15 (478.64)	0.083
Mother age (years)	28.87 (6.30)	30.31 (6.73)	0.164
Parity	2.16 (1.00)	1.97 (1.06)	0.232
Umbilical cord NRBC* Per 100 WBC	8.01 (5.93)	25.64 (22.61)	<i>p</i> <0.001

*Nucleated Red Blood Cells

indicates an increase in erythropoiesis for a variety of reasons, including chronic hypoxia, anemia, acute stress, or postpartum hypoxia. The results of several studies were indicative of the existence of a relationship between an increase in the number of NRBCs and an increase in postnatal morbidity and mortality.^[15] Valina *et al.* reported significant differences in the number of NRBCs between the group of term and preterm infants, especially on the first day of birth. It was revealed that in term newborns (relatively healthy and sick), the number of NRBCs decreased significantly between days 0 and 1 and to a lesser degree between days 1 and 4. They also found that in preterm infants, the number of NRBCs decreased dramatically between days 1 and days 2-4.^[16]

It was found that NRBC was significantly higher in dead newborns than in discharged live neonates. Among patients admitted to the pediatric intensive care unit, NRBC levels, especially more than 200 per microliter, are associated with a mortality rate of post-admission in the intensive care unit and post-discharge.^[17] It was revealed that increased NRBC on days 2-5 of birth is associated with high mortality.^[15] Furthermore, increased adverse neonatal outcomes, such as white matter injury, necrotizing enterocolitis, and open arterial duct, are also associated with increased NRBC in preterm neonates.^[18] According to the results of a study carried out by Morton, there was a significant relationship between the number of NRBCs and the increased risk of neonatal mortality among newborns hospitalized over 7 days in the ICU.^[19] Christensen *et al.* found that an increase in the number of NRBCs in newborns at birth indicated the onset of hypoxia from at least 28 to 29 hours before birth. To date, limited data have been provided regarding the diagnostic and predictive value of NRBC in sick neonates.^[14] In research conducted by Sokou, NRBCs showed significant predictive power for mortality in neonates with sepsis, especially in preterm newborns with sepsis, with a cutoff point of $\geq 1\%$ and 81.60% sensitivity and 78.10% specificity.^[20] Therefore, NRBC counting can be considered an early diagnostic and predictive marker for sick neonates.^[4]

The most important limitation of our study involved not investigating the causes of emergency C-section and preterm labor. Furthermore, studies could be conducted taking these causes into account. It is also suggested to conduct a similar study with a larger sample size.

Conclusion

The findings of the present study suggest that umbilical cord NRBCs increase during emergency C-section and in cases of neonatal death. Therefore, the examination of NRBC in premature infants can serve as a prognostic factor for the newborn. On the other hand, it may be affected by the method of delivery, which had better be considered in the evaluation of NRBC of the newborn.

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Conflicts of interest

Nothing to declare.

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Effect of Jacobson's Progressive Muscle Relaxation on Anxiety and Happiness of Older Adults in the Nursing Home

Abstract

Background: Older adults encounter serious psychological challenges in addition to physical problems. Reducing stress and anxiety, along with promoting happiness, is critical to maintaining the mental health of the elderly. Jacobson's Progressive Muscle Relaxation (JPMR) will lead to peace of mind by relieving physical stress. The present study aimed to investigate the effect of JPMR on the anxiety and happiness of older adults. **Materials and Methods:** A single-group pretest-posttest design as a type of quasi-experimental study was conducted on 34 older adults living in a nursing home in Rasht, the north of Iran, in 2021. The intervention was performed one session per week, for 8 weeks. The research instruments included the Geriatric Anxiety Inventory (GAI) and the Oxford Happiness Inventory (OHI). Descriptive statistics and the Wilcoxon test were used for data analysis. **Results:** After the intervention, the Mean (Standard Deviation [SD]) of anxiety was 4.91 (1.96), and the Mean (SD) of happiness was 37.18 (7.92). The mean score of anxiety among older adults after the intervention was significantly lower compared to the before intervention ($Z = -4.73, p < 0.001$). In addition, the mean score of happiness of the samples after the intervention was significantly higher compared to the before intervention ($Z = -5.09, p < 0.001$). **Conclusions:** JPMR has a positive effect on reducing anxiety and promoting happiness in the elderly. Developing training programs and allocating time to non-pharmacological treatments such as JPMR for the elderly living in nursing homes will help make them happier and healthier.

Keywords: Aged, anxiety, happiness, nursing homes, progressive muscle relaxation

Introduction

Anxiety is one of the most prevalent mental disorders among older adults.^[1] The prevalence of anxiety disorders in older adults living in nursing homes is higher than others and varies from 3.2 to 20%.^[2] Typical amounts of anxiety increase attention, but if not controlled, in addition to negative impacts on physical health, it could have adverse consequences such as reduced quality of life, emotional suffering, loss of interest,^[3] and also disruption of performance.^[4] As most countries around the world have entered the status of aging society, anxiety as a prevalent and important challenge in late-life raises the numbers accessing health care, and individual and social costs.^[5] In contrast, happiness could be a barricade against the impact of negative feelings among the elderly, especially residents living in nursing homes.^[6] This is while physical deprivation and anxiety in old age could induce

unhappiness and trigger depression in the elderly.^[7] Happiness as a positive emotion increases the ability to cope with mental burdens,^[8] plays a vital role in raising physical and mental health,^[9] and can predict longevity and survival among older adults by correlating with life satisfaction and quality of life.^[10] Despite the significant advances in human comfort facilities, his happiness could be negatively affected by age and functional limitations.^[11]

Avoiding stress and anxiety concurrent with increasing happiness, especially in old age, is on the public health agenda around the world.^[12] Therefore, it is important to investigate interventions that reduce anxiety and increase happiness in older adults as, the most vulnerable group. A previous study indicated that physical activity could diminish negative feelings and improve positive ones, such as happiness.^[13] One of the most common relaxation techniques is progressive muscle relaxation, developed by

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Edmund Jacobson in the 1920s.^[14] Jacobson's progressive muscle relaxation (JPMR) involves exercises in which selected muscle groups respectively first contract and then expand to achieve a state of deep relaxation. In fact, JPMR is based on the rule that muscle relaxation brings peace of mind.^[15] With low muscle strength, no need for special equipment, easy learning, and low cost,^[16] JPMR as a non-pharmacological intervention can be utilized in elderly care, treatment, and education programs.^[15,17] Previous studies conducted on JPMR have shown its effectiveness in reducing depression^[18] and insomnia in older adults,^[19] increasing the quality of life, and adaptation to old age.^[20] Despite JPMR studies, the knowledge about the effect of this technique on psychological indicators such as anxiety and happiness of older adults living in nursing homes is limited. Therefore, considering the different structures of nursing homes in different countries and the accelerating trend of the aging population, the present study aimed to investigate the effect of JPMR on the anxiety and happiness of older adults living in a nursing home. It was hypothesized that JPMR would decrease anxiety and increase the happiness of the elderly living in the nursing home.

Materials and Methods

This is a clinical trial study of quasi-experimental type (IRCT20190315043062N3) with a single-group pretest-posttest design, which was conducted in a nursing home in Rasht, the north of Iran, in 2021. This type of study is commonly used to study design. First, a single pretest measurement is taken, followed by an intervention, and then a posttest measurement is taken.^[21]

The subjects in this study were older adults living in a nursing home. Due to the limited number of elderly people who met the entry criteria, the sample size was not calculated, and as shown in the Consolidated Standards of Reporting Trials (CONSORT) flowchart in Figure 1, finally, the information of 34 older adults was analyzed. Inclusion criteria included age of 60 years and older, having normal cognition status (a score of eight or more on the Abbreviated Mental Test (AMT)),^[22] informed consent to participate in the study, physical ability to perform JPMR, no use of anti-anxiety drugs, absence of cardiopulmonary, and no previous experience with the technique. The exclusion criterion was the absence from training sessions. Figure 1 shows the number of participants who reached the final stage of data analysis.

As shown in Figure 1, out of 182 elderly people living in a nursing home, 174 who were older than 60 years with normal cognition status and physically able to perform JPMR were recruited. The study protocol was announced to the older adults by one of the researchers of our research team. One hundred thirty-eight of the older adults were excluded from the research because of using anti-anxiety drugs and having a cardiopulmonary disease that would

affect undertaking JPMR training during the program or any cognitive problems that could impede the elderly from understanding and answering the content of the informed consent and questionnaires. Therefore, 36 of the samples entered the JPMR training. During the 8 weeks of the training, two of the samples were not willing to continue the exercise and quit the research, so 34 samples completed the JPMR exercise.

The tools included three questionnaires. The Geriatric Anxiety Inventory (GAI) was designed by Pachana *et al.*^[23] was used to measure anxiety. This scale has 20 items based on a 2-point scale (agree = score 1, disagree = score zero). The total score varied between zero and 20, and a score of 0–7 was considered as mild to moderate anxiety, and a score of 8 or 9 and above was considered severe anxiety. The validity and reliability of this scale were confirmed in a study on Iranian older adults. The exploratory factor analysis showed the questionnaire that jointly explained 59.48% of the overall variance observed. The findings indicated a positive and significant correlation between the two measures, lending support to its concurrent validity ($r = 0.67$, $P < .001$). Ultimately, the GAI was found to have a favorable internal consistency.^[24] The Oxford Happiness Inventory (OHI) is used to measure happiness. This tool has 29 items based on a 4-point Likert scale (not at all = score zero, low = score 1, high = score 2, and very high = score 3). The total score range varied from 0 to 87. A score of 0–25 was considered poor happiness, a score of 26–50 was considered moderate happiness, a score of 51–75 was considered good happiness, and a score of 76 and above was considered high happiness. In previous studies, the validity and reliability of this scale in Iran have been confirmed.^[25] In the present study, the reliability of the tools was calculated by internal consistency in 20 older adults living in nursing homes. Cronbach's alpha coefficient was 0.89 for GAI and 0.86 for OHI.

The cognitive status of the samples was investigated using the AMT, and a score of 7 or higher was considered as having no cognitive problem. The findings of a study conducted among Iranian older adults confirmed that the Persian version of the AMT is a valid tool for assessing cognitive function. The Cronbach's alpha coefficient of this scale was 0.90. Scores 6 and 7 showed the optimum balance between sensitivity (99% and 94%, respectively) and specificity (85% and 86%, respectively).^[22]

Before the intervention and in the 8 weeks of the intervention, the researcher, through face-to-face interviews using the tools, measured the anxiety and happiness of the samples. Each question was read to the samples, and the options were selected based on their responses. To avoid participant fatigue, data were collected at intervals and over time.

In this study, first, a training session was held for each of the subjects to introduce the JPMR technique, its effects, and how to do it. Then, for 8 consecutive weeks, a session

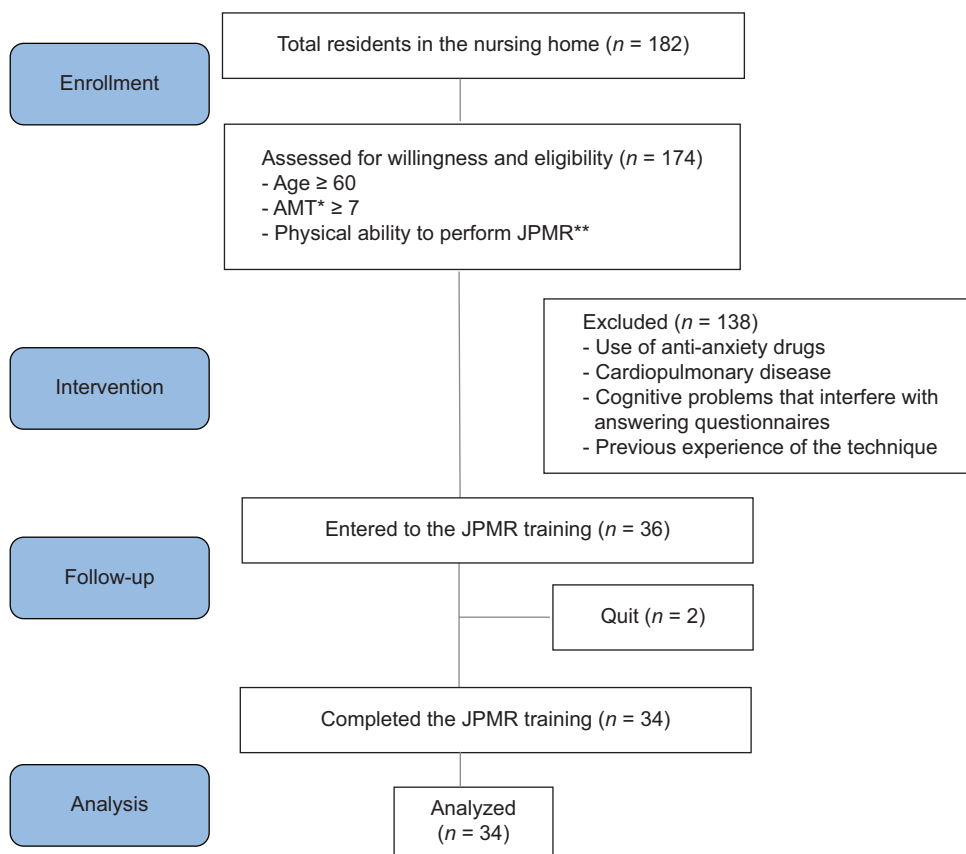


Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram of participants. * Abbreviated Mental Test. **Jacobson Progressive Muscle

of the JPMR technique was performed per week for 20 min individually in a room in the nursing home under the supervision of the researcher. When the individual was put in where his/her head and back were in a comfortable position (sitting), he/she was asked to close the eyes and take a few deep breaths. Then, the muscle groups (wrist, arm, forehead, eyes, jaw, shoulders, back, chest, abdomen, legs, and toes, respectively) contract symmetrically for approximately 10–15 s (inhalation) and then expand for 15–20 s (exhalation). The exercise was repeated two to three times for each muscle group. In the end, with a few deep breaths and the researcher countdown, five to one, the exercise was completed.^[15]

The intervention (JPMR) was designed by the research team based on valid references.^[14,26,27] One researcher (Master of Elderly Nursing) devoted a month to learning and studying the JPMR technique, about how it works, its effects, and possible side effects, and took steps to gain acceptable mastery of the technique. Therefore, she provided the intervention. After choosing a specific day of the week, she was at the nursing home at certain times during that day to perform the JPMR technique for the samples under the supervision of an ergo therapist at the nursing home. She taught the JPMR technique to the participants, and the progressive muscle relaxation (PMR) was done under her supervision. She had full control over how the intervention (JPMR technique) was performed by the

samples in the training session and then through the whole eight intervention sessions.

After selecting the eligible samples to enter, the study informed consent to participate in the research was obtained from them. To obtain informed consent, the researcher first explained the purpose and method of the study to the participants. The researcher then gave the consent form, which was written in plain language, to the samples that agreed to participate in the study, and asked the samples to read it. For the illiterate, the researcher read this form. After confirming that the samples understood the content of the consent form, they were asked to participate in the study and sign the consent form. To implement the intervention, at first, an individual training session was held for each sample in their room. During the training session, sufficient explanations were given to the samples about the JPMR technique, its effects, and implementation steps. In addition to practicing the JPMR technique, the contents were repeated several times, and the researcher answered the samples' questions. By ensuring that the samples had learned the JPMR technique correctly, a fixed day per week (Saturdays) was set aside to perform the intervention, which ensured equal and comparable conditions for all samples.

The JPMR technique was performed for 8 weeks, one session per week, with a fixed duration (20 min),

individually, by the elderly on their bed in a nursing home in Rasht, with the supervision of the responsible researcher for the intervention. The educational content, intervention method, frequency, and duration of the intervention sessions were the same for all samples. The frequency and duration of intervention were monitored using a stopwatch and finger counting.

Data analysis was conducted using SPSS (Statistical Package for the Social Sciences) software version 22 (IBM, Chicago, USA), descriptive statistics (mean, standard deviation), and inferential statistics. The Wilcoxon test was used to compare the level of anxiety and happiness before and after the intervention.

To compare the mean scores of anxiety and happiness before and after the intervention, due to the abnormal distribution of anxiety, the Wilcoxon test was used, and, according to the normal distribution of happiness, a paired *t*-test was used. The significance level in all tests was considered 0.05.

Ethical consideration

This study is the result of a master's thesis approved by the Ethics Committee of Guilan University of Medical Sciences in Rasht, Iran (Ethics code No: IR.GUMS.REC. 1399.399). According to the principles of research ethics, all ethical principles are observed in this article. Participants were reminded that at each stage of the study, they could refuse to continue their cooperation if they did not want to. They were also reminded that, if they wished, the results of the research would be made available to them and that their information would be kept confidential.

Results

Most of the subjects were 60 to 74 years old (70.60%), male (58.80%), and illiterate (55.90%). Half of them had lost their spouse (50%), and more than half of them had been living in a nursing home for 1 to 5 years (52.90%). The majority of the subjects had at least one underlying disease (70.60%) and reported their economic situation as moderate-income (61.80%) [Table 1].

Before performing the JPMR technique, all subjects had anxiety; 58.80% had severe levels of anxiety, and 41.20% had mild to moderate levels of anxiety. Before performing the JPMR technique, the total Mean (Standard Deviation (SD)) of anxiety in subjects was 10.41 (5.24). After performing the JPMR technique, this value reached 4.91 (1.96). JPMR caused a statistically significant difference in the anxiety mean score of subjects after the intervention. The mean scores of anxiety in older adults were reduced significantly after the intervention ($Z = -4.73$, $p < 0.001$) [Table 2].

Before performing the JPMR technique, 52.9% of the subjects had poor levels of happiness, 47.10% of them

had moderate levels of happiness, and none of them had a good or excellent level of happiness. Before performing the JPMR technique, the total Mean (SD) of happiness in subjects was 26.59 (8.86). After performing the JPMR

Table 1: Demographic characteristics of the older adults living in the nursing home (n=34)

Variable	n (%)
Age	
60–74	24 (70.67)
75–90	9 (26.53)
>90	1 (2.93)
Total	34 (100)
Gender	
Female	14 (41.2)
Male	20 (58.86)
Total	34 (100)
Marital status	
Single	4 (11.81)
Married	9 (26.53)
Divorced	4 (11.81)
Dead spouse	17 (50)
Total	34 (100)
Living in the nursing home	
<1 year	12 (35.34)
1–5 year	18 (52.95)
>5 year	4 (11.81)
Total	34 (100)
Accommodation before living in the nursing home	
City	28 (82.48)
Village	6 (17.62)
Total	34 (100)
Education	
Illiterate	19 (55.96)
Primary	9 (26.53)
Diploma	3 (8.89)
Bachelor's degree and above	3 (8.89)
Total	34 (100)
Job	
Employed	2 (5.96)
Worker	1 (2.93)
Self-employed	12 (35.34)
Retired	5 (14.72)
Farmer	5 (14.72)
Unemployed	1 (2.93)
Housewife	8 (23.53)
Total	34 (100)
Economic status	
Adequate income	3 (8.89)
Moderate income	21 (61.86)
Low income	10 (29.4)
Total	34 (100)
Underlying disease	
Yes	24 (70.67)
No	10 (29.4)
Total	34 (100)

technique, this value reached 37.18 (7.92). JPMR caused a statistically significant difference in the mean score of happiness in subjects after the intervention. The mean scores of happiness in older adults increased significantly after the intervention ($p < 0.001$) [Table 3].

Discussion

The present study investigated the effect of the JPMR technique on the anxiety and happiness of older adults living in a nursing home. Regarding the level of anxiety of older adults living in nursing homes, the results of the present study showed that before performing the JPMR technique, all the older adults were anxious, so more than half of them had severe anxiety, and the rest had mild to moderate anxiety. In general, the level of anxiety in older adults was high, according to their scores. These results are consistent with the findings of previous studies. In the study by Levina *et al.*,^[28] an evaluation of self-mental conditions of older adults living in a nursing home, it indicated a high level of anxiety among 51% of the subjects, and average anxiety rates among 27% of them. In a study by Elias *et al.*^[29] on the prevalence of loneliness, anxiety, and depression in older adults living in care centers in various populations, including the United States, Norway, and Malaysia, the prevalence of anxiety was generally high among them.

In the present study, the implementation of the JPMR technique decreased the level of anxiety of older adults living in the nursing home. These results are consistent with the study results of Ghodela *et al.*^[30] and Tak *et al.*^[31] The results of the present study also support the findings of previous studies related to the effectiveness of JPMR in reducing the anxiety of COVID-19,^[15] and leprosy patients.^[14]

Regarding the happiness of older adults living in nursing homes, the results of the present study showed that before the implementation of the JPMR technique, the level of happiness of the study samples was weak and moderate, and none of them had a good or excellent level of happiness. In general, the overall happiness status of the older adults was evaluated as moderate according to the mean scores. These results are consistent with the findings of previous studies.^[32,33] Although Hong *et al.*^[34] found that happiness in older adults depended on a variety of individual and social factors, including income, health level, and literacy. However, it is agreed that educational and welfare programs play an important role in increasing happiness in old age.

In the present study, after performing the JPMR technique, the level of happiness of the older adults increased from weak to moderate. In addition, after the intervention, a group of the samples enjoyed a good level of happiness. In other words, the JPMR technique was useful for increasing the happiness of older adults living in the nursing home. These results are largely consistent with the findings of Alphonsa *et al.*^[35] and Bostani *et al.*^[36] Gaiswinkler *et al.*^[37] also compared the effectiveness of the 6-week Mindful Self-Compassion (MSC) and PMR programs for psychiatric patients and found the MSC program more successful for increasing happiness. The results of the present study also support the results of studies related to the effectiveness of JPMR in improving the quality of life of older adults with cancer^[38] and reducing depressive symptoms of aging living in nursing homes.^[39] Nevertheless, Meister *et al.*^[40] found no impact of anaerobic training on mental indices. Furthermore, Kianian *et al.*^[41] did not find any significant differences in depression symptoms or happiness levels

Table 2: Levels and mean scores of anxiety in older adults before and after the intervention Jacobson Progressive Muscle (JPMR)

Variable	Before intervention (n=34)		After intervention (n=34)		Relative* percentage changes	p
	n (%)	Mean (SD)	n (%)	Mean (SD)		
Anxiety						
Mild to moderate level of anxiety	14 (41.2)	10.41 (5.24)	30 (88.2)	4.91 (1.96)	52.83%	$p < 0.001$, $Z^{**} = -4.731$
Severe level of anxiety	20 (58.8)		4 (11.7)			
Total	34 (100)		34 (100)			

Note: *Relative percentage changes in mean scores before and after the intervention $((\text{After}-\text{Before})/\text{Before}) \times 100$, **Wilcoxon JPMR=Jacobson's progressive muscle relaxation JPMR, SD=Standard deviation

Table 3: Levels and mean scores of happiness in older adults before and after the intervention (JPMR)

Variable	Before intervention (n=34)		After intervention (n=34)		Relative* percentage changes	p
	n (%)	Mean (SD)	n (%)	Mean (SD)		
Happiness						
Poor level of happiness	18 (52.90)	26.59 (8.86)	2 (5.90)	37.18 (7.92)	39.83%	$p < 0.001$, $Z^{**} = -5.094$
Moderate level of happiness	16 (47.10)		30 (88.20)			
Good level of happiness	0 (0)		2 (5.9)			
Total	34 (100)		34 (100)			

Note: *Relative percentage changes in mean scores before and after the intervention $((\text{After}-\text{Before})/\text{Before}) \times 100$, ** Wilcoxon JPMR=Jacobson's progressive muscle relaxation JPMR, SD=Standard deviation

between aerobic and nonaerobic physical activity in nonathletic men. Differences in samples, duration of the course, and measurement tools could explain the inconsistencies with the current research.

Since the high prevalence of anxiety disorders among adults in nursing homes^[42] could increase disability and diminish well-being,^[43] it is necessary to pay more attention to the implementation of operational strategies that could affect psychological indicators of them. Using JPMR, which is based on the principle of muscle relaxation preceding mind relaxation, could decrease anxiety gradually in older adults, which contributes to their happiness. In particular, those living in nursing homes or hospitals could benefit from JPMR's mental health output.

The main limitation of this study was the absence of a control group. There is only one non-profit, a public nursing home in Rasht, the capital of the Guilan province, that operates free for the elderly and disabled, and the rest are small and private. Therefore, because of this and the quarantine due to the COVID-19 pandemic, which made access to the samples difficult, the present research has been conducted in a single research environment with one group. Sampling was conducted by coordinating with nursing home officials, following health protocols, using protective equipment, and performing polymerase chain reaction (PCR) tests. Other limitations were fatigue and the unwillingness of some study samples to cooperate. By explaining the purpose and significance of the study and observing rest intervals, the researcher encouraged subjects to cooperate until the end.

Conclusion

The present study provides non-invasive interventions that have been demonstrated to be effective in reducing anxiety and enhancing happiness in older adults. It was found that JPMR reduced anxiety and increased happiness among the elderly living in nursing homes. The use of JPMR by trained nurses in the daily care of the elderly in nursing homes could promote healthy and active aging. Therefore, older adults will be healthier and happier, reducing overhead costs for families and society as a whole.

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Conflicts of interest

Nothing to declare.

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An Agreement Among Nurse Educators on Infection Prevention and Control Practices to Ensure Safe Clinical Training Post-COVID-19

Abstract

Background: Infection Prevention and Control (IPC) practices during nursing students' clinical training are based on standardized precautions. However, the spread of COVID-19 raised the need to revise these practices. We aimed in this study to assess nurse educators' agreement on items that represent precautionary guidelines, which enhance safety during clinical training of students. It aimed to reach an agreement among nurse educators on IPC practices to ensure safe clinical training. **Materials and Methods:** This descriptive explorative, cross-sectional study included 243 Jordanian and Omani educators. The study questionnaire was based mainly on evidence reported in the literature. The study questionnaire comprised items for trainers to practice and items to supervise students. It was developed based on available evidence and recommended training practices during COVID-19 suggested by the WHO and the literature. Both the face and content validity processes were adopted to validate the study questionnaire. The final version was composed of 26 items for trainers and 20 items for students subsumed in the following themes: protecting self, protecting others, and essential training needs. **Results:** All questionnaire items were rated above the midpoint indicating agreement among participants on including the new IPC practices. All suggested practices (26 items for the trainers and 20 items for the students) were supported by the study participants. **Conclusions:** Clinical training is an important component of nursing students' preparation. Findings suggest the importance of adding new IPC practices to improve student IPC practices, protect themselves and others, minimize cross-infections, and enhance students' training within a safe clinical environment.

Keywords: *Clinical practicum, health educators, infection control, nursing, students*

Introduction

During the late months of 2019, China's mainland witnessed the spread of a new form of virus, which turned out to be a corona-type virus, then called COVID-19.^[1] The world after this pandemic is not like what it used to be. This pandemic has affected all industries, including nursing education and practice. Among the changes expected to form nursing education is the Infection Prevention and Control (IPC) guidelines adopted to ensure students', educators', nurses', and patients' safety during clinical training in healthcare facilities or laboratory settings. Nursing students participate in clinical training as a mandatory component of the curriculum. Nursing knowledge and skills are usually utilized during clinical training, which is essential to determining the outcome of nursing education.^[2] Therefore, focusing on clinical training and improving students' knowledge are important to ensure safe

practice, which involves the patient, the nurses, and other Healthcare Workers (HCWs).^[3] Nursing students should train in a well-structured and safe environment to ensure that they achieve the clinical objectives and keep students from being exposed to or causing a harmful situation.^[4] Therefore, updating IPC guidelines during the pandemic became an essential process to ensure safe clinical training for students, trainers, other HCWs, patients, and family members. This need is especially true after COVID-19, which influenced how HCWs viewed and perceived the importance of preventive measures to avoid being infected or a carrier of the infection.

Approximately 7–10% of patients admitted to acute care hospitals acquire an infection,^[5] which leads to increased cost, morbidity, and mortality rates.^[6] Compliance of HCWs and nursing students was recognized as an efficient means to

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prevent and control cross-infections.^[7] The COVID-19 pandemic has alerted the healthcare sector to different methods to manage cross-infections among HCWs and all members of the healthcare teams, including nursing students. Therefore, it was necessary to consider practice guidelines that govern IPC policies in nursing education as uncertainty about the efficacy of the current guidelines in preventing cross-infection might be present. This assumption is especially true after the COVID-19 pandemic and the level of uncertainty about its nature, particularly at the beginning of the pandemic.

Nurse educators know the environment where students train, and they are aware of the IPC guidelines. Therefore, their expertise represents a rich source that can provide a refined view of what to include in the sought IPC guidelines. These measures protect the students and the patient, and all individuals involved directly or indirectly in student training. We proposed this study to assess how much the educators agree with a group of suggested changes in IPC guidelines that aim to improve practices implemented during training nursing students. The findings in this study would support the development of IPC guidelines for safer clinical training.

We aimed to assess NE's agreement on items that represent precautionary guidelines, which would enhance the safety environment of the clinical training process during COVID-19 or possible future pandemics. We also aimed to present the items of IPC approved by NE, which could become guidelines adopted and implemented in clinical and lab training of students in a situation like the COVID-19 pandemic.

Materials and Methods

This descriptive explorative, cross-sectional study investigated what changes NE believed were necessary to ensure a safe, infection-free environment for nursing students and educators. Data were collected between October 2021 and April 2022.

Participants were recruited through convenience sampling from different 4-year nursing programs in the Hashemite Kingdom of Jordan and the Sultanate of Oman. They were recruited via electronic mail using electronic forms. Junior or senior nursing educators and trainers, who were engaged in clinical practice or laboratory training during the last 12 months and more, were invited to participate in this study.

The sample size was calculated using the G-Power 3.1 software with a significance level of 0.05 for the analysis of variance (ANOVA), an average effect size of 0.15, and a power of 0.95,^[8] and the required number was 134.

The study questionnaire was developed based on the most available evidence and recommended training practices during COVID-19 suggested by the WHO^[9] and the

literature.^[10,11] The study questionnaire was developed into two main sections. The first section addresses IPC precautionary practices for students and the second section addresses trainers' IPC precautionary practices. Items were reviewed by six Ph.D.-prepared NEs, who were experts in infection control, and two master's degrees. As modifications suggested by the reviewers were incorporated, items were pilot tested for clarity and readability among 12 NEs.

We adopted a Content Validity Index (CVI), a commonly used method that determines item relevancy in a newly developed study questionnaire. Experts assessed the relevancy of questionnaire items on a 4-point Likert scale (nonrelevant 1 to quite relevant 4). Both scale CVI (SCVI) and item CVI (ICVI) were computed by summing the responses. We used universal agreement (SCVI-UA) and content validity average (CVI-Avg), and among experts for the items. ICVI values greater than 0.74 indicated that the item was relevant, values between 0.60 and 0.74 showed that the item needed revisions, and if the value was below 0.60, the item was eliminated.^[12] Similarly, SCVI is calculated using the number of items in a tool that has achieved a "relevant" rating.^[13] SCV-UA was calculated by adding all items with ICVI equal to 1 divided by the total number of items. The SCVI-Avg was calculated by dividing the sum of the ICVIs by the total number of items.^[13,14] An SCVI-UA ≥ 0.8 and an SCVI-Avg ≥ 0.90 have excellent content validity.^[14]

We measured item essentiality using the Content Validity Ratio (CVR). Independently, each panelist was invited to rate his/her judgment of an item from one to three (nonessential 1 to essential 3); then CVR was calculated by this formula ($CVR = (Ne - N/2)/N/2$), where Ne refers to the number of panelists indicating an item as "essential" and N is the total number of panelists. CVR varies between 1 and -1, and a higher score indicates greater agreement among panel members. The minimum accepted value of CVR is 0.59 determined by Lawshe's table for eight panelists.^[15]

The response process (face validity) was quantified by computing FVI for item clarity and comprehension, like CVI. The 12 raters rated the evaluation on a 4-point scale ranging from 1 = not clear to 4 = very clear, and the importance of each item on a 4-point Likert scale (not important to very important). Item impact score was calculated according to the formula (impact score = frequency (%) \times importance item score), where the frequency is the percent of raters, scoring 3 or 4 "important," and importance is the average score of the item based on the Likert scale. The evaluation criteria depend on the value of the item impact score. In our case, only scores equal to more than the midpoint (≥ 1.5) were kept.^[13] In the final draft, 26 items for the trainers and 20 items for the students were included in the questionnaire.

The final version was composed of 26 items for the trainers and 20 items for the students as follows: protecting self (20

items), protecting others (11 items), and essential training needs (15 items).

Participants' responses were divided on these themes and then the total reflected the whole perspective of NEs. The study participants were asked to rate each item on a 4-point Likert scale, ranging from not necessary (1) to always necessary (4) to assess the consensus for each proposed item. The mean score was calculated for each individual item. The consensus was considered for items that achieved mean scores of ≥ 2.00 . Items with mean scores less than 2.00 were excluded from the final list, which indicates no agreement among the NEs.

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Data were analyzed using SPSS version 25 (Armonk, NY: IBM Corp, 2017), including means, standard deviation, scores of the items and their corresponding themes, and normality tests. No missing data were observed in the data, and ANOVA and *t*-tests were used. Internal consistency was measured using Cronbach's alpha.

Ethical considerations

This study has been approved by the institutional review board of the university of affiliation (03/421/2019–2020) from the Hashemite Kingdom of Jordan and from the Omani Ministry of Health (OCHS/REC/PROPSAL-APPROVED/13/2020). The authors have obtained all appropriate consent from all the participants.

Results

Sample characteristics

A total of 243 NE filled the study instrument, of which 180 (74.1%) were female, with a mean(SD) age of 41.5 (8.20) and 186 (76.50%) aged between 31 and 50. More than half of the participants had master's degrees ($n = 129$, 53.10%). Many participants ($n = 128$, 52.90%) specialized in adult health nursing or general nursing. The experience of the participants ranged between 3 and 38 years, with a mean(SD) of 13.00 (7.43) [Table 1].

Findings of the study questionnaire

Table 2 illustrates the findings and shows that the mean score on the questionnaire is high, which indicates that NE supported the proposed guideline items making the study questionnaire. All suggested practices (26 items for the trainers and 20 items for the students) were supported by the study participants, as the mean score for all the suggested items was greater than the midpoint of 2.00. For the trainer's guideline items, the highest mean score was "Trainers should wear a mask while training students" ($M = 3.71$, $SD = 0.65$) [Table 2], while the lowest mean score was "Trainer stays with students while caring for patients" Mean (SD) 3.26 (0.75). For the student's suggested items, the highest mean score was "Students maintain physical distancing with other students, minimum 3 feet" Mean (SD) 3.71(0.65), while the lowest mean score was "Students train in all departments, including closed units, such as the Intensive Care Units (ICUs) and the Neonatal Intensive Care Units (NICUs)" Mean (SD) 2.91(0.91).

The total mean score for the trainer and student sections was computed. These total mean scores reflect the level of support of the NE for the proposed practice guidelines. For the trainer section, the total mean(SD) score was 88.79 (11.55) out of 104 with a range between 51 and 100, and these values show that all responses were above the midpoint. This finding can also be seen in the student

Table 1: Sample characteristics (n=243)

Characteristic	n (%)
Gender	
Female	180 (74.10%)
Male	63 (25.90%)
Age: Mean (SD) 41.5 y/o (8.20)	
20–30	22 (9.10%)
31–40	96 (39.50%)
41–50	90 (37.00%)
51–60	35 (14.40%)
Academic degree	
Baccalaureate	51 (21.00%)
Master	129 (53.10%)
Ph.D.	63 (25.90%)
Nursing specialization	
Adult	128 (52.90%)
Maternity	46 (18.90%)
Pediatric	45 (18.50%)
Psychiatric	18 (7.40%)
Community	6 (2.20%)
Years of experience: Mean=13.00, SD=7.43	
1–5	49 (20.20%)
6–10	52 (21.40%)
11–15	61 (25.40%)
16–20	51 (21.00%)
<20	30 (12.30%)

Table 2: Educators' responses on the IPC* practice guidelines for trainers and students (n=243)

Theme	Item	Mean (SD)
Total (46 items)	Mean=157.90, SD=21.44), α^{**} 0.93	
Practices to protect self Mean (SD) 71.45 (10.19), α 0.88	Trainer's practice guidelines	
	Trainer maintains physical distancing between me and the students (minimum of 3 ft.)	3.66 (0.64)
	Trainer keeps alcohol (hygienic) sanitizers in my pocket	3.58 (0.64)
	Trainer prepares students to deal with patients with infectious diseases, including COVID-19	3.53 (0.76)
	Trainer emphasizes that students use cleanable personal belongings with sanitizers during the clinical day	3.60 (0.68)
	Trainer makes sure that lab is cleaned after each use with the recommended materials	3.69 (0.62)
	Trainer assesses each patient before assigning to students	3.54 (0.76)
	Trainer checks for the use of appropriate PPE for each department prior to sending students	3.61 (0.69)
	Trainer performs hand washing at the beginning and end of each clinical day before students	3.60 (0.76)
	Trainer emphasizes that bringing food to clinical setting/laboratory is prohibited	3.39 (0.87)
	Student's practice guidelines	
	Students maintain physical distancing with other students (minimum 3 ft)	3.70 (0.15)
	Students perform handwashing prior to working with patients in the setting/laboratory	3.70 (0.68)
	Students perform handwashing each time they leave the clinical setting/laboratory	3.63 (0.78)
	Students put on a face mask while in a clinical setting/laboratory	3.65 (0.75)
	Students put on disposable/latex gloves while in a clinical setting/laboratory	3.44 (0.89)
	Students put on disposable gowns while in the clinical setting	3.36 (0.87)
	Students are accompanied (attended) by a trainer when caring for patients	3.32 (0.80)
	Students keep alcohol (hygienic) sanitizers/scrubs in their pockets	3.54 (0.79)
	Students' temperature is checked prior to each clinical day	3.56 (0.80)
Students clean all belongings used during the clinical day prior to leaving the setting	3.58 (0.73)	
Students do not share personal belongings with each other (stationery, stethoscope, etc.)	3.64 (0.71)	
Practices to protect others Mean (SD) 38.42 (5.89), α 0.67	Trainer's practice guidelines	
	The trainer should be tested for COVID-19 before going to clinical setting/laboratory	3.39 (0.94)
	If a trainer has respiratory symptoms, she or he abstains from training	3.48 (0.87)
	Trainer wears a mask while training students	3.71 (0.65)
	Trainer puts on disposable/latex gloves when training students	3.36 (0.92)
	Trainer dresses a special dress/coat for the clinical setting and takes it off once finished	3.56 (0.80)
	Trainer emphasizes IPC guidelines prior to each clinical day as a reminder to students	3.61 (0.65)
	Trainer prepares IPC educational pocket card to all students	3.37 (0.83)
	Trainer explains to students how to use personal protective equipment (e.g., gloves, mask, and gown/apron, goggles) as indicated in the guidelines	3.66 (0.63)
	Trainer stays with students while caring for patients	3.26 (0.75)
	Trainer assigns students to patients, who do not have respiratory symptoms	3.41 (0.86)
	Student's practice guidelines	
	Students are tested for respiratory symptoms before going to a clinical setting/laboratory	3.44 (0.86)
	Essential practice needs Mean (SD) 41.19 (5.94), α 0.844	Trainer practice guidelines
The trainer needs to have enough information about COVID-19 to ensure safe practice		3.71 (0.68)
Policies about COVID-19 are adequate to keep trainers and students safe		3.47 (0.83)
Trainer receives training on how to deal with a patient with COVID-19/infectious disease		3.58 (0.76)
Trainer conducts training on infection prevention and control (IPC) guidelines before the beginning of each clinical course/semester		3.65 (0.61)
Trainer explains principles of visual triaging to students during laboratory training		3.59 (0.64)
Trainer explains why a student with respiratory symptoms needs to leave the setting/laboratory (e.g., fever, coughing, sore throat)		3.68 (0.64)
Trainer revises the IPC protocols at the beginning of each semester		3.63 (0.66)
Student's practice guidelines		
Students pass an IPC exam prior to joining the clinical course		3.38 (0.84)
Students have the IPC educational pocket card prior to each clinical day		3.40 (0.82)
Students are tested for IPC knowledge and skills at the beginning of the clinical training		3.51 (0.74)
Students' knowledge about visual triaging is tested during preparatory laboratory		3.48 (0.76)
Students breaching IPC guidelines undergo further laboratory training for two clinical days		3.38 (0.79)
Students acknowledge the procedure followed if they complain of respiratory symptoms		3.63 (0.70)
Students train in all departments, including the closed units (ICU, NICU)		2.91 (0.91)
Students provide care to all patients, including those who have respiratory symptoms	2.68 (1.10)	

*Infection prevention and control. **Cronbach's alpha

section, where the total mean score was 68.95 out of 80 (SD = 10.21) with a range between 27 and 80.

The midpoint of the total score in this study was 92 (range 46–184), and the mean score of the questionnaire was 157.90. Similar results can be noticed in the other themes, which also had high mean scores, indicating the support of trainers on the suggested IPC items in the study questionnaire. For instance, “protecting self” included 20 items and the mean score was 71.45, while the theoretical mean score was 50 (range 20–80). This also applies to the other themes [Table 2]. The theoretical midpoint for “protecting others,” which was represented by 11 items, was 27.5 (range 11–44), but the mean score was 38.42. The third theme “essentials practice needs” was subsumed by 15 items and had a midpoint of 30, but the mean score was 41.19. These scores generally indicate an inclination toward supporting the suggested changes in clinical practice as they depart positively away from the midpoint to reflect higher means.

To sum up, the scores on the total and themes of the study questionnaire indicate that NE support changes in the current clinical practice, which aim to ensure adherence to the IPC’s new practice guidelines.

Discussion

During the first half of the year 2020, many nursing programs around the world stopped students’ training in laboratories and clinical settings as COVID-19 was sweeping. The threat of this pandemic did not disappear to date (during the writing of this report). However, questions can be raised on whether training would be the same as before COVID-19 when students and NE resume training in the laboratory and clinical areas; we might even witness comparable conditions in the future. Therefore, the present study examined how NE involved in clinical and laboratory training expect changes in terms of IPC practices when resuming clinical training and to prepare students for any future pandemics after graduation. To avoid any accidental spread of COVID-19 among trainers and students, there is a need to set realistic and effective measures to ensure safe training for all involved, including nurses and patients, especially as some programs have adopted early deployment of students.^[12]

Findings in this study showed that trainers supported changes in the IPC practices as suggested in the study questionnaire. The need for these changes can become more persisting as the new academic year in many areas around the world is approaching and the pandemic is still hitting those countries. Response on the theme “protecting self” showed trainers’ concern about contracting COVID-19, and what practices were perceived as important to avoid contracting an infection, such as physical distancing, the use of sanitizers, and what ensures readiness for any outbreaks in the future.

Most trainers supported the items, which would ensure personal safety. Although studies emphasized the importance of protective measures, adherence to students using them was not satisfactory.^[13,14] Therefore, our findings emphasize the need for trainers to remind students prior to each clinical day of the measures they must follow to avoid cross-infections.

The second theme, “protecting others,” addresses how educators ensure training students safely without causing any IPC breach, which includes training students on standard precautions and directing students when providing care to patients and family members. Students do not follow standard precautions unless they are followed by trainers.^[15,16] We found that the trainers agreed on the need to keep students aware of the need to use personal protective equipment and sanitizers to protect others from contracting cross-infection through those students.

Our findings also emphasize what the literature reported about the need to have a component of IPC prior to clinical training.^[17] However, trainers believed that the need for this component extended to each clinical day briefing. Findings in the present study supported education about practices that highlight students’ safe practices. Many studies emphasized the importance of education in anchoring IPC principles and practices among nursing students.^[18-20] It was evident in the literature that knowledge about many other viruses, like Zika, Ebola, and Severe Acute Respiratory Syndrome (SARS), was generally low among nursing students.^[11,21] However, no assumptions could be made as limited support was present in the literature. Students received training on standard precautions during their early courses like fundamentals of nursing. But the need is still present to add new practices, which represent the new view of IPC after the COVID-19 pandemic. It is expected that further training is required for students and some trainers to ensure that proper practices are addressed and adhered to during clinical and laboratory training.

Further, training and education on IPC should be provided systematically as part of the curriculum to protect nursing students from contracting or causing infection among students, patients, HCWs, and family members. The responses of most of the trainers clustered around being selective when assigning students to ensure student and patient safety. The main concern raised by the trainers was related to students’ competency in both knowledge and skills. Perhaps trainers could not endorse students’ decision-making skills and clinical reasoning as the accumulative experience and knowledge are still not adequate for students to make sound decisions. Therefore, the trainers were conservative in their responses and indicated the need to have a careful selection of the units and departments where students could train.

The study limitations include involving only NE, who were involved in training students, not all educators such as those in managerial positions. In addition, nursing faculty

from the college and the preceptors were not included in this study. In addition, items investigated in this study did not go under a process of validation and were associated mainly with the current COVID-19 situation. Another limitation in the scope of the study is that it addressed only infection prevention in the clinical and laboratory setting and did not include other areas where students were gathered such as classroom and computer laboratories.

Further examination is required to confirm the study findings and set up clear rules for safe clinical training.

Conclusion

Fundings from the current study suggest that practices for both the trainer and students be revised as NE's perception of changes can lead to significant changes within the training areas, including the laboratories and the clinical settings. Our findings suggest the need to develop effective and systematic guidelines, including the strict following of IPC guidelines and precautions.

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Conflicts of interest

Nothing to declare.

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Complications in Pregnant Women and Newborns Before and During the COVID-19 Pandemic

Abstract

Background: One of the high-risk groups exposed to the coronavirus disease 2019 (COVID-19) pandemic was pregnant women at risk of pregnancy complications due to a weakened immune system and inability to use various drugs to treat COVID-19. Accordingly, this study was conducted to investigate the complications in pregnancy before and during the COVID-19 pandemic. **Material and Methods:** This cross-sectional study was performed on all pregnant women in Shahroud, Iran. The time interval from February 18, 2019, to February 17, 2020, was considered before the COVID-19 pandemic and from February 18, 2020, to February 17, 2021, was considered the COVID-19 pandemic. Sampling was conducted by census and included 6851 pregnant women. The required information was extracted from hospitals' health deputy registration system and high-risk pregnancy registration program. **Result:** Based on the findings, hypertension disorder, gestational diabetes, placental abruption, pre-eclampsia, cesarean section, hospitalization in neonatal intensive care unit (NICU), preterm birth, and hospitalization in other hospital wards increased by 1.88%, 1.93%, 0.12%, 0.45%, 5.45%, 1.00%, 1.20%, and 1.40%, respectively, in 2020 compared to 2019. A statistically significant difference was also observed between them ($p < 0.05$). Also, the regression results showed that the chances of high blood pressure, Gestational Diabetes Mellitus (GDM), placental abruption, and cesarean section were increased by 10.91, 1.53, 5.51, and 2.83 times, respectively. **Conclusions:** Pregnancy complications have increased during the COVID-19 pandemic. As a result, there is a need to take appropriate health and medical measures to reduce the risks associated with the COVID-19 epidemic for pregnant women and neonates.

Keywords: COVID-19, newborn, pandemics, pregnancy complications

Introduction

After the prevalence of the coronavirus disease 2019 (COVID-19) in China and its spread worldwide, pregnant women were one of the high-risk groups exposed to the clinical consequences of the disease.^[1] The first case of COVID-19 in pregnant women has raised many concerns about the susceptibility of pregnant women to the severe form of the disease and its transmission to the fetus and infant and the occurrence of adverse clinical outcomes in the mother and the infant.^[2] Evidence has shown that maternal systemic infection can affect pregnancy outcomes.^[3] The experience of pregnant women exposed to the family of coronaviruses such as Severe Acute Respiratory Syndrome (SARS) and Middle East respiratory syndrome (MERS) has shown that the occurrence of these diseases in pregnant women increases

miscarriages, premature births, and Intrauterine Growth Retardation (IUGR), but vertical transmission of the disease has not been reported.^[4]

Despite the experience of exposure to the coronavirus family in the past, the clinical course of the COVID-19 disease in pregnant women was unclear, and there were many ambiguities in this field. Then, studies showed that this disease is not transmitted vertically from mother to fetus. Due to the mother's physiological conditions during pregnancy, this disease's severity is less in pregnant mothers. However, recent studies have shown that the rate of death and severe respiratory complications in pregnant women with COVID-19 have increased in developed and developing countries.^[5,6] Also, COVID-19 causes an increase in pre-eclampsia, premature birth, low birth weight (LBW), stillbirth, mother's hospitalization in the intensive care

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unit (ICU), and newborns' hospitalization in the neonatal intensive care unit (NICU). In addition, infection with COVID-19 with symptoms and higher severity increased the mentioned outcomes.^[7,8] However, most studies are case reports and have been conducted on women with COVID-19. Individuals with pre-existing chronic diseases experience an impact on the severity of the disease and its consequences upon contracting COVID-19. It cannot be determined whether the consequences were related to COVID-19 or due to diseases or a history of pregnancy complications.^[9,10] Also, some studies have mentioned that there was no change in complications during the pandemic compared to before.^[11,12]

Given that limited studies have been conducted on complications in all pregnant women exposed to the COVID-19 pandemic (women with and without COVID-19), this study compared complications in pregnant women before and during the COVID-19 epidemic in Shahroud City to determine the effect of the COVID-19 epidemic on pregnancy complications in pregnant women and adverse clinical outcomes in neonates.

Material and Methods

This cross-sectional study was performed on pregnancy complications and adverse pregnancy outcomes before and during the COVID-19 pandemic in Shahroud City, Iran. This study considered the time interval of February 18, 2019, to February 17, 2020, before the COVID-19 pandemic. The time interval from February 18, 2020, to February 17, 2021, was considered the COVID-19 pandemic. It is noteworthy that the first case of COVID-19 in Iran was identified on February 18, 2020. Based on this, all pregnant women who have childbirth residences in Shahroud City were included in the study. Therefore, there were 6851 pregnant women in Shahroud City in the studied years, of which 6213 women had singleton fetuses and were studied. In this study, all pregnant women residents in Shahroud were included in the study by the census method. Notably, we have focused here on the overall effects of the COVID-19 pandemic and only severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) patients have not been evaluated. Also, excluded were women who became pregnant before the onset of the pandemic but who had been pregnant and childbirth for some time during the pandemic.

The researchers contacted the Vice-Chancellor for Health Affairs of Shahroud University of Medical Sciences to collect the necessary data. We obtained information on various aspects, including the number of pregnancies and deliveries and adverse pregnancy outcomes such as abortion, stillbirth, LBW, maternal death, neonate death, preterm delivery, and the type of delivery. For information on pregnancy complications and outcomes, refer to Vice-Chancellor of Treatment of Shahroud University of Medical Sciences and Bahar and Khatam Al-Anbia

Hospitals, and the required information, including eclampsia, pre-eclampsia, IUGR, cause of stillbirth, cause of death of mother, placental abruption, preterm birth, and hospitalization in the ICU, was extracted.

For this study, we obtained information on pregnancy outcomes according to the International Classification of Diseases codes of discharge diagnosis, including gestational hypertension (blood pressure 140/90 mmHg), Gestational Diabetes Mellitus (GDM), delivery mode, stillbirth, abortion, placental abruption, preterm birth, LBW, IUGR, maternal death, and neonate death. Preterm birth was defined as less than 37 weeks of gestation based on the interval between the last menstrual period and the newborn's delivery date. The delivery mode was categorized as either cesarean section or vaginal delivery. The cesarean section included medical and psychosocial indications, and vaginal delivery included spontaneous vaginal and assisted vaginal births. The infant's LBW was <2500 g and gestational hypertension (blood pressure) was 140/90 mmHg. The Maternal Mortality Rate (MMR) was calculated as the death of a pregnant mother divided by 100,000 live births, and the Neonatal Mortality Rate (NMR) was calculated as the death of the neonate from the first day to the 28th day after birth divided by 1000 live births.

Data analysis was conducted using descriptive statistical methods of frequency estimation and analytical tests, including Chi-square and logistic regression tests, conducted by the Statistical Package for the Social Sciences (SPSS) software version 22 (IBM SPSS Statistics, Chicago, USA).

Ethical considerations

This study was approved by the ethics committee of Shahroud University of Medical Sciences and was conducted following the Declaration of Helsinki (ethical code: IR.SHMU.REC.1400.034).

Results

In Shahroud City, 3,595 pregnancies were recorded in 2019, whereas in 2020, the number decreased to 3,261 pregnancies, indicating a reduction of 334 cases compared to the previous year. Based on the findings in years 2019 and 2020, respectively, 52.33% and 56.10% of women were 18–35 years old at the time of pregnancy, 50.82% and 50.18% had a baby boy, 39.61% and 41.32% had two children, 6.36% and 6.72% had a urinary infection during pregnancy, 8.36% and 9.12% had vaginal bleeding during pregnancy, 27.32% and 24.21% had a history of abortion, 8.21% and 6.81% had a history of premature birth, and 4.92% and 4.23% had a history of diabetes. In 2020, 95 people (2.91%) of pregnant women in this city were infected with COVID-19 [Table 1].

The study of pregnancy complications in women showed that in 2019, seven cases (0.19%) of hypertension disorder

Table 1: Demographic and clinical characteristics of pregnant women before and during the COVID-19 pandemic

Variable	Year 2019 (3595 pregnant women) n (%)	Year 2020 (3261 pregnant women) n (%)
Pregnancy age (year)		
<18	823 (22.89)	714 (21.88)
18-35	1881 (52.33)	1826 (56.01)
35<	891 (24.78)	737 (22.11)
Neonate's gender		
Boy	1827 (50.82)	1636 (50.18)
Girl	1768 (49.18)	1625 (49.82)
Number of children		
1	1311 (36.49)	1101 (33.78)
2	1423 (39.61)	1347 (41.32)
3	498 (13.88)	528 (16.18)
4≤	363 (10.11)	288 (8.82)
Urinary tract infection	229 (6.36)	219 (6.72)
Bleeding during pregnancy	301 (8.36)	297 (9.12)
History of abortion	928 (27.32)	789 (24.21)
History of premature birth	295 (8.21)	222 (6.81)
History of multiple births	128 (3.57)	125 (3.84)
History of diabetes	177 (4.92)	138 (4.23)
Infected with COVID-19	0 (0.00)	95 (2.91)

occurred in pregnant women, which in 2020 had increased to 68 cases (2.08%). Also, gestational diabetes, placental abruption, pre-eclampsia, and cesarean section increased by 1.92%, 0.12%, 0.46%, and 5.56%, respectively, in 2020 compared to 2019 with a statistically significant difference between them. The MMR had increased tripled in 2020 compared to 2019 (all three had died because of COVID-19), which had a statistically significant difference ($p = 0.031$). Among the studied variables were high-risk pregnancy, abortion, stillbirth, maternal hospitalization in the ICU, vaginal delivery, and IUGR in 2020 compared to 2019. Only vaginal delivery ($p = 0.001$) and IUGR ($p = 0.013$) showed a statistically significant difference in the 2 years. The ratio in Table 2 shows a decrease in 2020 compared to 2019.

In 2019, 3258 neonates were born, which in 2020 had decreased to 2955 neonates. A comparison of complications in infants born in 2019 and 2020 showed that the NMR in 2019 and 2020 was 4.29 and 5.07 per 1000 live births, respectively. However, no statistically significant difference was observed in neonatal mortality ($p = 0.390$). Among the causes of neonatal mortality, respiratory distress syndrome had increased by 32.38% in 2020 compared to 2019. Among other complications, hospitalization in NICU, preterm birth, and hospitalization of neonates in hospital wards increased by 1.01%, 1.16%, and 1.37%, respectively, in 2020 compared to 2019. Among the causes of neonatal hospitalization, respiratory distress syndrome had increased by 40.00% in 2020 compared to 2019.

There was no statistically significant difference between LBW and an Apgar score of less than seven between the 2 years [Table 3].

Evaluation of the relationship between complications in pregnant mothers and COVID-19 pandemics using a logistic regression test showed that hypertensive disorder in pregnant women increased by 10.91 times, gestational diabetes by 1.53 times, and cesarean delivery by 2.83 times in 2020. There was a statistically significant difference between them. However, IUGR was reduced by odds ratio (OR)=0.25 during the COVID-19 pandemic. Also, in the field of complications in newborns, there was no statistically significant relationship between preterm birth, NICU hospitalization, and infant hospitalization in hospital wards during the COVID-19 pandemic [Table 4].

Discussion

According to the findings, the number of pregnancies in Shahroud City had decreased during the COVID-19 pandemic and complications of pregnancy during the COVID-19 pandemic increased maternal mortality, hypertension, gestational diabetes, placental abruption, pre-eclampsia, and cesarean section, and reduced the high-risk pregnancies, abortion, stillbirth, maternal hospitalization in ICU, vaginal delivery, and IUGR. In the study, Molina *et al.*^[13] (2022) compared pregnancy outcomes before and during the pandemic of COVID-19. Compared to before, live births decreased by 2.50% during the pandemic, but the death of pregnant mothers increased from 5.17 to 8.69 per 100,000 people. In a review study by Gajbhiye RK *et al.*^[5] (2020), nine cases of maternal death occurred due to contracting COVID-19. Social conditions and physical health of women affect fertility. In the era of COVID-19, the uncertainty of the effect of this disease on pregnant women, the decrease in the immune level of pregnant women, and certain physiological conditions as obstacles can affect the reduction of women's desire to be fertile.^[14] One of the reasons for the increase in maternal mortality is COVID-19. In this study, three cases of maternal death occurred during the pandemic, and all three were due to infection with COVID-19, while in other studies, the death of pregnant mothers occurred due to infection with COVID-19.

In a study by Mattar *et al.*^[15] (2020) in Singapore which studied 16 women with COVID-19, the results showed that four women were hospitalized and two had abortions. In a review study by Gajbhiye RK *et al.*^[5] (2020), 441 pregnant women with COVID-19 were studied. According to the findings, 80.00% of deliveries were by cesarean section, 26.00% of cases led to preterm delivery, and 2.00% of cases led to stillbirth. Among pregnant women, 10.00% had high blood pressure, 9.00% had diabetes, and 2.00% had placental abruption. Studies have shown that viral infections can lead to placental disorders such as changes in the structure of the placental villi, chorioangioma,

Table 2: Comparison of pregnancy complications before and during the COVID-19 pandemic

Variable	Pre-COVID-19 (3595 pregnant women) n (%)	During COVID-19 (3261 pregnant women) n (%)	p**
High-risk pregnant women	138 (3.83)	113 (3.46)	0.210
High blood pressure	7 (0.19)	68 (2.08)	0.001
Pre-eclampsia	53 (1.47)	63 (1.93)	0.081
Eclampsia	1 (0.03)	0 (0.00)	0.520
Gestational diabetes	137 (3.81)	187 (5.73)	0.001
Maternal mortality rate*	1 (27.81)	3 (91.99)	0.310
Abortion	308 (8.56)	277 (8.49)	0.520
Stillbirth	29 (0.80)	29 (0.88)	0.910
Causes of stillbirth			
• Amniotic fluid disorder	8 (27.58)	1 (3.44)	0.012
• Genetic diseases	3 (10.34)	4 (13.79)	0.504
• Fetal abnormalities	0 (0.00)	5 (17.24)	0.02
• Placental abruption	0 (0.00)	1 (3.44)	0.540
• Unknown	18 (62.06)	18 (62.06)	0.930
Placental abruption	1 (0.03)	5 (0.15)	0.084
Mother's hospitalization in ICU***	118 (3.28)	87 (2.66)	0.073
Causes of mother's hospitalization in ICU			
• Pre-eclampsia	53 (44.91)	42 (48.27)	0.296
• Eclampsia	1 (0.84)	0 (0.00)	0.611
• Complications of abortion	7 (5.93)	0 (0.00)	0.026
• Systemic infection	3 (2.54)	7 (8.04)	0.072
• Vaginal bleeding	48 (40.67)	30 (34.48)	0.198
• Severe vaginal bleeding	6 (5.08)	7 (8.04)	0.296
• Rupture of the uterus	0 (0.00)	1 (1.15)	0.601
Type of delivery			
Vaginal	1598 (44.45)	1275 (39.09)	0.001
Cesarean section	1997 (55.54)	1986 (61.10)	0.001
IUGR****	13 (0.36)	3 (0.09)	0.013

*Per 100000 live births. **Chi-square test. ***Intensive care unit. ****Intrauterine growth restriction

Table 3: Comparison of complications in neonates born before and during the COVID-19 pandemic

Variable	Pre-COVID-19 (3258 neonates) n (%)	During COVID-19 (2955 neonates) n (%)	p**
Neonatal mortality rate*	14 (4.29)	15 (5.07)	0.390
Causes of neonatal death			
• Preterm birth	7 (50.00)	4 (26.66)	0.230
• Respiratory distress syndrome	2 (14.29)	7 (46.67)	0.071
• Fetal abnormalities	3 (21.43)	2 (13.33)	0.490
• Systemic infection	0 (0.00)	1 (6.67)	0.520
• Unknown	2 (14.28)	1 (6.67)	0.480
Apgar*** score <7	37 (1.13)	37 (1.26)	0.081
Hospitalization in NICU****	93 (2.85)	114 (3.86)	0.024
Preterm birth	259 (7.94)	269 (9.10)	0.062
Low birth weight	233 (7.15)	209 (7.07)	0.480
Neonatal hospitalization	521 (15.99)	513 (17.36)	0.079
Causes of neonatal hospitalization			
• Postnatal resuscitation	24 (4.60)	16 (3.18)	0.110
• Respiratory distress syndrome	216 (41.47)	418 (81.47)	0.001
• Systemic infection	267 (51.25)	79 (15.39)	0.001
• Congenital anomalies	9 (1.73)	0 (0.00)	0.002
• Addiction	5 (0.95)	0 (0.00)	0.031

*Per 1000 live births. **Chi-square test. ***Appearance, pulse, grimace, activity, and respiration. ****Neonatal intensive care unit

Table 4: Investigation of the relationship between COVID-19 pandemic with pregnancy and neonatal complications by using the logistic regression test

Variable	Beta coefficient	Wald	Odds ratio (95% CI****)	p
High blood pressure	2.39	36.12	10.91 (5.00-23.80)	0.001
Pre-eclampsia	0.27	2.14	1.31 (0.91-1.90)	0.143
Gestational diabetes	0.42	13.86	1.53 (1.22-1.92)	0.001
Placental abruption	1.70	2.43	5.51 (0.64-47.26)	0.119
Mother's hospitalization in ICU*	-0.21	2.21	0.80 (0.61-1.07)	0.107
Type of delivery				
Vaginal	-0.22	20.09	0.80 (0.72-0.88)	0.0001
Cesarean section	1.04	43.58	2.83 (2.57-3.12)	0.001
IUGR**	-1.37	4.57	0.25 (0.07-0.89)	0.032
Hospitalization in NICU***	0.27	2.31	1.31 (0.92-1.86)	0.128
Preterm birth	-0.01	0.01	0.99 (0.75-1.32)	0.992
Neonatal hospitalization	0.05	0.25	1.04 (0.87-1.25)	0.611

*Intensive care unit. **Intrauterine growth restriction. ***Neonatal intensive care unit. ****Confidence interval

and multifocal infarction. Also, systemic infection and subsequent inflammation can lead to impaired placental angiogenesis, and placental hemodynamic changes can lead to premature birth, pre-eclampsia, and stillbirth. Placental hypoxia increases the production of inflammatory biomarkers such as TNF- α and IL-6, leading to endothelial dysfunction in pre-eclampsia.^[16,17] In this study, pre-eclampsia and placental abruption were increased during COVID-19, which is consistent with the findings of the studies conducted, which can be caused by the changes caused by exposure to the COVID-19 infection. In our study and other studies, cesarean delivery was increased. Some studies have mentioned that cesarean delivery is safe and does not transmit the disease to the baby. Also, the perception of women regarding the convenience of cesarean delivery and the fear of transmitting the disease to the baby can be the reason for women's desire to increase cesarean delivery.^[18,19]

In a study by Ko *et al.*^[7] (2021) in the United States, 6550 pregnant women with COVID-19 were compared with 482921 pregnant women without COVID-19 in terms of pregnancy complications due to COVID-19. Based on the findings in infected women compared to non-infected women, respectively, 1.90% and 1.40% with gestational diabetes, 5.30% and 6.60% with hypertension, 9.40% and 6.80% with pre-eclampsia, 1.00% and 7.70% with stillbirth, 4.80% and 3.60% with preterm delivery, 4.50% and 1.50% of hospitalization in ICU, 3.30% and 0.10% with respiratory distress syndrome, and 33.50% and 32.00% of cesarean section were reported. Also, only 0.10% of infected women died of a pregnant mother. Du *et al.*^[20] (2021) in China compared pregnancy complications in pregnant women before and after the COVID-19 pandemic. Accordingly, 4511 cases of pregnant women before COVID-19 and 3188 pregnant women during COVID-19 were included in the study. The findings showed that before and during the COVID-19 pandemic, respectively, 27.99% and 27.38% of pregnant women with

gestational diabetes, 6.23% and 6.15% with hypertension, 0.04% and 0.09% with stillbirth, and 45.80% and 16.60% 48.00% of cesarean section occurred. In this study, during the COVID-19 pandemic, there were three cases of maternal mortality, all caused by COVID-19. In other studies, infection with COVID-19 has led to the death of pregnant mothers. Also, in this study, 95 pregnant women were infected with COVID-19. Getting infected with COVID-19 in pregnant women can lead to hypoxia. Maternal hypoxemia can subsequently lead to placental hypoxia. Hypoxic placenta activates pro-inflammatory and anti-angiogenic factors, disrupting endothelial function, organ damage, and high blood pressure. As a result, these disorders can increase adverse pregnancy outcomes such as pre-eclampsia, premature birth, and placental abruption.^[21,22] As a result, during the COVID-19 pandemic, maternal infection can lead to adverse pregnancy outcomes such as high blood pressure, placental abruption, and pre-eclampsia in pregnant mothers. In this study, stillbirths and abortions were reduced during the pandemic, and stillbirths were rare in women with COVID-19 in the studies conducted. Nevertheless, in the field of abortion during the COVID-19 era, medical services were mainly directed to patients with COVID-19, and healthy people did not want to be present at medical centers.^[23,24] Based on this, the abortion may have been done outside the medical center, and it was not reported.

In this study, the findings on neonatal complications after the COVID-19 pandemic showed that the NMR had increased by 0.70 per 1000 live births. Respiratory distress syndrome, preterm birth, hospitalization in NICU, and hospitalization were also increased. A study by Khan *et al.*^[9] (2021) investigated three cases of neonates born to a pregnant mother with COVID-19. Only one case resulted in preterm delivery. Apgar score and birth weight were normal, and none of the infants required hospitalization or NICU. In a systematic review study by Qin Wei *et al.*^[8] (2021) that examined pregnancy outcomes in

women exposed to COVID-19 versus non-exposed women, the findings showed that COVID-19 increased NICU hospitalization by 3.69 times. However, neonates' mean birth weight in the two groups was only 69 grams different. In a review study conducted by Gajbhiye RK *et al.*^[5] (2020) on pregnant women with COVID-19 in the field of neonatal complications, the findings showed that in 25.00% of cases of preterm birth, 8.00% of cases of respiratory distress syndrome and 80.00% of cases had pneumonia. There were also four cases of neonatal death. Biopsies performed on people who died due to COVID-19 showed that contracting this disease causes pathological damage, including alveolar damage, alveolar bleeding, hyaline membrane formation, pulmonary edema, and extensive infiltration of neutrophils and macrophages in the interstitium and alveoli, which can ultimately increase respiratory distress syndrome.^[25] In this study, 95 mothers with COVID-19 could transmit the disease to their neonates; also, it is possible that the babies were infected with COVID-19 and had no symptoms. This can lead to respiratory distress and other lung diseases. An increase in respiratory distress can lead to an increase in hospitalization and infant death. In this study and other studies conducted, respiratory distress increased during the COVID-19 pandemic, as a result of which hospitalization in the ICU and neonatal death can also increase. In a review study by Ali Khan *et al.*^[26] (2020), 59 pregnant women with COVID-19 were studied. According to the findings, 16.40% of neonates were underweight, and one neonatal death occurred. In a study by Du *et al.*^[20] (2021) in China that compared pregnancy outcomes in pregnant women before and after the COVID-19 pandemic, before and during the COVID-19 pandemic, respectively, 4.41% and 3.80% preterm birth and 3.04% and 3.01% underweight occurred but no statistically significant difference was observed between them. Causes of increased respiratory distress syndrome in neonates and hospitalization in hospital wards and NICU can infect with COVID-19 disease or inadequate maternal conditions due to this disease or preterm delivery, which can affect the hospitalization conditions of the neonates and respiratory distress effect. Also, studies have predicted that infant mortality would increase in low-income and middle-income countries due to limited access to medical services, medicine, and health care.^[27] The study's limitations include the following: migration of women to other cities, childbirth in other cities, non-reporting of illegal abortions, and low probability of reporting all clinical outcomes.

Conclusion

In conclusion, the findings of this study indicate an increase in pregnancy complications among all pregnant women, along with adverse clinical outcomes in infants. However, the precise relationship between these disorders and COVID-19 infection and the influence of underlying contextual changes remains uncertain. Further research

focusing on investigating these disorders individually while controlling for confounding variables is strongly recommended to gain a deeper understanding. By conducting such studies, we can elucidate the specific impacts of COVID-19 on pregnancy outcomes and enhance our ability to provide targeted interventions and support for pregnant individuals.

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Conflicts of interest

Nothing to declare.

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Explaining the Nurses' Spiritual Needs in the Oncology Department: A Qualitative Study

Abstract

Background: It seems that improving the spiritual dimension of cancer patients can play an effective role in their mental and emotional peace. Meanwhile, oncology ward nurses are one of the most important healthcare providers that can help improve patients' relationship with God due to their more interaction and communication with patients. For this reason, this study aimed at explaining nurses' spiritual needs in an oncology ward. **Materials and Methods:** This study was conducted based on the qualitative content analysis method. The participants included 11 nurses from the oncology ward of Seyed Al Shahada Hospital in Isfahan from 2021 to 2022. A semi-structured interview was administered to determine nurses' spiritual needs. **Results:** Analysis of 11 interviews conducted with nurses revealed a total of four main codes, 13 sub-codes, and four sub-sub-codes. According to nurses' point of view, their spiritual needs can be classified into four dimensions as follows: communication with God, communication with oneself (intrapersonal communication), communication with others (interpersonal communication), and communication with environment. Administered interviews revealed the role of communication with God with six sub-codes as nurses' most important point of attention. **Conclusions:** According to nurses' point of view, nurses' spiritual needs were divided into the dimensions of communication with God, communication with oneself, communication with others, and communication with environment. Therefore, it is necessary to simultaneously pay attention to oncology nurses' personal and social aspects to increase their spirituality.

Keywords: Iran, oncology nursing, spirituality

Introduction

Cancer is one of the growing diseases^[1] that changes the normal life process of patients and creates a feeling of fear of death and anxiety in them.^[2] Those who are close to death suffer from spiritual grief to find meaning and purpose in life.^[3] Therefore, paying attention to these patients' spiritual distress and spiritual resources related to their quality of life can play a crucial role throughout their cancer experience.^[4,5] Considering that nurses, as compared to other healthcare providers, spend more time with patients, they play a very important role in helping patients find meaning and purpose in life, improve health status, and resolve crises of illness, hospitalization, and death of loved ones.^[5] It seems that nurses knowledgeable about spirituality provide better spiritual care. Spiritual nurses bring their knowledge and experiences of spirituality to the care center and respond to a portion of patients' spiritual needs.^[6]

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Some researchers believe that spirituality in nurses is one of their most important value and belief systems and can have a great impact on their attitude and performance in caring for patients and their professional commitment. Studies have shown that nurses with higher spirituality take care of their patients with more love and affection and pay more attention to their spiritual care.^[7] In fact, it can be stated that nurses' spirituality can play an imperative role in their attention to spiritual aspects of care such that nurses' spirituality increases self-awareness, communication, and building trust with patients to provide spiritual care.^[8] A study in three European countries showed that nurses who have more spiritual needs rarely provide spiritual care to patients.^[9] In addition, studies in Iran have also evaluated nurses' spiritual needs in different wards of hospitals. They have shown that strengthening the relationship with God and trusting in Him and asking for healing from

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God through their mediation is one of nurses' spiritual needs. However, it is worth mentioning that the main purpose of these studies was to point out the importance of teaching spiritual care to patients in different age-groups^[10,11]

Although nurses believe that spiritual care is a central part of nursing care, they rarely pay attention to their patients' spiritual needs.^[12] This issue can be due to time limitation, high workload, lack of private space for nurse and patient, nurses' non-understanding of help in the spiritual dimension, nurses' inexperience, difference in their religion and beliefs, and non-explanation of nurses' needs. In this regard, despite the importance reported about nurses' spiritual needs and spirituality, few studies have paid attention to explaining nurses' spiritual needs, especially in an oncology ward. Nurses should be able to identify and respond to their patients' spiritual needs during their interactions with patients. These needs and the way they are responded to vary according to the perception of patients and the nurses, which is affected by individual, cultural, and social differences.^[13] Perhaps the individual characteristics of nurses (including physical, mental, and psychological characteristics), social outlook, spiritual evaluation and the importance of its role in patients' mental health, and the prevailing spirituality in a country can have an effect on medical staff's spiritual needs.^[11,14] However, regular research studies addressing spirituality in the field of health have been performed mainly in Western countries, so the information is limited regarding specific religious and cultural contexts.^[15] In fact, religion has been proposed as a way to answer basic questions about life and death in spiritual care models,^[13] which may have a special position in patients' spiritual adaptation in the Islamic culture of Iran.

Therefore, discovering nurses' real perceptions and experiences that are directly related to cancer patients can be a more accurate and valid measure to determine nurses' spiritual care in the real world. This understanding and discovery of experiences can be obtained in qualitative studies, in which individuals' actual events, opinions, and experiences can be addressed in various areas.^[16] Hence, this study was conducted with a qualitative approach to identifying nurses' spiritual needs in the oncology ward of Seyed Al Shahada Hospital in Isfahan, Iran.

Materials and Methods

This study was qualitative and based on a qualitative content analysis method with a descriptive and exploratory approach. Sampling was conducted from March 2021 to February 2022. The participants in this study were selected from among nurses working in the oncology ward of Seyed Al Shahada Hospital in Isfahan. Sampling was continued using purpose-based method until saturation of data was achieved. The inclusion criterion was employment in the oncology ward with at least 2 years of working experience and willingness to cooperate in the study.

A semi-structured interview was used to collect information. To organize and integrate the information, an interview guide prepared by Galletta was used.^[16-18] Then, a final guide was prepared and compiled by conducting three pilot interviews.^[17,18] During the interview, the interviewer tried to help the researcher to focus on important and specific information by asking clear and exploratory questions and clarifying ambiguous points. In addition, it was attempted to provide an opportunity for participants to fully describe their feelings and beliefs without any biased comments on their statements. To meet the mentioned goal, the researcher started the interview with an open-ended question such as "What gives you peace and meaning?" As the interview progressed, the focus on specific issues increased and the researcher followed the interview in a semi-structured manner through probing questions. Examples of probing questions comprised the following ones: "What worries you?" "What is the source of your worry?" "What do you think a nurse needs psychologically and spiritually in their professional life?" "Do patients require spiritual matters?" "Have you ever talked to your patients about their spiritual needs?" and "If possible, express your experiences in conversation with patients in order to reassure them." Moreover, the researcher used field and reminder notes. Field notes included descriptions of conditions and some informal interviews. To avoid any possible problems during interview recording, the interviewer used two audio recorders. The interview continued until theoretical saturation was reached. Thus, 11 interviews were conducted with an average time of about 35 minutes in this study. In all stages of the study, the researcher tried to avoid any orientation and prejudice about the phenomenon under study. Interviews in the hospital were preferably conducted in a physicians' room or in places where participants could feel more relaxed. At the same time as interviews were conducted, transcription of the content was performed in a word file format, and important points of each interview were noted down to improve the quality of future interviews.

Moreover, to classify qualitative data and achieve a suitable level of abstraction, data analysis was performed using the conventional method of qualitative content analysis. In this analysis, raw data were classified into categories based on researchers' precise interpretation and inference. This process is conducted using the logic of induction, which is extracted by careful investigation of the researcher and constant comparison of data, categories, and themes. Then, these concepts were coded, summarized, and classified, and themes were extracted. In detail, primary codes were obtained using open coding. Internal codes were used to name and choose titles. Internal codes were expressions or concepts expressed by interviewees. In the next step, core codes were obtained. In other words, sub-codes were obtained through making association between internal codes. Finally, selective coding was used to obtain main codes. In this way, participants' perspectives were considered in a more comprehensive way

by taking advantage of all interviews. All decisions taken in this process were clearly recorded so that readers could easily understand the progress of the study.

In this research, the research validity and the reliability of the data were determined using four procedures including credibility, transferability, dependability, and confirmability. To get credible data (Internal validity), observation, interview, and documentation were used. After transcribing interview data, the researcher also reduced and wrote it on paper, and got confirmation from informants individually. To comply with transferability (External validity) of data, the researcher had tried to report the research in a clear and understandable way. The researcher wrote it in a detailed, clear, systematic, and believable format. All information, the way of collecting data, and the manner of presenting data were explained clearly so that the study can be transferred to different settings or contexts by other researchers. Dependability (Reliability) of qualitative data is concerned with consistency of research results when observing the same point twice. To get a good quality of measurement, the research data were also checked by one university lecturer as an interrater. The result showed that both researcher and interrater had the same contemplation on research data. Confirmability of research refers to the objectivity of the research. This has similarity with dependability so that they can be done together in the process of research. Accordingly, the researcher used interrater to measure both dependability and conformability of the study.^[19]

Ethical considerations

This study was approved by the Research Ethics Committee of Isfahan University of Medical Sciences (approval code: IR.MUI.MED.REC.1400.046). Ethical considerations including confidentiality of participants' information, obtaining informed consent from participants, explanation of research goals, voluntary participation in the research, permission to leave the study at any time, and trust in using texts were taken into account.

Results

This research reported the results of 11 interviews. Eight and three of interviewees (nurses) were female and male, respectively. Four, five, and two nurses had a master's, bachelor's, and postgraduate degree in nursing, respectively. The work experience of these nurses varied from 2 to 23 years. Moreover, their mean age was between 40 and 45 years. According to Table 1, four main codes, 13 sub-codes, and four sub-sub-codes were obtained from interviews.

Communication with God

Communication with God means those factors that, according to nurses, can be felt as a need to communicate with God. This main code had six sub-codes including the need for strengthening inner-spiritual drives, the need for spiritual gratitude, the need for spiritual relaxation

and stress relief, the need to trust in God, the need to resolve spiritual conflicts, and the need to share spiritual experiences.

The need for strengthening inner-spiritual drives

In the sub-code of the need to strengthen inner-spiritual drives, according to nurses, despite the fact that providing services to these patients is difficult, only inner-spiritual drives and motivations can be effective in improving nurses' services to patients as much as possible. For example, one interviewee expressed that: "*When I help patients and when I see the joy in their faces, I have a good and sacred feeling inside*" (Interview 5/female).

The need for spiritual gratitude

According to nurses' point of view, believing in God supervision over their services to patients can be the greatest gratitude for them. Therefore, the need for spiritual gratitude can be one of their most important needs. For instance, one interviewee stated that: "*I feel God is watching me; I receive 100% good energy to continue working*" (Interview 4/male).

The need for spiritual relaxation and stress relief

According to nurses' perspective, considering their stressful work conditions, having a spiritual relaxation such as patients' praying for them and spiritual support can reduce their stress and give them relaxation. In this respect, one interviewee mentioned that: "*The spiritual view gives me relaxation in doing my work in the hospital and it is a kind of brake for cases when I want to be ungrateful*" (Interview 1/female).

The need for trusting in God

Regarding the coexistence and interaction with cancer patients, as nurses accentuated worry about the future and fear of the occurrence of this disease for them, which can be overcome only by trusting in God. Some interviewees have stated that: "*Due to my relationship with a cancer patient, I am constantly worried that I might get this disease, so I always try to trust in God*" (Interview 7/female).

The need for resolving spiritual conflicts

Considering types of cancer patients in different ages, ethnic groups, and socioeconomic levels, one of the concerns is the occurrence of spiritual conflicts expressed in some questions such as why should this patient suffer from this disease? Why at this age? And many unanswered questions. Therefore, nurses feel the need for resolving these spiritual conflicts. In an interviewee's words: "*Sometimes I wonder why God gives so much misery to a person? I think it is not fair at all*" (Interview 10/female).

The need for sharing spiritual experiences

According to the nurses' vantage point, each nurse might

Table 1: Main and sub-categorizations extracted from qualitative data from needs analyses of nurses in an oncology ward

Main code	Sub-code	Sub-sub-code
Communication with God	The need for strengthening inner-spiritual drives	
	The need for spiritual gratitude	
	The need for spiritual relaxation and stress relief	
	The need for trusting in God	
	The need for resolving spiritual conflicts	
Communication with oneself (intrapersonal communication)	The need for self-esteem	
	The need for patience and tolerance	
	The need for self-care	
Communication with others (interpersonal communication)	Communication with family	The need for improving negative relationships with family The need for an optimistic view of the future of their family
	Communication with the patient	The need for controlling anger and discomfort in dealing with patients The need for increasing hope
Communication with environment	The need for dominance of a positive atmosphere in the ward and removal of feelings of emptiness in life	

have experienced different spiritual events based on their religious beliefs and length of their work experience. Therefore, according to them, sharing these experiences is another sub-category in the communication with God dimension. In one interviewee's terms: *"I personally have experiences about spiritual care, but these are very few and personal. Therefore, I really need to be trained in this respect and use experiences of my colleagues"* (Interview 5/female).

Communication with oneself (intrapersonal communication)

The communication with oneself relates to increasing nurses' patience and tolerance, having self-importance along with paying full attention to the patient, and being less engaged with patients' issues. In fact, they seek to compensate for the void of their forgetfulness. This main code had four sub-codes as follows: the need for self-esteem, the need for patience and tolerance, the need for self-care, and the need for not accusing oneself.

The need for self-esteem

Nurses believed that, as compared to other medical staff, they are overlooked and their work value is not noticed by patients and their companion. Therefore, they have a feeling of weakness and inferiority and consider dealing with this feeling as one of their main needs in relation to themselves. One of the interviewees expressed that: *"In some cases, I am not noticed by patients. For example, there have been many times when I was calling the physician and the patient's companion said that you did not do anything, you were speaking on the phone!"* (Interview 3/male).

The need for patience and tolerance

Due to stressful working conditions, many nurses have

admitted that they have lost their tolerance when faced with some patient's difficulties and problems and felt the need for resilience training in these conditions. For example, in this regard, one interviewee said that: *"Nursing these patients requires a lot of patience. If we are not patient, we may get into trouble with them over minor matters. If you don't tolerate and communicate well with them, you will have a very hard time"* (Interview 11/female).

The need for self-care

In this sub-code, nurses' lack of self-care due to their engagement with patients' problems and their inability to fully assist them have been considered. For example, according to the nurses' standpoint, the only thing that was not important for them was themselves and they only thought about their patients. In this respect, one interviewee stated that: *"Our work is so hard that during these few years of serving patients, the only thing that was not important for me was myself"* (Interview 11/female).

The need for not accusing oneself

Nurses believed that due to some patients' difficult conditions and their death, many times they felt guilty for not being able to do more for those patients, and in various ways, they consider themselves delinquent in patients' death or their failure to recover. For instance, one of the interviewees stated that: *"Nightmares, sometimes I see that I am questioned, I fear God so much in these matters. For example, I wonder whether I paid attention to patients' rights in the hospital"* (Interview 10/female).

Communication with others (interpersonal communication)

Communication with others means those factors that, according to nurses, can be felt as a need in communicating

with patients' or nurses' family. These communications were divided into four sub-codes consisting of the need for improving the negative relationship with the family, the need for having an optimistic view of the future of the family, the need for controlling anger and discomfort in dealing with the patient, and the need for increasing hope.

Communication with family

The need for improving negative relationships with nurses' family

Nurses expressed that their stressful work conditions have made their relationship with their families weak, and they have a lot of family tensions. Therefore, they felt this void and it seems that there is a need for fixing this problem. For example, an interviewee stated that: *"I constantly have problems at home. We are under a lot of mental pressure, and arguments arise at home due to an insignificant matter and I get upset"* (Interview 5/female).

The need for an optimistic view of the future of nurses' family

Nurses believe that they are constantly afraid of their family's future due to experiencing unfortunate events in their hospital. It seems that they need to reduce this stress and develop an optimistic view toward the future of their family. In this regard, an interviewee noted that: *"I am more worried about my family and my mother. For example, I find any small incident such as coughing or lethargy of my family members worrying. I keep thinking that they might have got some diseases, I always consider the future dark"* (Interview 10/female).

Communication with patients

Nurses highlighted that this sub-code refers to their point of view regarding factors affecting their relationship with patients. These factors have created gaps and problems, and there is a requirement to solve these matters. The following two sub-codes are discussed in this respect.

The need for controlling anger and discomfort in dealing with patients

Many nurses have suffered from extreme fatigue due to difficult work conditions, and this fatigue has caused them to be unable to control their anger. In one of the interviewees' words: *"In such a difficult working condition, several issues make me angry, so that I can't control myself"* (Interview 3/male).

The need for increasing hope

According to critical conditions of cancer patients, the possibility of death in this ward is more likely, and it is necessary for nurses to have a higher patience in this ward and be able to increase their life expectancy while dealing with these patients. One of the interviewees highlighted that: *"Communicating with a dying patient affects me a lot. There were times when I was next to the patient's*

bed and cried. Maybe if I had a better mood, I could have given the patient hope and encouragement until the last moments" (Interview 10/female).

Communication with environment

Communication with environment includes those factors that can be effective in creating positive atmosphere in hospitals and removing feelings of emptiness and meaninglessness of life. Therefore, this main code has been addressed under the sub-code the need for dominance of a positive atmosphere in wards and removal of the feelings of emptiness in life.

The need for dominance of a positive atmosphere and removal of the feelings of emptiness in life

As pointed out by nurses, the positive and negative atmosphere of environment has been very significant and, in many cases, has been associated with a feeling of emptiness and meaninglessness of life for nurses. For example, some interviewees stated that: *"It used to be significant for me that how long I will live, but now I don't care"* (Interview 11/female).

Discussion

This study outlined nurses' spiritual needs in an oncology ward. In communication with God dimension, nurses need a lot of spiritual support so that they can improve their spiritual skills by sharing their experiences and use those of their colleagues and achieve a spiritual relaxation to avoid tension and stress.

In this regard, Zamanzadeh *et al.*^[11] also identified strengthening relationships with God and trusting in Him as the supreme power and resorting to Imams and seeking healing from God through their mediation as nurses' spiritual needs. In addition, according to the results of the Amoah study, three main axes of strengthening faith, creating hope, and cultivating love and affection in nurses have been listed as their basic spiritual needs. These axes increased nurses' spirituality and improved their professional qualification to provide spiritual care for their patients.^[20]

Furthermore, oncology nurses in intrapersonal communication dimension were the need for self-esteem, patience and tolerance, self-care, and not accusing themselves. In fact, nurses need to reduce feelings of guilt induced by patient death and increase their patience to improve their intrapersonal communication. In fact, it is necessary to pay special attention to increasing nurses' self-esteem in this ward due to the existence of mental tensions.

The results of previous studies have also indicated that improving nurses' spiritual needs can cause job satisfaction, satisfaction, happiness, well-being, patients' satisfaction with nursing care, improved self-esteem, increased social abilities, and oncology nurses' augmented life satisfaction and positive mood. Moreover, nurses' confrontation with patients' spiritual needs was facilitated.^[8,21-23]

In addition, due to the pressure and difficulty of work in such wards, nurses may have problems in interpersonal communication dimension, especially with their family and patients that are two groups closely related to nurses. For example, they get annoyed with their family members very soon due to their decreased patience and tolerance, or they may not have a positive view of the future of their family due to observing unfortunate conditions. They may not have enough motivation to create and increase patients' life expectancy due to terrible conditions of some patients. Therefore, from nurses' perspective, there are needs related to their family and patients to improve the negative relationship with their family, develop a positive view toward the future, control anger and discomfort in dealing with patients, and increase hope in patients and their companion.

According to previous reports, it can be claimed that manifestations of spiritual care in nurses (especially Iranian nurses) comprise having empathy and hope, facilitating worship and communication with God, maintaining inner solitude with oneself, respecting fellow humans, and listening and paying attention.^[13,24,25] In fact, tendency toward spirituality in nursing profession is related to optimal care in interaction with patients, constructive cooperation with colleagues, avoiding negative behaviors, and tending to constructive behaviors.^[8]

Finally, the last dimension to explain nurses' need in the oncology ward was related to the environment. Actually, nurses' view of hospital or oncology ward environment can be negative or positive. Patients of these wards are more in need of God and are interceding due to considering themselves closer to death; consequently, this state can cause a positive and spiritual atmosphere in their hospital. In contrast, some other nurses have considered that patients' death and difficult conditions create a negative atmosphere in their hospital. Therefore, in this interview, it seems that creating a positive and hopeful atmosphere that eliminates feelings of emptiness and meaninglessness of life can be considered a basic need.

In this regard, many previous studies have also stated that it is possible to provide adequate spiritual care in a good and facilitative care environment.^[9,26-31] In such a situation, nurses can support their patients by understanding their spiritual experiences, set conditions for spiritual practices, and respect their spiritual beliefs.^[26] The results of previous studies indicated that neglecting nurses' spiritual needs causes a sense of loss of meaning in life,^[27] confusion,^[28] tension,^[29] stress, anxiety, and anger,^[30] and fatigue^[31] in their life and can weaken their communication with their environment.

It is worth mentioning that cultural and religious differences in Muslim and Western countries can play a role in observed differences in the codes obtained from nurses' spiritual needs as spirituality in Islam is based on Allah's words in the Holy Quran. Moreover, Muslims consider worship and lifestyle according to Allah's instructions presented in the Holy Quran as the spiritual

resource for developing their spiritual life.^[14] Considering Islam the dominant religion in Iran, religious beliefs can play a special role in confronting stressful events so that nurses' higher spiritual needs (especially in the oncology ward) may not only help nurses in providing spiritual care to patients but also may provide higher physical, social, mental, and health status as well as a higher quality of life.

It is necessary to mention that oncology departments, as one of the most stressful hospital wards and in need of a spiritual dimension, are of special importance. In addition, in this study, we were able to identify and code nurses' spiritual needs in this ward comprehensively and through interviews administered with these nurses. So far, few studies have addressed the spiritual needs of nurses in oncology wards. Therefore, these cases can be considered the strong points of this study. Considering that demographic characteristics of nurses (including age, gender, work experience, education level, and different religious beliefs) were not controlled in explaining their needs, it is not possible to judge whether demographic characteristics affect their spiritual needs or not. Therefore, this can be another weak point of this study. So, it is suggested to carry out further studies to evaluate spiritual needs of nurses taking care of cancer patients by paying due attention to their demographic characteristics. Furthermore, although this study aimed at performing in-depth interviews to provide a more extensive and inclusive framework of aspects, it is still possible that some aspects of nurses' spiritual needs have been overlooked. Besides, although the focus of this study was not on comparing the possible effect of different departments on nurses' perspective, it will be more illuminative to perform studies addressing various departments in hospitals.

Conclusion

According to nurses' point of view, their spiritual needs comprised the dimensions of communication with God, communication with oneself, communication with others, and communication with environment. From nurses' perspective, the first dimension, that is, communication with God, had six sub-codes including the need for strengthening inner-spiritual drives, the need for spiritual gratitude, the need for spiritual relaxation and stress relief, the need to trust in God, the need to resolve spiritual conflicts, and the need to share spiritual experiences. The second dimension, that is, communication with oneself, included four sub-codes: the need for self-esteem, the need for patience and tolerance, the need for self-care, and the need for not accusing oneself. The third dimension, that is, communication with others, consisted of four sub-codes: the need for improving the negative relationship with the family, the need for having an optimistic view of the future of the family, the need for controlling anger and discomfort in dealing with the patient, and the need for increasing hope. The final dimension, that is, communication with environment, was addressed under the sub-code the need for

dominance of a positive atmosphere in wards and removal of the feelings of emptiness in life. The obtained findings can shed more light on nurses' way to more successfully identify and respond to their own and their patients' spiritual needs during their interactions with patients.

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Conflicts of interest

Nothing to declare.

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Nurses' Experiences of Practical Challenges Associated with Nurses' Prescription: A Qualitative Study

Abstract

Background: Because nurse prescription has numerous benefits for the health systems, in many countries around the world, nurses are given the right to prescribe medication. In Iran, the role of nurses in prescription drugs is not well understood, and nurses face various challenges in this regard. **Materials and Methods:** A qualitative content analysis methodology based on the Graneheim and Lundman model was used. Thirteen nurses working in medical wards of hospitals affiliated with the Tehran University of Medical Science were selected to participate in this study by purposeful sampling. Participants were interviewed via telephone using a semi-structured tool. After thirteen interviews, data saturation was reached. Data collection was undertaken between April 2020 and April 2021. **Results:** The results of this study are summarized in one theme, four categories, and ten subcategories. The theme extracted from the data analysis was “the practical challenges of nurse prescription,” which included four main categories: structure challenges, personnel-related barriers, interprofessional separation, and society’s attitudes. **Conclusions:** The results of this study explain the barriers and practical challenges of nurse prescription in Iran. Identifying these challenges and barriers provides the necessary evidence for policymakers to remove and adjust these challenges and barriers. Moreover, the elimination of identified challenges will help nurses better perform their new roles and develop the nursing scope and profession.

Keywords: Iran, nurses, prescription, qualitative study

Introduction

Today, due to many changes in the health needs of society, the nursing profession has become more professionalized to respond to these changes.^[1,2] Currently, the provision of health care by nurses at the international level has undergone significant changes for a variety of reasons, including economic conditions, lack of access to appropriate medical services in rural and growing areas, and increasing expertise among different medical professions.^[3] One of these changes is that healthcare organizations in leading countries have licensed nurses as health or treatment team members to better comply with these conditions. Prescription medication is a historical movement in nursing that can have numerous positive consequences for health care, including nursing.^[4] Nurse prescription has begun in many countries and is rapidly evolving and expanding. It is also a new practice for nurses.^[5-7]

Nurse prescription has countless benefits, such as increased continuity of patient

care, better access to medicine for patients, especially in deprived areas, better efficiency in drug delivery to clients, reduced waiting time for patients, and reduced financial burden of healthcare systems.^[8-10] According to the available evidence, it also improves nurses' caring role and increases patient satisfaction.^[11,12] That is why, today, many healthcare systems in different countries have given nurses the right to prescribe medication to better meet the health needs of clients. Granting the right of drug prescription to nurses, to the mentioned benefits, has caused a significant leap in professional development and nursing independence.^[13,14] In Canada, today, for instance, the government is making an effort to increase access to primary care by strengthening the healthcare system and reducing the financial burden and costs. One approach taken by policymakers is to increase the role of specialist nurses, those with a postgraduate degree in nursing who can order and interpret diagnostic tests, diagnose patients, and prescribe medication for them.^[7]

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In Iran, medication is prescribed by general practitioners and specialized and subspecialty physicians. General practitioners often have less experience and skills than experienced and specialized nurses, and clients' access to specialized and subspecialty physicians is often costly and impossible. However, given the above points, in the healthcare systems of developing countries, including Iran, nurse prescription can control treatment costs, reduce the growing financial burden of second-level prevention, and increase client satisfaction.^[4,15] Unfortunately, in Iran, no attempt has been made to authorize professional nurses to prescribe drugs despite the shortcomings, such as increased costs, increased access time to treatment, and reduced client satisfaction due to independent physician prescription. Moreover, projects such as advanced practitioner nurses or nurse practitioners are not followed by Iranian health managers. In many countries, by creating the project of the Advanced Practice Nurse (APN), they have been better able to respond to society's needs and create a balance between supply and demand in the healthcare system.^[9,16] Implementation of nurse prescription in any country, including Iran, requires expert, evidence-based, and accurate practice, and in the first step, the challenges of and obstacles to the nurse prescription in the health or medical context of Iran must be identified. However, few studies in Iran have been conducted on nurse prescription, and the health context of Iran has not been well studied for implementing nurse prescription and identifying its challenges and barriers. Therefore, this study was conducted with the general purpose of explaining the challenges of nurse prescription in Iran based on the nurses' experiences.

Materials and Methods

A qualitative content analysis methodology was used to answer the research question. This study was conducted between January and September 2021. According to its philosophical foundations, this research approach provides new insight into phenomena and experiences. Therefore, the qualitative research method provides an in-depth understanding of nurses' experiences regarding the challenges of nurse prescription in Iran.

As Tehran University of Medical Science (TUMS) is the largest university of medical sciences in Iran and most changes in health policies are usually initiated at this university, the research team selected the hospitals affiliated with TUMS as the research environment. Because the purpose of this study was to explain the challenges of nurse prescription, the research population in this study consisted of all nurses working in hospital wards affiliated with TUMS. Nurses who met the inclusion criteria were invited to participate in this study. Inclusion criteria included having a bachelor's degree in nursing or higher, being employed in the medical ward, and being willing to participate in the study. After obtaining ethical licenses, the researcher selected the participants by purposeful sampling

method and continued sampling until the data were saturated. After identifying the participant, the researcher introduced himself to them and explained the objectives and method of the study. The interview date and time were agreed upon by those who agreed to participate in the study.

Data were collected and analyzed simultaneously between January and September 2021 for 9 months. Data were collected through semi-structured interviews. Due to the new coronavirus pandemic, participants were interviewed via telephone. Their voices were recorded during the interview with their consent. The interview began with questions about nurses' experience of nurse prescription, such as Have you ever had any experience of nurse prescription? Have you taken any action in this regard? If not, why not? If you took action, what challenges did you face? Afterward, to clarify the desired concepts, supplementary and follow-up questions, such as "What do you mean by that?", were asked of participants using the information provided. A total of 13 interviews were conducted with 13 participants, and each interview lasted between 30 and 60 minutes. After 13 interviews, the researcher achieved theoretical saturation about the concept under study.

Data analysis was performed simultaneously with the data collection based on the proposed model of Graneheim and Lundman. This model for qualitative data analysis consists of five steps: In the first step, the recorded interviews are transcribed immediately after each interview. In the second step, each interview text is read several times to determine the meaning units. In the third step, a code is designated for each dense and abstract meaning unit. The codes are then placed in their related subcategories. In the fourth step, the categories are derived from the subcategories based on conceptual and semantic similarities. In the last step, the content of the data is explained. Data analysis in this study was performed using MAXQDA10 software.

Four criteria of transferability, dependability, credibility, and conformability were used in this study to increase the data trustworthiness. These criteria have been proposed by Lincoln and Guba to increase the reliability of the qualitative data.^[17] The dependability of the data was achieved by the member check, peer check, and the researcher's long-term involvement with the study field and data. To perform the member check, a summary of the results was selected and provided to nurses to ensure that the researcher reflected the participants' experiences. For peer check, a qualitative researcher from TUMS reviewed and approved the coding process and extracted categories. Transferability was achieved by providing a complete and rich description of the data collection and analysis process. This process helps readers match the study results with their context and use them.

Ethical considerations

This study was approved by the Ethics Committee of TUMS with code: IR.TUMS.FNM.REC.1399.143. At

the beginning of each interview, the study objectives and method were explained to the participants, and their consent for participating in the study and recording their voices was obtained. They were also assured of the anonymity and confidentiality of their personal information and recorded audio, and the fact that participation in the study was voluntary, and they could leave the study at any time without any consequences.

Results

The results of this study have been obtained from 13 interviews with nurses working in the medical wards of hospitals affiliated with TUMS. The nurses were requested to talk about the challenges of nurse prescription. The mean age of participants was 38.4 years. Table 1 shows the participants' characteristics. Results of this study showed that the executive challenges of nurse prescription could be categorized into four main categories: structure challenges, barriers related to professional staff, interprofessional separation, and society's attitude [Table 2].

Theme: Practical challenges of nurse prescribing

Despite the advantages of nurse prescription for the healthcare system, the rights of nurses to prescribe drugs

Table 1: Characteristics of the participants

Demographic characteristics	Frequency (%)
Age range (mean)	26–51 years (38.4)
Gender	
Female	7 (54)
Man	6 (46)
Level of education	
BSc	8 (61)
MSc	4 (31)
PhD	1 (8)
Work experience	
1 to 5 years	1 (8)
6 to 10 years	3 (23)
11 to 15 years	5 (38)
16 years and over	4 (31)

in Iran are not well recognized. Based on the nurses' experiences, the factors preventing nurses from prescription drugs in practice included the structure challenges, barriers related to professional staff, interprofessional separation, and society's attitude.

Category 1: Structure challenges

Prescription drugs by nurses in Iran's healthcare system structure is highly challenging. The main factor that prevents nurses from prescription medication is legal issues. There is no clear law on nurse prescription in Iran. Other factors include the weakness of nurses' training programs, lack of support for nurse prescription, and the negative organizational culture and atmosphere.

1-1 legal issues

The nurses initially saw the legal issues as a barrier to nurse prescription. They repeatedly stated in their statements that under the Iranian health law, their rights to prescribe medication were not well-defined. Nurses stated that although they had the necessary knowledge and experience to prescribe medication in certain situations, they did not prescribe drugs due to legal restrictions.

Participant No. 4, a 34-year-old registered male nurse, stated, "If I have lots of knowledge, but I do not have legal permission to use it, what is the point? That is the case now for some nurses who are very knowledgeable but do not have legal permission to prescribe drugs."

Legal restrictions and lack of responsibility in prescription medication lead to the fear of consequences following nurse prescription, which prevents nurses from prescription medication in many situations. "I do not do what is not my responsibility because it has consequences, and the drugs I give may cause complications. For instance, if I prescribe a drug to a patient and he/she develops a complication, no one will support me. I will face a legal problem and be sued" (Participant No. 10, a 38-year-old male nurse with a master's degree in nursing).

Legal restrictions on nurse prescription are potentially dangerous for nurses and can have negative consequences for them. In this regard, participant No. 11, a 26-year-old

Table 2: Practical challenges associated with nurse prescription

Theme	Category	Subcategory
Practical challenges of nurse prescription	Structure challenges	Legal issues
		Weakness of nurses' training programs
		Lack of support for the nurse prescription
		Negative organizational culture and atmosphere
	Personnel-related barriers	Physician-related barriers
		Nurse-related barriers
		Poor nurse-physician communication
	Interprofessional separation	Nurse or physician distrust
	Society's attitude	Positive attitude toward the physician prescription
		Negative attitude toward the nurse prescription

female registered nurse, stated, “. *Our goal was to get the patient out of shock. The patient had been bleeding for several hours, and we did not have normal saline but had plenty of half saline. In fact, there was a national deficiency for it. Unfortunately, because of the order that the resident gave for saline, the patient’s nurse got involved in forensic medicine and was found guilty. No one noticed that saline is not very different from half saline in normal shock, but it happened, and legally, the nurse did not have the power to change the saline serum to half saline.*”

1-2 Weakness of nurses’ training programs

Based on nurses’ experiences, nurses’ training curriculum was not diagnosis and prescription oriented, and the educational content of the nursing curriculum was often very weak in this regard. There is a lack of training on nurse prescription in all nurses’ training courses, including bachelor’s, master’s, and doctoral degrees. Nurses’ weaknesses in diagnosis and drug prescription are among the consequences of excluding drug prescription from their educational structure, as one of the tasks nurses can perform for the patient. Regarding the weakness of nurses’ training programs, one of the nurses stated, “*I have never seen anyone teach us about prescribing medicine, neither in the bachelor’s nor master’s degree in nursing. These programs are all about nursing diagnosis and care, but they don’t cover drug prescription.*” (Participant No. 10, a 38-year-old male nurse with a master’s degree in nursing)

In this regard, another participant stated, “*In our country, the diagnosis and treatment is the physician’s responsibility, while in other countries, the nurse may also prescribe drugs. They are taught about drug prescription, but in our school, they do not teach anything about prescribing medication. In our country, nursing education focuses solely on nursing care.*” (Participant No. 5, a 38-year-old woman with Ph.D. in nursing)

1-3 Lack of support for nurse prescription

Despite legal restrictions and poor training programs, nurses can prescribe medication in some situations, especially emergencies. Nurses do not receive any support or encouragement from managers, including physicians and nurses, for prescription drugs. In some cases, it may even be troublesome for nurses. The consequence of such action is that the nurse will not prescribe drugs in similar situations in the future. “*I had an argument with the head nurse because I had requested a lab test without a physician’s order for a patient who had surgery the following day. She punished me for what I had done. Requesting a lab test without a physician’s order helped the patient and prevented the cancellation of her surgery. But I will not do it next time.*” (Participant No. 11, a 26-year-old female registered nurse).

According to nurses’ experiences, not only senior- and middle-level health managers do not support nurse prescription, but also basic-level managers, including

head nurses and supervisors, provide no support for nurse prescription due to legal issues. Participant No. 8, a 48-year-old male registered nurse, stated, “*When a head nurse or a nursing manager knows my competencies, they should support me in prescribing medication. For example, once I did something for a patient, and when the physician realized it, he complained to the head nurse and told her that her nurse had interfered in their work. The head nurse and supervisor also said that they would give notice. Well, they could have told the physician that the reason was that he came late to visit his patient.*”

1-4 Negative organizational culture and atmosphere

The Iranian healthcare structure is physician-dominated, which has affected hospitals’ organizational culture and atmosphere. Unfortunately, due to the organizational culture and atmosphere in Iranian hospitals, nurses’ abilities in prescription medicine are not taken into account. In general, in medical centers in Iran, attitudes and beliefs toward the nurse’s ability to prescribe medication are negative. In this field, participant No. 2, a 32-year-old female registered nurse, stated, “*I know that blood culture should be taken twice, and Apotel ampoule must be administered for a patient with a fever of 40 degrees. But I have to wait for the physician to come and tell me to do the same thing. If I do this without the physician’s order, I have to answer the head nurse and physician the following day because no one accepts my prescription.*”

Another participant said, “*I have often commented or consulted with the physician about prescribing medication for patients, but unfortunately, other colleagues and even other nurses look at it negatively and sometimes even make fun of me.*” (Participant No. 4, a 34-year-old male registered nurse)

Category 2: Personnel-related barriers

Personnel-related barriers refer to challenges related to healthcare providers, including physicians and nurses. In this category, many factors, such as physician-dominated culture, the conflict of interests between nurses and physicians and nursing staff, lack of knowledge and experience, and low self-esteem, prevent nurses from prescription drugs practically.

2-1 Physician-related barriers

After the legal issues in nurse prescription, physician-related barriers had the highest citation in the participants’ statements. Nurses referred to the physician-dominated culture, the conflict of interests between nurses and physicians, lack of support for the nurse’s prescription from physicians, and the physician’s inappropriate behavior toward nurses as factors preventing nurse prescription. Based on the nurses’ experiences, medicine prescription is exclusively performed by physicians, and there are conflicts of interest in this field. Moreover, it is impossible

for a nurse to prescribe medicine due to the medical system regulation. In this regard, a participant with a master's degree in nursing stated, *"Physicians do not allow us to prescribe medicine. They are more powerful. What difference do I have with a physician if I have a right to prescribe drugs?"* (Participant No. 3).

In this structure, sometimes sparks are created due to the nurse's prescription, especially in emergencies when the physician is absent. This often has negative consequences for the nurse and is associated with the physician's inappropriate behavior. These negative consequences are exerted by managers who are often physicians. *"It has happened many times that physicians have accused me of prescribing. In one case, the physician told me that nursing staff needed to know their scope and would not enter physicians' work field."* (Participant No. 8, a 48-year-old male registered nurse).

2-2 Nurse-related barriers

According to the results, there are weaknesses in nurses and the nursing community that prevent suitable and appropriate prescription by nurses. These barriers include the lack of knowledge, lack of experience, low self-esteem, and lack of motivation. Nurses referred to numerous situations where they lacked the necessary knowledge and experience to prescribe medication. The following is the experience of one of the nurses concerning nurses' poor knowledge of drug prescription. *"Sometimes the patient's condition is so complicated that I do not understand. I may prescribe medication for the patient, which may be wrong. I do not prescribe medicine wherever I feel wrong or have doubts."* (Participant No. 5, a 38-year-old woman with Ph.D. in nursing).

Moreover, in cases where the nurses had the necessary knowledge and experience to prescribe medication, a lack of self-confidence or motivation prevented them from prescription drugs. Lack of self-confidence results from inadequate drug prescription training in nursing education, and lack of motivation is due to a lack of benefits for nurses. Participant No. 9, a 51-year-old man, stated, *"Several times I could have properly prescribed a drug for the patient, but I did not do so due to reasons, such as lack of motivation. Why would I do that? It is the doctor's duty and has no benefits for me."*

Category 3: Interprofessional separation

Interprofessional separation refers to the gap between medical and nursing professions and the lack of collaboration between these professions to help nurse prescription. In this category, the poor communication between the nurse and physician and nurse-physician distrust was among the practical challenges for nurse prescription.

3-1 Poor nurse-physician communication

Poor communication between physicians and nurses is

one of the challenges of nurse prescription. Nurses considered the lack of interaction between physicians and nurses, one of the factors hindering nurse prescription. They also acknowledged that not only was there no cooperation between professionals to facilitate nurse prescription but also that the relationship between physicians and nurses was so weak that, in most cases, it was a basis for distrust between them and prevented nurse prescription. *"Most physicians do not understand the concept of inter-profession and Interprofessional collaboration. It is also true for some nurses, as they do not communicate well with the physician until the physician recognizes their ability. It prevents them from prescribing drugs."* (Participant No. 5, a 38-year-old woman with Ph.D. in nursing)

Another participant stated, *"In my professional relationship with the physician, I have to show my professional ability and gain the doctor's trust. On the other hand, the physician should have a good relationship with the nurses and at least trust the nurses who are good at their practice."* (Participant No. 3, a nurse with a master's degree in nursing)

3-2 Nurse-physician distrust

Fundamental mistrust between medical and nursing teams, rooted in a weak relationship between physicians and nurses, is another obstacle to nurse prescription. It is a two-way distrust. In other words, in some cases, it is the physician's distrust of the nurse, and in other cases, it is the nurse's distrust of the physician that prevents the nurse from prescription medication. The following is an excerpt from an interview with one of the participants, which indicates the nurse's distrust of the physician. *"I have witnessed that the physician does not even trust the nurse to follow his orders. It was an emergency, and I did not want to lose the golden time; I was trying to get a phone order from the physician, but he did not trust me and said he should see the patient."* (Participant No. 4, a registered nurse).

Category 4: Society's attitude

In this category, society's attitude toward physician prescription and nurse prescription is expressed. Unfortunately, Iranian society prefers physicians' prescription much more than nurse prescription. Iranians tend to consult physicians for medical treatment and advice more than nurses.

4-1 Positive attitude toward the physician prescription

Society's positive attitude toward the medical profession and physicians has not been created overnight. Based on the nurses' experiences, the client, in particular, and the community, in general, value physicians more than other healthcare professionals and listen to them better, especially in drug prescription. Participant No. 12, a 41-year-old man with a master's degree in nursing, admitted it: *"Patients*

trust physicians more because they believe whatever they say is correct. In many situations, especially at the time of discharge, I thought I would devalue myself if I said something to the patient about medication because patients always seek a physician for consultation."

Another participant stated, *"The truth is, if I tell a patient to take certain medication when you go home, he may not listen to me, but if a physician tells him the same sentence, he will listen."* (Participant No. 7, a 35-year-old female registered nurse)

4-2 Negative attitude toward the nurse prescription

According to the participants' experience, Iranian society lacks a good attitude toward nurse prescription. They prefer medical consultation with a physician. Moreover, society's attitude toward the nursing profession is so weak that in most situations, it not only prevents nurse prescription but also destroys nurses' confidence to experiment with it. *"The community does not trust nurse prescriptions. I provide home care. When I go to a patient's house, although I know a medicine suitable for their condition, I usually do not recommend it because the patient does not accept the nurse as a prescriber."* (Participant No. 10, a nurse with a master's degree in nursing).

Discussion

This study aimed to explain the executive challenges of nurse prescription based on the nurses' experiences in Iran. The four main categories of structure challenges, barriers related to professional staff, interprofessional separation, and society's attitude were identified as the executive challenges of nurse prescription from the data.

The main challenge for nurses in prescription medication is the structure challenges, particularly the lack of a clear law on nurse prescription, which has been identified and referred to in various studies.^[4,15,18] For instance, in Ireland, the fear of legal consequences is among the barriers to nurse prescription.^[19] However, due to the benefits of nurse prescription for the healthcare system, in many countries, the right to prescribe medication has been granted to nurses.^[6,13] Of course, the legal right for nurses to prescribe drugs has not been established overnight, and at first, its obstacles and challenges have been identified. For example, in Poland, a country where nurses have recently been given the legal right to prescribe medication, nurses' lack of awareness about the role and regulation associated with drug prescription and their poor readiness for taking on this role were among the factors and obstacles to the implementation of nurse prescription plan.^[20] In another study, in addition to the legal and ethical aspects of nurse prescription, training nurses on drug prescription and strengthening their clinical decision-making were other important issues that facilitated the implementation of nurse prescription.^[6,21] Therefore, the government's proper strategy and facilitating the new role of nurses in

prescription medication is essential for nurses.^[22] Lack of support and negative organizational atmosphere were other concepts of the challenge of nurse prescription in Iran. In their study, Naderi *et al.* pointed out that the lack of financial support from managers was the barrier to nursing prescription in Iran.^[23] Furthermore, in Nuttall's study, the lack of infrastructure to support prescription is one of the barriers to nurse prescription.^[24] Arian *et al.*, in their study, state that the critical view of healthcare providers, lack of support, bureaucratic structure, and strict control of physicians out of legal requirements are the challenges of nurse prescription.^[4]

In the present study, other obstacles to nurse prescription in Iran included the physician-dominated culture of the health system and the conflict of interests between physicians and nurses. Physicians' resistance has always been considered an important obstacle to nurse prescription. Physicians are usually at the top of the hierarchical health system and defend their credibility and power.^[25] Nuttall noted in his study that GP boundary challenges prevent nurse prescription.^[24] In the United Kingdom, before the implementation of the nurses' prescription plan, many physicians had a negative attitude toward the idea of nurse prescription, arguing that despite the prescription role of nurses, the principle of nursing would suffer.^[26] In Ireland and the Netherlands, there has also been resistance from physicians toward the implementation of nurse prescriptions.^[27,28] Although there was resistance from physicians when initiating the project, health policymakers in many countries overcame this resistance to improve the quality of health care and create health justice. In this study, in the subcategory of nurse-related barriers, nurses' lack of knowledge and experience and poor self-confidence in drug prescription were other challenges of nurse prescription. A study by Courtenay *et al.* in the United Kingdom showed that drug prescription was one of the most challenging topics in personal development and gaining the knowledge and skills needed in this area. Therefore, nurses must receive adequate and appropriate training to acquire the necessary knowledge and skills regarding safe drug prescriptions. In this study, it was found that almost one-third of nurses were not qualified to prescribe medication.^[13] Another study found that nurses were anxious about their prescription role, including that nurses were unsure about their competence and pharmacological knowledge, and they considered it a role that requires the necessary and in-depth pharmacological knowledge. There was also evidence of anxiety and feelings of insecurity in self-diagnosis and self-confidence among nurses in regard to drug prescription.^[29] Lack of pharmacological knowledge is one of the important obstacles to the implementation of the nurse prescription plan mentioned in studies.^[24,30]

Poor communication between professionals and nurse or physician distrust is a challenge in implementing nurse prescriptions. Evidence shows that the relationship and

mutual trust between physicians and nurses in the medical structure of Iran are weak.^[31,32] Poor communication and collaboration not only have adverse consequences for the community's health promotion and healthcare recipients^[33,34] but are also a major challenge for the implementation of prescription drugs by nurses.^[4,15] For instance, Naderi *et al.* consider physicians' objection to nurses' prescriptions due to their fear of nurses' involvement in patients' treatment protocols.^[35] Moreover, Nuttall, in his study, stated that nurse relationship with General Physicians (GP) was a need for nurse prescription, and weak communication between nurses and GPs is one of the challenges of prescription medication by nurses.^[24] Andrilla *et al.* state in their study that lack of physician support or collaboration is a barrier to drug prescription in urban and rural areas of Washington State in the United States.^[36] Karimi-Shahanjarini *et al.*, in their study, expressed that communication, trust, and mutual respect were important factors in doctor–nurse substitution that helped nurses expand and develop their roles. They stated that doctors' trust and acceptance of nurses were critical in developing nursing scope, including nurse prescriptions.^[37]

Other findings of this study regarding the factors affecting the implementation of the nurse prescription plan include society's attitudes and interprofessional separation, about which there is often little or contradictory evidence. For instance, Shoqirat and Cameron, in their study, referred to cultural and social factors, such as nurses' poor credibility in public opinion and poor public image of nurses as obstacles to nurse prescription.^[38] Evidence refers to the weak image of nursing in the social and cultural structure of Iran,^[39] which does not trust nurses as therapists as it trusts physicians. This issue has likewise been expressed in the study by Darvishpour *et al.*^[15] Additionally, society's lack of knowledge about the nurse's role in prescription and the client's preference to see a physician instead of a nurse is evident in the study by Arian *et al.* In their study, they suggest community awareness and promotion of holistic care to overcome this barrier.^[4] Therefore, to better implement the nurse prescription plan in Iran, the reasons for the poor image of nursing in society should be identified, and society's attitude toward nurse prescription should be altered.

The limitation of this study was collecting the data only from three hospitals, which could create a bias associated with the policies and practices specific to those hospitals. Therefore, it is suggested that the practical challenges of nurse prescription be investigated in different hospitals in Iran. Moreover, the interviews were conducted by phone due to the coronavirus disease 2019 (COVID-19) pandemic; therefore, we did not observe participants' faces and body language, which was another limitation of this study.

Conclusion

It is necessary for the policymakers of Iran's healthcare

system to clarify the legal aspect of nurse prescription. Also, the projects of APN and training nurses on drug prescription, training physicians and nurses on collaboration and teamwork, and changing society's attitude toward nurse prescription through mass media are among the factors that can help nurses perform better in their new role by removing the existing barriers. Moreover, in the Iranian healthcare system, the general physician does not have the experience of nurses in prescription and access to specialist physicians is cost-effective and time-consuming for the client. Identifying and eliminating the challenges of nurse prescription facilitate community access to health care, increase client satisfaction, and lead to the development and independence of the nursing profession.

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Conflicts of interest

Nothing to declare.

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Effect of Carob and Ginseng Supplements on Semen Analysis Parameters, Sexual Function, and Sex Hormones in Infertile Men: Double-Blind, Randomized Controlled Trial Study

Abstract

Background: Infertility is one of the most common problems in the world; there is a growing demand for herbal medicines to treat infertility-related problems. **Materials and Methods:** A randomized controlled trial with three groups was conducted, each with 30 participants. The first group was administered 1.5 grams of Carob daily, the second group was administered 1.5 grams of Ginseng daily, and the third group received a placebo. The treatment was administered for 12 weeks, and before and after the intervention, semen parameters, testosterone, prolactin, luteinizing hormone, follicle-stimulating hormone, thyroid hormones, and sexual function were evaluated. Sexual function was assessed using the International Index of Erectile Function Questionnaire. **Results:** The mean (SD) age of participants was 34.83 (6.22), 34.60 (5.78), and 33.67 (5.82) years in Carob, Ginseng, and Placebo groups, respectively. The results showed that in the Carob group, the normal volume of semen ($Z_{133} = 3.05, p = 0.02$) and the normal shape of sperm ($Z_{134} = 2.97, p = 0.01$) increased significantly compared to the control group. In the Ginseng group, the normal volume ($Z_{133} = 3.90, p = 0.001$) and the normal viscosity of semen ($Z_{133} = 2.36, p = 0.01$) increased significantly compared to the control group. The Carob group showed a significant increase in normal sperm counts and testosterone hormone levels ($Z_{131} = 2.81, p = 0.05$). The Ginseng group demonstrated a significant improvement in orgasm function ($H_2 = 6.14, p = 0.04$) and the total score of the International Index of Erectile Function (IIEF) ($H_2 = 5.8, p = 0.05$). **Conclusions:** Carob supplements are suggested to enhance some semen parameters and male sex hormones. For infertile men, Ginseng can be beneficial in improving sexual function.

Keywords: Herbal medicine, infertility, locust bean gum, Panax, sexual dysfunctions

Introduction

According to the World Health Organization (WHO) definition, infertility is the inability of a couple to conceive after one year of unprotected intercourse. It is one of the most common problems worldwide, affecting about 15% of couples. In 50% of infertility cases, there are male causes and sperm problems.^[1] The prevalence of male infertility in Iran, Hamadan, was 43.9%. The most common cause of male infertility was an abnormality in semen fluid. Infertility has both male and female causes. The male factor is involved in about half of all infertility cases.^[2] The most important causes of male infertility include congenital or acquired abnormalities of the genitourinary system.^[3] The presence of the malefactor is often based on abnormal sperm parameters.^[4] Impaired sperm

production and function and damage to the spermatogenesis process are among the most common causes of male infertility.^[5] Leukocytes overproducing reactive oxygen species (ROS) have emerged as a leading cause of male infertility in recent years. The resulting oxidative stress leads to abnormal semen parameters.^[6]

Studies have shown that infertile men have a lower antioxidant capacity than fertile men. The researchers claimed that they could reduce motility, increased mortality, and DNA damage by oxidative stress in infertile people by using antioxidants. Plants were considered the most important source of medicine for treating the disease about half a century ago.^[7,8] Ginseng is an aromatic and durable medicinal plant belonging to the genus

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Panax and Araliaceae family. The medicinal properties of Ginseng are related to its root. The root of this plant contains triterpene saponins, essential oils, polyacetylene, polysaccharides, peptidoglycans, nitrogen compounds, fatty acids, carbohydrates, and phenolic compounds. This plant's most crucial active ingredient is saponins with a triterpene structure; Ginseng's pharmacological activities are related to this compound.^[9] Carob is another plant antioxidant that is native to the Mediterranean region and is found in southern Syria.^[10] Studies on the chemicals of *Ceratonia siliqua* seeds show that it has high fiber, polyphenols, arachidonic acid, lignin, fats, proteins, carbohydrates, calcium, potassium, and phosphorus.^[11] They also contain aspartic acid, glutamic acid, linolenic acid, linoleic acid, vitamin E, beta-sitosterol, silica, iron, and magnesium. Carob antioxidant activity is associated with phenolic compounds and the presence of substances. In a small number of studies, the effects of Carob on improving semen quality parameters have been investigated.^[12] There are two hypotheses regarding the effects of antioxidants on fertility. The first one proposes that these compounds enhance sperm quality. The second hypothesis suggests that antioxidants boost testosterone levels by positively affecting spermatogenic and Sertoli cells, which are responsible for maintaining the reproductive system's health in men and promoting spermatogenesis.^[13]

Adaptogens, such as Ginseng and Carob, possess antioxidant properties that enhance the body's resistance to stressors, trauma, anxiety, weakness, and fatigue. These plants also act as a mental stimulant and tonic. Their extracts impact the central nervous system, leading to the dilation of blood vessels in the circulatory system and activation of the hypothalamic–pituitary–adrenal axis.^[14] Following infertility, sexual function is sometimes impaired. Antioxidants may affect improving sexual function. Sexuality has a profound effect on marital life and its cohesion and stability. The WHO recognizes sexual health as the integration and harmony between the mind, the senses, and the body.^[15] Various studies found that red Ginseng improves erection in males but does not improve the sexual experience in general.^[16] The effect of antioxidants on sexual function is not yet fully understood in studies.^[7,16] Infertility medications often result in complications such as dizziness, gastrointestinal disorders, bloating, hot flashes, nausea, and headache. However, side effects are significantly reduced with the use of herbal medicines. Traditional medicine has recently explored the use of Carob and Ginseng in treating male infertility. However, there is limited research on their effectiveness, which means that the findings of review studies and clinical trials may not accurately reflect the true impact of treatments for male infertility. As a result, this study was conducted to address the observed sexual dysfunction and adverse effects associated with the chemical drugs currently used in male infertility treatment. The present study aimed

to analyze the impact of Carob seed and Ginseng root intake on sperm parameters, sex hormone levels, and sexual function in men with infertility issues. The findings could potentially contribute to the treatment of male fertility.

Materials and Methods

This study was conducted in a randomized, three-group, double-blind, placebo-controlled clinical trial (IRCT20120215009014N284) in infertile men from June 2019 to September 2020. The sample size was determined using the Sampsi module in Stata 13 software. Using the data from Mahdiani *et al.*'s article^[7] and considering $M1 = 17$, $M2 = 21$, $Sd1 = 4$, $Sd2 = 1.5$, $\alpha = 0.05$, power = 0.90, and 25% attrition, the sample size was calculated for each group of 30 men. At the start of the study, an allocation sequence was generated by an individual not involved in the research team. The participants were then assigned to the Carob, Ginseng, or Placebo groups using balanced block randomization [Figure 1]. The study included men under 40 with primary infertility who did not have infertility caused by female factors or sexual dysfunction in women. Participants were required to have at least one abnormal parameter of semen (volume, concentration, number of sperm, motility, and morphology of sperm) according to the WHO definition; they could not have chronic diseases, a body mass index over 30, consume alcohol, psychiatric disorders, take drugs that interfere with spermatogenesis and pituitary suppressors or use medicines that cause ejaculation failure and erectile dysfunction. Participants also could not have a history of testicular and vasodilator surgery, contact with pesticides, heavy metals, and solvents, or use antioxidant supplements in the last 3 months.

Initially, male participants provided a semen sample while receiving 10 ml of blood to assess their sex hormones (luteinizing hormone, follicle-stimulating hormone, prolactin, and testosterone) and Thyroid-Stimulating Hormone (TSH) levels at the start of the research. The capsules were packaged and labeled as A, B, and C by an individual not affiliated with the researchers. The researcher and the patient were blind to the study groups in this study. The three drugs administered had a similar appearance, and the participants were not informed about the specific type of drug they were receiving. The first group was given 1.5 grams of Carob seed powder capsules, the second group received 1.5 grams of Ginseng, and the third group was given a Placebo daily. It is important to note that all three groups received the same routine infertility treatments during the 12-week study period. The levels of Luteinizing Hormone (LH), FSH, serum testosterone, prolactin, and TSH were measured using the enzyme-linked immunosorbent assay method.

The study examined the sexual function of men in three groups before and after the intervention, using the International Index of Erectile Function (IIEF) questionnaire.

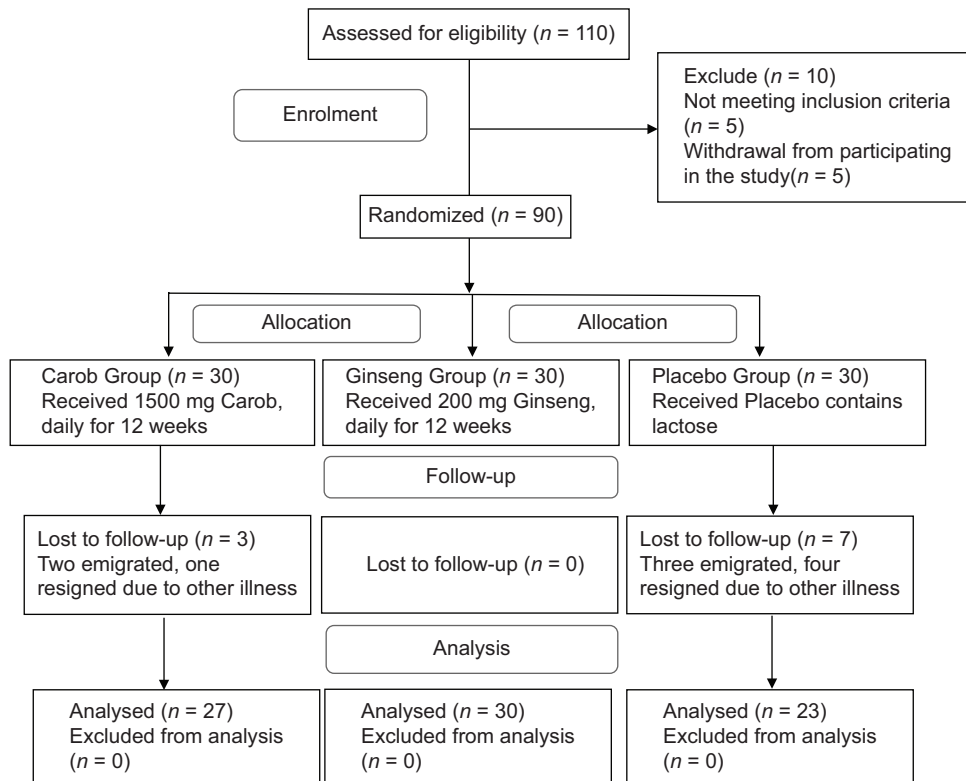


Figure 1: Flowchart of sampling

The questionnaire comprised 15 questions, divided into five categories: erectile and orgasm function, sexual desire, sexual satisfaction, overall satisfaction, and International Erection Performance Index. Previous studies have confirmed that the questionnaire's reliability, measured by Cronbach's alpha, was 0.85%. Furthermore, sexual function is classified as low for scores between 15 and 25, moderate for scores between 25 and 50, and high for scores above 50.^[17] Following the intervention, a second round of tests was conducted to measure semen analysis, hormones, and sexual function. The distribution of quantitative variables was assessed using the Kolmogorov-Smirnov test. Data analysis involved the use of one-way analysis of variance, Wilcoxon test, Kruskal-Wallis, Chi-square, Fisher's exact test, and multivariable regression. A p value less than 0.05 was deemed statistically significant. Stata-13 software was utilized for statistical analysis.

Ethical considerations

This research was approved by the Ethics Committee of Hamadan University of Medical Sciences under code (IR.UMSHA.REC.1398.155). Written informed consent was obtained from all the study participants. The objectives of the study and the procedure taken to conduct it were explained to the participants. Moreover, they were reassured about the anonymity and confidentiality of their information and the right to leave the study if they wished.

Results

The Placebo, Ginseng, and Carob groups had a mean (SD)

age of 34.83 (6.22), 34.60 (5.78), and 33.67 (5.82) years, respectively. There was no significant difference in demographic variables observed among the three groups. The multivariate analysis results indicated that before the intervention, the Carob group had a 9% lower normal semen volume than the placebo group ($Z_{133} = 3.05$, $p = 0.02$) when semen parameters were controlled. Similarly, the Ginseng group had a 30% lower normal semen volume than the placebo group ($Z_{133} = 3.90$, $p = 0.001$) and a 28% decrease in normal viscosity compared to the placebo group ($Z_{133} = 2.36$, $p = 0.01$). Conversely, in the Carob group, the normal volume of semen ($Z_{133} = 3.05$, $p = 0.02$) and the normal shape of sperm ($Z_{134} = 2.97$, $p = 0.01$) increased significantly compared to the placebo group [Table 1].

There were no significant differences ($p > 0.05$) in the mean scores of all areas of the IIEF questionnaire among the three groups in the pre-intervention stage, except for sexual satisfaction ($H_2 = 9.13$, $p = 0.01$). Similarly, in the after-intervention stage, there were no significant differences ($p > 0.05$) in the mean scores of all areas of the IIEF questionnaire among the three groups, except for orgasm function ($H_2 = 6.14$, $p = 0.04$) and the total score of IIEF ($H_2 = 5.8$, $p = 0.05$). The orgasm function was compared pairwise, revealing statistically significant differences between placebo and Ginseng ($W_2 = -2.16$, p -value = 0.03) and Carob and Ginseng ($W_2 = -2.18$, p -value = 0.03). Similarly, a pairwise comparison of the IIEF scores demonstrated a statistically significant difference between placebo and Ginseng ($W_2 = -2.22$, p -value = 0.02) [Table 2].

Table 1: Comparison of semen analysis results after intervention between groups*

Variables	Placebo group ^a n (%)	Ginseng group ^b n (%)	Carob group ^c n (%)	Statistical result of a/b ^{**}		Statistical result of a/c ^{**}	
				RR ^{***} (95% CI ^{****})	p	RR ^{***} (95% CI ^{****})	p
				Volume			
≤1.5	21 (91.30)	19 (63.33)	25 (92.59)	0.70 (0.59, 0.84)	0.001	0.91 (0.86, 0.96)	0.02
>1.5	2 (8.70)	11 (36.67)	2 (7.41)				
Viscosity							
Normal	19 (82.61)	16 (53.33)	25 (92.59)	0.72 (0.55, 0.94)	0.01	1.15 (0.99, 1.33)	0.29
Abnormal	4 (17.39)	14 (46.17)	2 (7.41)				
Sperm count per ml (million)							
≤15	18 (78.26)	23 (76.67)	23 (85.19)	0.97 (0.81, 1.16)	0.59	0.99 (0.85, 1.17)	0.88
>15	5 (21.74)	7 (23.33)	4 (14.81)				
Fast or slow progressive movement							
≤32%	14 (60.87)	20 (66.67)	20 (74.07)	0.96 (0.73, 1.25)	0.77	1.07 (0.84, 1.37)	0.48
>32%	9 (39.13)	10 (33.33)	7 (25.93)				
Normal shape							
≤4%	19 (82.61)	23 (76.67)	27 (100.00)	0.95 (0.81, 1.12)	0.51	1.17 (1.05, 1.30)	0.01
>4%	4 (17.39)	7 (23.33)	0				
WBC number							
Normal	23 (100.00)	30 (100.00)	27 (100.00)	-	-	-	-
Abnormal	0	0	0				

*In each item of hormones, the reference group was an abnormal outcome. **Binomial regression (by controlling before intervention values), reference: control group (a). ***RR: Risk ratio, ****CI: confidence interval

Table 2: Comparison within and between groups of the total score of sexual function domains before and after the intervention

Domains	Placebo ^a Mean (SD)		Ginseng ^b Mean (SD)		Carob ^c Mean (SD)		Analysis results of a, b, and c Before intervention		Analysis results of a, b, and c After intervention	
	Before	After	Before	After	Before	After	Statistic test* (H)	p	Statistic test* (H)	p*
	Erectile function	22.96 (4.31)	23.80 (3.78)	24.34 (4.53)	24.94 (4.92)	22.81 (6.63)	22.72 (7.89)	2.06	0.35	2.66
Statistic test ^{**} (W)		-1.25		-0.28		-0.74				
p		0.21		0.77		0.45				
Orgasm function	7.85 (1.53)	8.20 (1.29)	8.70 (0.95)	9.00 (1.00)	7.73 (2.11)	7.84 (2.24)	4.58	0.10	6.14	0.04
Statistic test ^{**} (W)		-0.87		-0.36		-0.44				
p		0.38		0.71		0.65				
Sexual desire	7.50 (1.47)	7.76 (1.30)	7.51 (1.45)	7.84 (1.34)	7.34 (1.43)	7.61 (1.09)	0.24	0.88	0.44	0.80
Statistic test ^{**} (W)		-1.09		-0.86		-0.68				
p		0.27		0.38		0.49				
Sexual satisfaction	10.03 (2.06)	10.12 (1.89)	11.56 (2.47)	11.52 (2.01)	9.45 (3.52)	9.73 (3.84)	9.13	0.01	4.94	0.08
Statistic test ^{**} (W)		-0.09		-1.34		-0.28				
p		0.92		0.17		0.77				
Overall satisfaction	9.00 (1.26)	8.32 (1.97)	8.89 (1.89)	9.26 (1.09)	8.04 (1.98)	8.57 (1.53)	4.10	0.12	2.64	0.26
Statistic test ^{**} (W)		1.58		-0.06		-0.98				
p		0.11		0.95		0.32				
International Erection Performance Index	56.51 (9.56)	58.12 (7.54)	60.33 (8.78)	62.57 (8.55)	54.95 (13.09)	56.52 (14.65)	4.28	0.11	5.80	0.05
Statistic test ^{**} (W)		-1.27		-0.31		-0.45				
p		0.20		0.75		0.64				

*Kruskal–Wallis, **Wilcoxon

The results of multivariate analysis compared to the placebo group showed that by controlling the levels of hormones in the pre-intervention stage, in Carob users, the probability of normal levels of LH, prolactin, and testosterone were, respectively, 18%, 37%, and 40% higher than that of abnormal levels. However, this difference was only statistically significant for testosterone ($p = 0.05$) [Table 3].

Discussion

A comparison between the Carob, Ginseng, and Placebo groups in the current study showed that the number of normal sperm increased in the Carob group. Protecting cells, particularly in sperms, against free radicals is a crucial function of antioxidants. A decrease in the activity of antioxidants within the body’s physiological system may lead to a decline in the quality of sperm cells. Studies indicate that ROS can significantly impact sperm parameters, such as morphology and motility. Sperm’s plasma membrane’s high content of unsaturated fatty acids is believed to cause its high sensitivity to ROS.^[8] Carob is an herb known for its antioxidant properties. Carob extract in animal studies has been effective in cAMP production and enzyme activity involved in the steroidogenesis of rat testis. Studies by Alsalman *et al.* in 2014^[8] and Elsheikh MG *et al.* in 2015^[18] showed that the consumption of antioxidants improves sperm quality. In the study of Mahdiani *et al.*,^[7] in 2018, in the group receiving Carob, the mean total antioxidant capacity and plasma malondialdehyde concentration changes were significant. As the results of our study, Faramarzi *et al.*,^[19] in 2020, showed an increase in the progressive motility of sperm after administration of Carob.

Our study revealed that the Carob group had a higher level of normal testosterone following the intervention compared

to the other groups. Carob is a nutrient-dense food that contains essential minerals such as iron, calcium, sodium, potassium, phosphorus, and vitamins E, C, D, niacin, folic acid, and pyridoxine. Additionally, Carob powder is rich in 11 phenolic compounds, including pyrogallol, catechol, and chlorogenic acid, with smaller amounts of other phenolic compounds, such as coumarin, cinnamic, ferulic, and gallic acid. The substance comprises 17 fatty acids, with oleic, linoleic, palmitic, and stearic acids being the most prominent. These components, along with vitamins and minerals, influence the body’s natural production of sex hormones and, consequently, male fertility.^[20] However, these studies have not explored the impact of antioxidant supplements on adrenal androgens. In 2020, Sadeghzadeh *et al.*^[21] examined the potential effects of Carob seeds on FSH, LH, testosterone and dihydrotestosterone levels, testicular tissue, and improved fertility in male rats. The results showed that consumption of Carob seed extract caused a significant increase in the concentration of testosterone and dihydrotestosterone and decreased LH levels in the experimental groups, which was similar to the results of our study. Aghajani’s research and our own both revealed an increase in testosterone levels following Carob consumption. However, unlike our study, Aghajani’s findings showed a reduction in normal LH levels, which may be attributed to the difference in Carob dosage.^[22] The increase in testosterone by Carob is due to its direct effect on Leydig cells and in testosterone biosynthesis.^[20]

These effects are implemented by stimulating PGE2 synthesis. In addition, Carob seeds contain gamma-linolenic acid and alpha-linolenic acid, which can be converted to dihomo-gamma-linolenic acid and PGE2, ultimately increasing the production of cyclic adenosine monophosphate and stimulating testosterone production.^[23]

Table 3: Comparison of hormones levels after intervention between groups*

Variables	Placebo group ^a n (%)	Ginseng group ^b n (%)	Carob group ^c n (%)	Statistical result of a/b		Statistical result of a/c	
				RR*** (95% CI****)	p**	RR*** (95% CI****)	p**
LH							
Normal	12 (52.20)	19 (63.30)	25 (92.60)	1.00 (0.76, 1.30)	0.80	1.18 (0.94, 1.47)	0.11
Abnormal	11 (47.80)	11 (36.70)	2 (7.40)				
FSH							
Normal	18 (78.30)	18 (60.0)	21 (77.80)	0.88 (0.73, 1.07)	0.11	1.04 (0.91, 1.20)	0.86
Abnormal	5 (21.70)	12 (40.0)	6 (22.20)				
Prolactin							
Normal	10 (43.50)	11 (36.70)	18 (66.70)	0.87 (0.55, 1.37)	0.49	1.37 (0.95, 1.99)	0.20
Abnormal	13 (56.50)	19 (63.30)	9 (33.30)				
Testosterone							
Normal	14 (60.90)	19 (63.30)	21 (77.80)	1.27 (0.97, 1.65)	0.40	1.40 (1.10, 1.78)	0.05
Abnormal	9 (39.10)	11 (36.70)	6 (22.20)				
TSH							
Normal	21 (91.30)	22 (73.30)	23 (85.20)	0.86 (0.73, 1.00)	0.11	0.97 (0.86, 1.08)	0.89
Abnormal	2 (8.70)	8 (26.70)	4 (14.80)				

*In each item of hormones, the reference group was an abnormal outcome. **Binomial regression (by controlling before intervention values), reference: control group (a). ***RR: Risk ratio, ****CI: confidence interval

Our study revealed a significant increase in both the mean score of orgasm and the overall score of IIEF in the Ginseng group following the intervention. This improvement can be attributed to the antioxidant properties of Ginseng herbal medicine and the active compounds called Ginsenosides. These compounds have the ability to synthesize nitric oxide in endothelial cells and nerves around the arteries, thereby increasing the sensitivity of vascular smooth muscle cells to nitric oxide.^[24] Choi *et al.*^[25] (2013) showed that Ginseng effectively improves sexual dysfunction in men. Dordin *et al.*^[26] (2015) showed that the root of a species of Ginseng reduces the sexual side effects of specific serotonin reuptake inhibitors. Our study's results were consistent with the results of these studies. Lee *et al.*^[27] conducted a systematic review study in 2021, which found that Ginseng has a noteworthy impact on enhancing male sexual function, specifically in orgasm and sexual satisfaction. In our study on the comparison of other areas of IIEF between the three groups, such as sexual satisfaction, erectile function, and overall satisfaction, no statistically significant difference was observed. These herbal supplements may not have a clinically statistically significant effect on erectile function and sexual satisfaction, but their effects have been without increasing side effects. Infertile men with erectile dysfunction have expressed in self-reports that they have an improved ability to have intercourse compared to placebo.

There were limitations to this study. The use of a nonparametric test meant that the effect on sexual satisfaction could not be controlled before the intervention, despite being significant. Additionally, the limited number of participants due to time constraints during sampling restricts the generalizability of the results to the broader population. These limitations should be taken into consideration. Future studies should compare the effects of Carob with other antioxidants, such as vitamin E, and explore different dosages.

Conclusion

According to the results of this study, Carob supplements can enhance some semen parameters, including the normal shape of sperm and testosterone levels. Additionally, Ginseng supplements have been shown to improve sexual function in infertile men. As a result, it is recommended that Carob supplements be used to enhance semen parameters and Ginseng supplements be used to improve sexual function in infertile men.

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Conflicts of interest

Nothing to declare.

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Assessment of Cognitive Impairment and Related Factors Among Elderly People in Jordan

Abstract

Background: With an increase in elderly people, it is essential to address the issue of cognitive impairment and support healthy aging. This study aimed to assess cognitive impairment and factors associated with it among older adults. **Materials and Methods:** A cross-sectional study was carried out in different catchment areas within the Jerash governorate in the north of Jordan. The Elderly Cognitive Assessment Questionnaire (ECAQ) and a household face-to-face interview were used to collect data from 220 older adult participants aged 60 years and more. Descriptive statistics were conducted to describe the study variables. Correlation tests were applied to find associations between them. Logistic regression analysis was applied, with a minimum significance level ($p < 0.05$). **Results:** About 9.10% of the older adults had cognitive impairment. Cognitive impairment was correlated with age, self-perceived health, hypertension, stroke, and mental illness. The primary predictors of cognitive impairment were age [odds ratio (OR) = 1.07 (1.01–1.14), $p = 0.001$] and stroke [OR = 10.92 (1.44–82.85), $p = 0.001$]. **Conclusions:** While many factors were correlated with cognitive impairment, the strongest predictors of cognitive impairment were age and stroke.

Keywords: Aged, cognition disorders, cross-sectional studies

Introduction

In 2019, about 703 million older adults aged 65 and older worldwide.^[1] And, by 2050, the number of older adults will exceed 1.5 billion.^[1] This increase in the number of older adults will be associated with more age-related health problems.^[2,3] Cognitive impairments are one example.^[4] Cognitive impairment is a chronic condition preceding dementia.^[5] In mental impairment, the cognitive deficit is less severe than dementia because independence and regular daily activities are maintained.^[6] Cognitive impairments have negative economic and psychosocial consequences. It increases the use of health care services,^[7,8] costs of health care,^[9] disabilities, and decreases the quality of life.^[10]

The prevalence of cognitive impairment in studies conducted across several countries varies.^[10-15] In Egypt, a cross-sectional study was carried out on a sample of 122 older adults aged 50 years or older. Using the Montreal Cognitive Assessment Test (MoCA), the study found that 73.7% of the participants had mild cognitive

impairment, 9.3% had moderate, and 0.8% had severe.^[10] In India, a recent cross-sectional study used the Minimum Mean Square Error (MMSE) to assess the prevalence of cognitive impairment among 100 randomly selected urban older adults aged 60 years or more. The study reported that most cognitive impairments were 26% among older adults.^[11] Another recent Indian study screened for cognitive impairment among 260 Noncommunicable Disease (NCD) patients attending a rural Primary Health Center (PHC). Using the MMSE, the study found that 10.8% of the elderly with chronic conditions.^[12] In China, in a study including 2626 older adults aged 55 and over with diabetes, they used the MMSE to assess cognitive impairment. The prevalence of cognitive impairment was 9.9%.^[13] Similarly, in Malaysia, a study used the MoCA to assess the prevalence of cognitive impairment among 113 older adults aged 55 years and

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more. The study found that the prevalence of cognitive impairments was 49.90%.^[14] In the United States, data from the National Health Interview Survey (NHIS) regarding 155,682 older adults aged 60 or more showed that the prevalence of cognitive impairment had increased from 5.7% in 1997 to 6.7% in 2015.^[15] Cognitive impairment among older adults is associated with various factors. Age,^[12,16,17] gender,^[16,17] marital status,^[13,16] education level,^[10,12,16,17] living arrangement,^[14] and self-perceived health are examples of these factors.^[16] Many recent studies have found a correlation between chronic illnesses and cognitive impairment among older adults. Hypertension,^[10,13] stroke,^[13] and mental illness are examples of chronic illnesses associated with cognitive impairment.^[11,13,16,17] However, all the previous studies were conducted in developed countries, and none were conducted in Jordan. A middle-income nation like Jordan may not have the same risk factors and chronic illness associations as other parts of the world.

In low- and middle-income nations, the population over 60 is increasing. In 2050, the number of Jordanian older adults is expected to reach 13.8% of the population.^[18] With this anticipated increase in older people, the prevalence of cognitive impairment is expected to grow and will have significant financial, personal, and social influences. So, it is essential to address the issue of cognitive impairment and support healthy aging. However, there is a dearth of studies describing the prevalence of cognitive impairment and associated risk factors in Jordan. For the purpose of creating management strategies, it is essential to understand the prevalence of cognitive impairment and associated factors in Jordan.

This study aimed to assess cognitive impairment and factors associated with cognitive impairment among older adults living in the Jerash governorate region of north Jordan.

Materials and Methods

A cross-sectional design was used to identify factors associated with and predictive cognitive impairment among the older adult^[19]; and was carried out between September and November 2021.

The study was carried out in different catchment areas within the Jerash governorate north of Jordan. Jerash is located 40 km north of Amman (the capital city).^[20] According to the population estimates, the Jerash governorate has approximately 1,088,100 people, constituting 17.8%.^[20]

A catchment area is a geographical area served by a government institute or particular health facility.^[21] The present study was done in the catchment areas linked to three PHCs. These areas are rural and situated in different locations of the Jerash governorate. They were chosen randomly to ensure that the study sample was representative of the Jerash governorate.

The sample size was calculated using the RaoSoft sample size calculator. Based on a margin of error of 5%, a confidence level of 95%, a population size of 500, a response distribution of 50%, the estimated measurement, the appropriate sample size was 218. A sample of 220 older adults, participated in the present study. The inclusion criteria are: (a) agreeing to take a 15-min interview and (b) being aged 60 years and over. The exclusion criterion is incapable of responding to questions because of diseases. The target population comprised all older adults whom the PHCs served in the Jerash governorate in the current study. The accessible population comprised all older adults who lived within the catchment areas of three PHCs in the Jerash governorate.

It is hard to offer recommendations in binary logistic regression to have sufficient statistical power.^[22] A minimum N has been recommended to be no less than ten times K , where K is the predictors' number in the model.^[23] Still, a larger N may be required to obtain sufficient statistical power.^[22] A sample size of less than 100 must be avoided, and 500 observations must be suitable for nearly all situations.^[24] In the current study, the number of predictors was 15. Subsequently, with the criteria recognized by Peduzzi *et al.*,^[23] the minimum sample size required in the present study was 150 participants.

A multi-stage sampling design was done: (1) choosing three PHCs within the Jerash governorate. These centers were chosen randomly, (2) selecting the households from the areas within the range of the three PHC's services. They were nominated using a convenience sampling technique, and (3) in the chosen spots, the investigator presented himself to the home and asked if all members of the family, 50 years of age or more, would agree to participate in the study and be interviewed.

Cognitive impairment was assessed using the Elderly Cognitive Assessment Questionnaire (ECAQ).^[25] The ECAQ is an applied instrument to determine the cognitive impairment of older individuals living in developing countries.^[25] It is a 10-item cognitive test, which is categorized into three categories: memory (three items), orientation (six items), and memory recall (one item). Every item has a value of 1 for every correct response, and the highest score is 10 points. Participants who had total scores of 5 or less were recognized as having a cognitive impairment.^[25] This 10-item questionnaire demonstrates a sensitivity of 85.30%, a specificity of 91.50%, and a positive predictive value of 82.80%.^[25]

Demographic variables were identified by using the questionnaire/self-report from respondents. They were age (years), gender (male or female), marital status (married, unmarried), education level (no education, primary education, and secondary and higher education), employment status (unemployed, employed), smoking status (smoker or nonsmoker), monthly income, self-perceived health (poor health, good health), chronic illness (yes or no), type of

chronic illness (heart diseases (yes, no)), hypertension (yes, no), diabetes mellitus (yes, no), stroke (yes, no), mental illness (yes, no), and bronchial asthma (yes, no).

Descriptive statistics were conducted to describe the study variables. Correlation tests were applied according to the level of measurement of variables to find associations between them. Logistic regression analysis was applied using SPSS software version 17, with a minimum significance level ($p < 0.05$).

Ethical considerations

Permission to carry out the study was obtained from the university's Ethical Committee (NO. 5/2/7/48). An agreement to use the ECQA was obtained. Informed verbal consent was obtained from the participants. In addition, the anonymity and confidentiality of the participant's data were protected.

Results

The participants' mean age was 64.70(9.96). About 57.30% were males, the remaining 42.70% were female, and the majority of participants were married (88.60%). More than one-third of participants (36.80%) had no education, 42.70% had a primary school education, and 20.50% had a secondary or higher level of education. The majority were unemployed and nonsmokers, with the mean income for each participant equaling 232.36 Jordanian Dinars monthly. Most of the participants perceived their health as good. About 71.40% of participants had a chronic illness. The most commonly cited chronic conditions were heart diseases, hypertension, diabetes mellitus, stroke, mental illness, and bronchial asthma [Table 1].

Based on the ECAQ, 9.10% of the participants showed cognitive impairment. Increasing age, self-rated perceived health, and having hypertension, stroke, or mental illness were significantly associated with cognitive impairment ($r = 0.25$, $p = 0.01$). These factors, especially cognitive impairment, were entered into the logistic regression analyses. However, gender, marital status, education level, employment status, smoking, family monthly income, and having heart disease, diabetes, or bronchial asthma were not significantly associated with cognitive impairment ($p > 0.05$) and consequently were excluded from the logistic regression analyses. On the other hand, the average income of the participants suggests that they are in a low-income group. This may show that they might be a socially deprived group with limited access to resources.

The factors significantly associated with cognitive impairment among the older adults in the logistic regression analysis were age (OR 1.07, 95% CI 1.01–1.14) and stroke (OR 10.92, 95% CI 1.44 – 82.85) [Table 2].

Discussion

The current study indicated that the prevalence of cognitive

Table 1: Descriptive statistics (n=220)

Variables	n (%)	Mean (SD)
Age (years)		64.77 (10.02)
Gender:		
Male	126 (57.30)	
Female	94 (42.70)	
Marital status:		
Married	195 (88.60)	
Unmarried	25 (11.40)	
Education level:		
No education	81 (36.80)	
Primary education	94 (42.70)	
Secondary and higher education	45 (20.50)	
Employment status:		
Employed	52 (23.60)	
Unemployed	168 (76.40)	
Smoking status:		
Smoker	68 (30.90)	
Nonsmoker	152 (69.10)	
Monthly income (in JD)*		232.36 (102.47)
Self-perceived health:		
Poor health	58 (26.40)	
Good health	162 (73.60)	
Chronic illnesses:		
Yes	157 (71.40)	
No	63 (28.60)	
Heart diseases		
Yes	39 (17.70)	
No	181 (82.30)	
Hypertension		
Yes	98 (44.50)	
No	122 (55.50)	
Diabetes mellitus		
Yes	83 (37.70)	
No	137 (62.30)	
Stroke		
Yes	5 (2.30)	
No	215 (97.70)	
Mental illness		
Yes	5 (2.30)	
No	215 (97.70)	
Bronchial asthma		
Yes	10 (4.50)	
No	210 (95.50)	
Cognitive impairment		
Yes	20 (9.10)	
No	200 (90.90)	

*JD: Jordanian Dinar

impairment is 9.1% among the elderly Jordanian population. A recent survey conducted among the Chinese elderly with diabetes found a similar majority^[13] and less than 6.70% among Americans aged 60 years and older.^[15] At the same time, a study conducted among the elderly in South India found a higher prevalence (26.06%).^[11] Also, a survey conducted

Table 2: Logistic regression analysis of predictors of cognitive impairment among old adult

Predictors	B	S.E.**	Wald	p	Exp (B)	95% CI*	
						Lower	Upper
Age	0.076	0.031	6.171	0.013	1.079	1.016	1.145
Self-perceived health	-0.857	0.553	2.407	0.121	0.424	0.144	1.253
Hypertension	0.545	0.562	0.942	0.332	1.725	0.574	5.187
Stroke	2.391	1.034	5.348	0.021	10.92	1.440	82.858
Mental illness	0.823	1.135	525	0.469	2.277	0.246	21.060

*Confidence interval (CI)=95%. **S.E.=Standard error

in Egypt found a much higher prevalence of cognitive impairment among older adults (32%).^[10] This dissimilarity among studies could be a function of the self-reported nature of some studies, the differences in study populations, the setting where studies were conducted, and the differences in tools used to assess cognitive impairment. Therefore, there is a need for a national and international effort to design a multi-center study considering all the factors.

In the present study, the results indicated that the prevalence of cognitive impairment increased with aging. Correspondingly, studies have shown that increasing age is associated with cognitive impairment.^[12,16,17]

The present study found a relationship between self-perceived health and cognitive impairment among older adults regarding the self-perceived health variable. This result was consistent with Indian studies.^[16] However, it was inconsistent with a Brazilian study, which found no association between cognitive impairment and self-perceived health.^[26] In previous studies, self-perceived health was examined as a significant predictor of cognitive impairment.^[27]

The present study indicated that hypertension was associated with cognitive impairment among older adults, similar to other study findings.^[13] On the other hand, the association between hypertension and cognitive impairment is still unproven.^[28] Future studies may advance our understanding of the direction and amount of the interaction between hypertension and cognitive impairment and the impact of hypertension treatment on the decline of cognitive impairment.

The current study found that stroke was significantly associated with cognitive impairment among older adults. This is comparable to findings from a survey of 2626 aging in China.^[13] Whereas, in India, a cross-sectional study found that stroke was not associated with cognitive impairment among 100 older adults.^[16] On the other hand, the wide confidence interval around our finding that there was an association between stroke and cognitive impairment pointed to the fact that we are less assured. Therefore, data needs to be gathered in future studies to increase our confidence and have more data about the influence.

Regarding mental illness, this study reported a significant association between cognitive impairment among older adults and mental illness. Similar findings were found in a recent survey conducted in China^[13] and India.^[11,16] Across

the globe, studies have shown that risk factors for cognitive impairment include anxiety and depression.^[29] Therefore, to improve the detection of cognitive impairment, it is essential to evaluate cognitive status among older adults once a new mental illness is diagnosed.^[30]

Age and stroke were the strongest predictors of cognitive impairment among older adults in the present study. The current study found that cognitive impairment increased with age. Similar to a cross-sectional study conducted in Malaysia^[14] and India,^[16] in this study, logistic regression showed that an old adult with a stroke was 10 times more likely to have cognitive impairment than those who did not have a stroke. The current study results were consistent with a Chinese study.^[28]

The current study has some limitations. A cross-sectional study limits our ability to examine detailed causal inferences; further longitudinal studies are needed. The results cannot be generalized to all Jordanian old age as the participants were selected from the north of Jordan only. The ECAQ is a screening instrument only. Also, the cognitive impairment was measured with a single tool. In addition, participants of this study were community-dwelling older adults (50–92 years) with a pretty low frequency of cognitive impairment (about 9.10%) who had evidence of cognitive impairment based on ECAQ.^[25] The strengths of the present study were that all significant risk factors were addressed in this study, the cognitive impairment was assessed among different chronic illnesses, and the use of a valid instrument.

Conclusion

Compared with some other countries, the percentage of older adults who had cognitive impairment in this study was lower. The current study identified several factors that were associated with cognitive impairment. However, the predictors of cognitive impairment were age and stroke. Therefore, it is essential to encourage older adult patients with chronic illnesses about the importance of lifestyle modifications (such as engaging in physical activity, avoiding smoking, and use of alcohol), which may help to improve their illness condition and cognitive functions. The study findings add to the senior nursing body of knowledge regarding the health status of older adults, which will help develop an effective nursing program that promotes the health of older adults. Moreover,

such findings will help create a comprehensive healthcare program in PHCs that allows care providers to screen and refer to cognitive impairment cases.

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Conflict of interest

Nothing to declare.

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Breakfast Skipping and Associated Factors Among Jordanian University Students

Abstract

Background: Although breakfast skipping among university students is a significant concern, its prevalence and the contributing factors among university students have received little attention in the literature. This study aims to determine the prevalence of skipping breakfast among Jordanian university students and examine the associated factors and variations in rates of skipping breakfast by day of the week. **Materials and Methods:** A cross-sectional study was conducted among undergraduate students between March and May 2022 through a self-questionnaire. A convenience sample of 891 students was chosen at four Jordanian public universities. The data were analyzed using descriptive and inferential statistics. **Results:** The prevalence of skipping breakfast among university students was 66%. The reasons for skipping breakfast were having no time due to oversleeping and having no feeling of hunger (59% for both), followed by having no energy to prepare the breakfast and making no difference (49% and 48%), and not being able to afford to eat or buy breakfast (19%). There is a strong correlation between eating fast food and skipping breakfast. With whom the student eats breakfast is significantly associated with breakfast skipping, revealing that the highest percentages of skipping occur with friends. About 63% of students skipped breakfast through university days compared with 37% on the weekend, while 37% of them had breakfast through university days compared with 67% on the weekend. **Conclusions:** A high percentage of university students in Jordan skip breakfast. More attention should be paid to correlating factors and developing interventions to help students adhere to the breakfast.

Keywords: Breakfast, cross-sectional studies, prevalence, students

Introduction

Breakfast is the most significant meal of the day and is defined as any meal between 6 and 9 in the morning.^[1] Eating between the beginning of the day and 2 hours after waking up helps meet the body's daily nutritional demands, maintain a healthy weight, enhance academic performance, activate the metabolism, boost mood, and protect against malnutrition problems.^[2] In addition, regular breakfast consumption lowers the risk of chronic illness, insulin resistance, and metabolic syndrome and plays a significant role in dietary regulation and maintaining energy balance.^[3,4]

Previous studies showed an elevated prevalence of breakfast skipping across age groups.^[1,5] In the transition stage from school life, behavioral and psychological changes occur, including breakfast consumption, which can be translated into unhealthy behaviors such as skipping

breakfast.^[6] Research findings indicate that breakfast skipping is associated with diabetes mellitus, insulin insensitivity, elevated body mass index, body storage fat, cardiometabolic disease, hypertension, high systolic blood pressure, and mortality.^[7,8] Also, it is correlated with poor mental health, including depressive mood, stress, being mentally distressed, poor sleep, nocturnal sleeping problems, and developing suicidal behavior and substance use such as smoking and alcohol.^[3,9] Evidence regarding the prevalence of breakfast skipping among university students varies. For example, breakfast skipping in Bahrain was 50%, whereas in Turkey, it was 47.7%.^[6] More than 50% of adults in the United States have

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inadequate breakfast patterns, including 33% of females and 24% of males.^[10] In Saudi Arabia, the prevalence of breakfast skipping is comparatively high among Saudi young males.^[11] Among children and adolescents from 33 countries, a recent comprehensive study found that on average, between 10% and 30% of young people skipped breakfast.^[8] Young people between 18 and 25 years of age are often neglected. Thus, their dietary habits tend to decline when they leave home and go to college, where they have to be independent. Also, they have the habit of breakfast skipping and consuming fast foods.^[12] There are different reasons for students' breakfast skipping. For example, the students lacked time to eat, had no interest in eating early, experienced a lack of appetite and did not feel hungry, desired to lose weight, lacked something to eat, and were no longer living with their parents, who used to prepare them breakfast.^[5,7,12] In addition, students who smoked, lived in rented places or lived alone, were physically inactive, had separated parents, and were stressed were found to be associated with eating patterns.^[13]

According to previous studies, the prevalence of breakfast skipping was associated with gender, age, household type, marital status, educational level, parents' educational levels, race, accommodation, academic performance, skipping dinner, consumption of fast food, consumption of vegetables and fruits, smoking, sleep quality, places the students resided, and monthly income.^[4,7,12,14,15] Also, environmental factors such as mushrooming shopping malls, convenience stores, vending machines, and fast-food outlets and encouraging unhealthy eating practices contribute to breakfast skipping.^[16] Psychological factors such as mental health status play a crucial role in students' skipping breakfast.^[6] Mental health includes how stressed one is, depressed mood, low happiness scores, suicidal behaviors, short sleeping patterns, nocturnal sleeping problems, and poor sleeping quality.^[6] Depression, loneliness, short or long sleep or sleep problems, restless sleeping, and lack of sleep due to traumatic events also contributed significantly to students' skipping breakfast.^[6] Physical inactivity and sedentary behavior were also reported to be associated with breakfast skipping.^[6]

Breakfast skipping is a critical negative indicator of the health of the body and is prevalent among university students.^[4] There is a shortage of studies on the prevalence and reasons for students' skipping breakfast among university students in Jordan. This study aims to assess the prevalence of breakfast skipping and the associated factors among Jordanian university students.

Materials and Methods

A cross-sectional design was used to carry out the present study between March and May 2022. For this study, the target population is all students at Jordanian public universities. Al al-Bayt University was included as the sponsoring university, along with Yarmouk University in the northern region, Hashemite University in the central

region, and Mutah University in the southern region. These universities include scientific, medical, and humanities faculties and offer bachelor's and master's programs.

To select the study's participants, the stratification technique was employed. The universities were categorized into colleges (strata). Then, students were grouped according to their majors. After that, random sampling was performed in each faculty. Then came the second stage, where the convenience sampling technique was used to recruit participants. The sample size was estimated using Slovin's formulas.^[17] Based on a margin of error of 5%, a confidence level at 95%, a population size of 35,64, a response distribution at 50%, and the estimated measurement, the appropriate sample size was 891. The eligibility criteria were being a Jordanian student enrolled in the selected universities for the second semester of 2021–2022. The exclusion criteria included non-Jordanian students.

A self-reported questionnaire was used to collect the data between March and May 2022. The questionnaire was designed based on the literature review.^[4,5,18] To enhance the instrument's validity, it was reviewed by a panel of three experts and pilot-tested for accuracy and consistency. Primarily, an initial draft of the questionnaire was built. Then, the initial version was sent to other research members for feedback and to determine its content validity, and it was modified to be ready for a pilot phase. The pilot study was conducted with 40 participants from other universities to determine the content validity of the questionnaire from the recipients' point of view, identify the time needed to answer it and any anticipated problems in the time needed for data collection, and determine the suitability of the items in the questionnaire. This step enabled the author to evaluate and ensure the clarity and familiarity of the questionnaire's words and phrases from the participants' perspectives. Their comments revealed that the items were clear, comprehensive, suitable, and easy to complete.

The questionnaire was divided into three sections: The socio-demographic section included questions on the participant's age, gender, weight, height, university, faculty, academic year, living with, area of living, family income, religion, and work status and education level of the mothers and fathers. In the breakfast patterns and characteristics section, data on the patterns and characteristics of breakfast consumption were collected. This section included 18 questions, such as the following: How many days did you eat breakfast the past week? Who prepares your breakfast most of the time? How many meals do you usually eat per day? Do you eat vegetables, eat fruit, skip lunch and dinner, eat fast food, smoke, and exercise physically? In addition, general information included how often the students ate breakfast, what foods made up their breakfast, and when they would have breakfast. The third section, the reasons for breakfast skipping section, included 12 questions related to the reasons behind breakfast skipping.

At first, we visited every university to confirm that the deans of the individual faculties and departments had given their consent for us to gather data. Data were gathered by handing out face-to-face and online self-reporting questionnaires that were based on similar questions from previously published works and created using Google Forms. It was launched via the “G-mail Google” technology, and the link to a Google form was distributed to every WhatsApp group set up by four colleges for their students. Before distribution, this survey link underwent usability and technical functioning testing with 40 students who met the requirements for study participants. The results of this pilot testing were not used in the study’s final report. All the items were marked as mandatory; therefore, all submitted forms were complete, and the participant had 15 minutes to complete the questionnaires. Further, each participant had one chance to submit the survey, and a second try was automatically denied.

The study utilized the Statistical Package for Social Sciences (SPSS) version 28 (SPSS Inc., Chicago, IL, USA). Percentage and frequency were calculated to express the categorical data. A Chi-square test was used to assess the association between demographic variables and skipping breakfast. The p value of <0.05 was considered the level of significance.

Ethical considerations

The institutional research committee at the faculty of nursing at Al al-Bayt University approved the study (23/144/2022, 15.1.2022). The permissions to conduct the study were obtained from the selected universities. The study fully complied with the participant’s right to confidentiality. Before signing the consent form, participants had to acknowledge that they fully understood the study’s purpose. No coercion was applied to force the participants to sign the form. To maintain the confidentiality, data were encrypted before storage.

Results

A total of 891 university students were enrolled in the study. The distribution of gender and universities was almost equal in the study sample [Table 1]. However, the majority of students (30.90%) were in their first year of education, with more than half of the sample (57.70%) being from scientific or health science colleges, and 41.20% of the students were in the age group of 20–21 years old. Most of them reported living with their parents (85.30%), living in urban areas (69.40%), and claiming that they have sufficient monthly income to meet their basic family needs (58.80%). Furthermore, around 72.70% of their mothers work as housekeepers, and 52.20% of their fathers work full time. Additionally, 46.40% of students’ mothers and 42.60% of students’ fathers had a university degree.

Three-quarters of the students reported being non-smokers. More than half of the sample (57.90%) did not practice exercise, 62.10% had a normal BMI,

and 84% of the participants did not have any disease. Moreover, 682 students (76.50%) stated that they eat fast food. A total 591 students (66.33%) skipped their breakfast meal [Table 1].

As shown in Table 2, having no time due to oversleeping and having no feeling of hunger accounted for the exact percentages of (58.98% vs 58.75%) cases, respectively. Additionally, having no energy to prepare breakfast makes no difference in my day and is accounted for in the exact percentages of cases too (48.82% vs 48.46%). While I cannot afford to eat or buy breakfast, this has accounted for a minor percentage (19.27%).

Eighteen socio-demographic variables were tested using the Chi-square test to explore their association with breakfast skipping. The university had a statistically significant association with breakfast skipping, $X^2_3 = 8.13$, $p = 0.04$, indicating a higher percentage of skipping among students from Yarmouk University [Table 3]. Moreover, eating fast food is significantly associated with skipping breakfast, $X^2_1 = 4.46$, $p = 0.03$, reflecting that a higher proportion of those eating fast food skip breakfast (68.20%) compared to the proportion of those who did not eat fast food (60.30%). Additionally, “with whom you eat breakfast” is significantly associated with breakfast skipping, $X^2_3 = 8.20$, $p = 0.04$, reflecting that the highest percentages of skipping occur “with friends”, followed by being “alone”.

About 72.50% of participants eat fried potatoes, 53.42% eat sandwiches, and the minority eats vegetables (5.72%) and beans (2.81%). For beverage style, tea accounted for the highest percentage (47.92%), while soda products accounted for the most nominal rate (6.85%).

The rates of breakfast skipping were higher during university days, with Wednesdays having the highest percentage of breakfast skipping (65.40%). Moreover, the trend of skipping has remarkably declined on Fridays and Saturdays, which are the weekend days in Jordan. About 63.14% of students skipped breakfast during university days compared to 36.82% on weekend days. Only 37% of them had breakfast during university days, while on weekend days, 66.85% of them had breakfast. It can be concluded that the ratio of breakfast skipping on weekend days to university days is nearly 1:2.

Discussion

The result showed a high prevalence of breakfast skipping among university students. The high prevalence of breakfast skipping in this study is similar to previous studies.^[4,12,19] Previous research reported that lockdown is associated with inactivity and sedentary behavior.^[20] Additionally, researchers found that the COVID-19 pandemic increased the sitting time among university students due to the dramatic changes in their lifestyles.^[21] An interpretation is that dieting after the pandemic may occur as adults are attempting to lose weight, change dietary habits, and

Table 1: Participant's characteristics (n=891)

Variables	n (%)
Gender	
Male	447 (50.20%)
Female	444 (49.80%)
University	
Al al-Bayt	220 (224.70%)
Mutah	219 (24.60%)
The Hashemite	228 (25.60%)
Yarmouk	224 (25.10%)
Academic year	
First	275 (30.90%)
Second	227 (25%)
Third	229 (25.70%)
Fourth	132 (14.80%)
Fifth	22 (2.50%)
Sixth	6 (0.70%)
Faculty	
Life or Health Science	514 (57.70%)
Engineering	153 (17.20%)
Literary or Human Science	224 (25.10%)
Age groups	
Less than 19 years	308 (34.60%)
20–21 years	367 (41.20%)
22 and above	216 (24.20%)
Living with	
Parent	760 (85.30%)
Father only	40 (4.50%)
Mother only	12 (1.30%)
University housing	71 (8%)
Others	8 (0.90%)
Area of living	
Rural	273 (30.60%)
Urban	618 (69.40%)
Income	
Not sufficient	153 (17.20%)
Sufficient	524 (58.80%)
Sufficient and saving	214 (24%)
Work of mother	
Full time	165 (18.50%)
Part-time	78 (8.80%)
Housekeeper	648 (72.70%)
Education of mother	
Less than secondary level	141 (15.80%)
More than secondary	337 (37.80%)
University	413 (46.40%)
Work of father	
Full time	465 (52.20%)
Part-time	223 (25%)
Housekeeper	203 (22.80%)

Contd...

Table 1: Contd...

Variables	n (%)
Education of mother	
Less than secondary level	154 (17.30%)
More than secondary	357 (40.10%)
University	380 (42.60%)
Smoking status	
Yes	221 (24.80%)
No	670 (75.20%)
Do you practice exercise regularly?	
Yes	375 (42.10%)
No	516 (57.90%)
BMI* classification	
Underweight (BMI <19)	151 (16.90%)
Normal (BMI 19-25)	553 (62.10%)
Overweight (BMI 25-30)	161 (18.10%)
Obese (BMI >30)	26 (2.90%)
Health problems	
Yes	139 (15.60%)
No	752 (84.40%)
Eating fast foods	
Yes	682 (76.50%)
No	209 (23.50%)
With whom you eat breakfast	
Alone	292 (32.80%)
One of my family members	238 (26.70%)
All my family members	232 (26%)
With my friends	129 (14.50%)
Breakfast skipping	
Yes	591 (66.33%)
No	300 (33.67%)

*BMI: Body Mass Index

Table 2: Reasons for breakfast skipping among Jordanian university students

Reason	n (%)
No time due to oversleeping	525 (58.98)
Don't feel hungry	525 (58.75)
No energy to prepare	435 (48.82)
No difference	432 (48.46)
Reduce body weight	324 (36.41)
My friends don't eat	300 (33.69)
We don't eat it at home	248 (27.90)
I don't like types of food items	247 (27.78)
Other reasons	245 (27.54)
I don't know why eat it	233 (26.12)
I can't afford	172 (19.27)

change in their lifestyles to a sedentary lifestyle. Breakfast skipping seems beneficial for weight gain and obesity.

A study showed that three-quarters of students who ate fast food skipped breakfast, which indicates that young adults

Table 3: Association between socio-demographic characteristics and breakfast skipping

Socio-Demographic	Skipping breakfast at home		X ²	df	p
	Yes n (%)	No n (%)			
Gender					
Male	292 (65.30%)	155 (34.70%)	0.406	1	0.52
Female	299 (67.30%)	145 (32.70%)			
University					
Al al-Bayt	141 (64.10%)	79 (35.90%)	8.137	3	0.04
Yarmouk	162 (72.30%)	62 (27.70%)			
The Hashemite	156 (68.40%)	72 (31.60%)			
Mutah	132 (60.30%)	87 (39.70%)			
Academic year					
First	183 (66.50%)	92 (33.50%)	5	6,440	0.26
Second	162 (71.40%)	65 (28.60%)			
Third	144 (62.90%)	85 (37.10%)			
Fourth	81 (61.40%)	51 (38.60%)			
Fifth	16 (72.70%)	6 (27.30%)			
Sixth	5 (83.30%)	1 (16.70%)			
Faculty					
Life and Health Science	335 (65.20%)	179 (34.80%)	2	0,726	0.69
Engineering	104 (68%)	49 (32%)			
Literary and Human Science	152 (67.90%)	72 (32.10%)			
Age groups					
Less than 19 years	196 (63.60%)	112 (36.40%)	2	2,856	0.24
20–21 years	255 (69%)	112 (30.50%)			
22 years or older	140 (64.80%)	76 (35.20%)			
Living with					
With parent	507 (66.70%)	253 (33.305)	4	0,553	0.96
With father only	26 (65%)	14 (35%)			
With mother only	7 (58.30%)	5 (41.70%)			
University housing	46 (64.80%)	25 (35.20%)			
Others	5 (62.50%)	3 (37.50%)			
Area of living					
Rural	406 (65.70%)	212 (34.30%)	1	0,363	0.54
Urban	185 (67.80%)	88 (32.20%)			
Income					
Not sufficient	107 (69.90%)	46 (30.10%)	3	5,567	0.06
Sufficient	356 (67.90%)	168 (32.10%)			
Sufficient and saving	128 (59.80%)	86 (40.20%)			
Work of mother					
Full time	105 (63.30%)	60 (36.40%)	2	0,863	0.65
Part-time	54 (69.20%)	24 (30.80%)			
Housekeeper	432 (66.70%)	216 (33.30%)			
Education of mother					
Less than secondary level	87 (61.70%)	54 (38.30%)	2	2,327	0.31
More than secondary	221 (65.60%)	116 (34.40%)			
University	283 (68.50%)	130 (31.50%)			

Contd...

Table 3: Contd...

Socio-Demographic	Skipping breakfast at home		X ²	df	p
	Yes n (%)	No n (%)			
Work of father					
Full time	315 (67.70%)	150 (32.30%)	2	1,136	0.56
Part-time	147 (65.90%)	76 (34.10%)			
Housekeeper	129 (63.50%)	74 (36.50%)			
Education of father					
Less than secondary level	92 (59.70%)	62 (40.30%)	2	4,414	0.11
More than secondary	236 (66.10%)	121 (33.90%)			
University	263 (69.20%)	117 (30.80%)			
Smoking status					
Yes	147 (66.50%)	74 (33.50%)	1	0,005	0.94
No	444 (66.30%)	226 (33.70%)			
Do you practice exercise?					
Yes	242 (64.50%)	133 (35.50%)	1	0,936	0.33
No	349 (67.60%)	167 (32.40%)			
BMI classification					
Underweight (BMI <19)	98 (64.90%)	53 (35.10%)			
Normal (BMI 19-25)	362 (65.505)	191 (34.50%)	3	1,610	0.65
Overweight (BMI 25-30)	112 (69.60%)	49 (30.40%)			
Obese (BMI >30)	19 (73.10%)	7 (26.90%)			
Health problems					
Yes	90 (64.70%)	49 (35.30%)	1	0,185	0.66
No	501 (66.60%)	251 (33.40%)			
Eating fast food					
Yes	465 (68.20%)	217 (31.80%)	1	4,465	0.03
No	126 (60.30%)	83 (39.70%)			
With whom you eat breakfast					
Alone	203 (69.50%)	89 (30.50%)	3	8,203	0.04
One of family members	145 (60.90%)	93 (39.10%)			
All family members	148 (63.80%)	84 (36.20%)			
With my friends	95 (73.60%)	34 (26.40%)			

skip breakfast when they consume fast food.^[12] This result was similar to the current study. It can be concluded that the likelihood of engaging in unhealthy behaviors such as sedentary lives, poor diets, poor dietary management, and an imbalance in one's energy balance increases when one does not have breakfast.^[22] Also, this result could be related to the characteristics of the study sample, in which most students were in their first year of education, with more than half of the sample being from scientific and health science colleges. Furthermore, 41.2% of the students were in the age group of 20–21 years old, which could increase the prevalence of breakfast skipping.

According to Moy *et al.*,^[23] young people between 18 and 25 are often neglected compared to children and adults. Thus, their dietary habits decline when they leave home and go to college, where they have to be independent.^[12] On the other hand, ALBashtawy^[5] showed that the prevalence rate of breakfast consumption was decreasing with age. On the

contrary, the study result was inconsistent with Alkhalidy *et al.*^[24] study, which revealed that 67% of university students ate breakfast daily.

The most common reason for breakfast skipping among university students was a lack of time to eat breakfast due to oversleeping. This result was consistent with ALBashtawy^[5] study, which found that the students who were satisfied with their sleeping quality were more likely to have breakfast. On the other hand, those with poor-quality sleep were reported to have poor appetites. Poor sleep quality was also associated with difficulties when it was time to get up and mood swings; those with poor-quality sleep were reported to have poor appetites.^[15] Although it has been discovered that breakfast skipping was associated with more restless nights, which limited their time to eat breakfast, students who reported getting a good night's sleep were more likely to eat breakfast than those who did not.^[25]

A study reported that the factors associated with breakfast skipping were financial constraints, habits, and lack of time to eat or prepare breakfast.^[12] Also, this could be related to the lifestyle characteristics of the study sample. One of the most common reasons was the lack of hunger in the morning because they love to drink stimulant drinks early in the morning, they did not like to eat early, time constraints in the morning, waking up late for their morning lectures, and heavy traffic in the morning.

Another reason for breakfast skipping among university students was having no feeling of hunger. This result was similar to that of previous studies, which indicated that the two most common reasons for skipping breakfast were a lack of hunger and time constraints.^[5,7] The current study indicated that breakfast skipping among university students is due to a lack of energy to prepare breakfast after waking up. About 49% of the students in this study reported that having breakfast daily makes no difference. The research by ALBashtawy^[5] indicated that breakfast skippers do so because they do not have someone to prepare it. However, Badrasawi *et al.*^[7] found that 50% of those who skipped breakfast did so because there was no reason for eating early. Additionally, the transition to university life caused poor eating habits. The new exposure to stress and lack of time might lead to an unhealthy lifestyle, a habit that might end after university or persist in people's lives. Only three out of the 18 examined characteristics have significant associations with breakfast skipping. These characteristics were eating fast food, the university, and with whom breakfast is taken. Eating fast food is significantly associated with breakfast skipping, reflecting that the proportion of those eating fast foods is skipping breakfast. Snacking has increased energy intake while simultaneously decreasing hunger and satiety. In regard to breakfast consumption, the lifestyles and habits of university students had a significant influence on the results. Consistently, according to Moy *et al.*,^[23] consumption of fast food was one of the factors associated with missing breakfast. Students who ate fast food at least once a week also had a higher likelihood of skipping breakfast. Moy *et al.*^[23] and King *et al.*,^[26] reported that one environmental factor that leads to skipping breaks is fast food outlets.^[12,16]

According to the findings, students at Yarmouk University are more likely to skip breakfast. This could be explained by the abundance of restaurants on the University campus and around it. In addition, most of the students at Yarmouk University are from the villages and nearby cities. Given the distance, most students go early in the morning to their universities without eating any meal until they finish their morning lectures to avoid class delays or absenteeism. Further, the result showed that with whom the student eats breakfast is significantly associated with breakfast skipping; most students were influenced by their peers since psycho-social issues affect the health literacy of the adolescents.^[27-29] Community health nurses may design activities to raise awareness among university students regarding the risk of breakfast skipping,

motivate adult nutritional knowledge, and change behavior to promote health.

The results show that three-quarters of participants consumed fried potatoes, while half of them consumed sandwiches. Most students' breakfasts consist of fried potatoes and other high-fat, low-nutrient foods. For beverages, tea accounted for the highest percentage, while soda products accounted for the most nominal rate (6.85%).

The result of the comparisons between the percentages of student breakfast skipping on university days (Sunday through Thursday) and the weekend days (Friday and Saturday) in the present study indicates that 63% of students skipped their breakfast on university days compared with 36.82% on the weekend days. The result is consistent with Badrasawi *et al.*^[7] study, which reported a higher prevalence of breakfast skipping on school days than on weekend days. Similarly, a previous study found that skipping breakfast on weekends for university days is nearly 1:2.^[7] Most students have breakfast with their families on the weekends. However, breakfast skipping varied according to the days of the week. University students living in dorms, sororities, and states had higher chances of having a regular breakfast, and students living with their families were less likely to skip breakfast than those in rented accommodation.^[30,31] Community health interventions may focus on strategies and policies available to universities to provide breakfast served in their canteens and on-campus restaurants with incentives such as subsidized prices by public universities. This study has limitations. The use of convenience sampling and a cross-sectional design may restrict the generalizability of the results.

Conclusion

A high percentage of university students in Jordan skip breakfast, especially on weekdays. Many reasons may contribute to the skipping, including no time because of oversleeping, consuming fast food, having no feeling of hunger in the morning, having no energy to prepare breakfast, and living arrangements. The university, where you eat fast food, had a statistically significant association with breakfast skipping. The rates of breakfast skipping were higher during university days, with Wednesdays having the highest percentage of breakfast skipping, and the trend of skipping has remarkably declined on Fridays and Saturdays, which are the weekend days. More attention should be paid to correlating factors and working on developing strategies and interventions to eliminate the effects of these factors to help students adhere to breakfast meals and minimize the prevalence of breakfast skipping among university students.

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Conflicts of interest

Nothing to declare.

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Exploring Factors affecting Missed Nursing Care in Cardiovascular Care Units: A Qualitative Study

Abstract

Background: Cardiovascular care units are among the most crucial departments in any healthcare system. In these units, nurses play the most pivotal roles, and the quality of nursing care is essential; missing certain aspects of care can have irreversible adverse effects on patient health. This qualitative study aims to investigate the factors influencing Missed Nursing Care (MNCs) based on the experiences of nurses and patients in cardiovascular care units. **Materials and Methods:** This qualitative study utilized the conventional content analysis approach to explore the factors affecting MNCs in cardiovascular care units. Data were collected between December 2021 and September 2022 through in-depth, semi-structured individual interviews with 11 participants selected through purposive sampling. Data analysis followed the five-step method proposed by Graneheim and Lundman. **Results:** The analysis revealed five main themes: nurse's job characteristics, work-life conflict, nurse's professional competence, the cardiac work environment atmosphere, and organizational management. **Conclusions:** The findings of this study suggest that authorities should consider factors such as understanding the occupational characteristics of nurses when assigning them to cardiovascular care units, providing solutions to mitigate work-life conflicts for nurses, enhancing nurses' professional competence, improving the working environment for nurses, and enhancing the performance and skills of organizational managers.

Keywords: Cardiovascular nursing, missed nursing care, nursing care left undone, qualitative research

Introduction

The increase in the number of heart failure patients worldwide is driving up the costs of managing this disease, with projections indicating that by 2030, these costs will reach almost 400 billion US dollars.^[1] Among the medical staff in cardiac care units, nurses play the most crucial role, as their performance directly impacts patients' health outcomes.^[2] However, given the high rates of mortality, disability, and patient readmissions, as well as the substantial costs associated with providing optimal care in these units, enhancing nurses' productivity in cardiac departments becomes a critical and imperative issue.^[3] Nevertheless, nurses working in cardiac care units face various challenges that can affect the quality of care they deliver.^[4] In many cases, these challenges force nurses to prioritize certain aspects of patient care while making difficult decisions about what care to

provide and what to forgo. Unfortunately, this prioritization can result in the omission of essential patient care tasks.^[5]

MNC is defined as a care error or omission that can be life-threatening, according to international standards of patient safety and quality of care.^[6,7] MNC is a widespread problem within healthcare systems globally.^[8] Numerous studies have revealed that MNC is consistently associated with negative outcomes, including prolonged hospital stays, reduced patient satisfaction,^[9] compromised patient safety, diminished hospital reputation in the eyes of patients,^[10] and increased medication errors.^[5] Given the critical nature of cardiac care units within healthcare systems, any omission of nursing care can be significantly more detrimental and perilous for patients compared to other hospital departments. Consequently, it is crucial to identify the factors that may contribute to MNC.

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Although previous research has explored this topic extensively and identified factors such as staffing shortages, inadequate facilities,^[8,11] poor teamwork,^[12] and subpar management^[13-15] as potential causes of missed care in various healthcare systems, the question remains: In Iran's healthcare system, with its specific cultural, social, economic, and political characteristics, what factors influence the missed nursing care, particularly in cardiac care units? A comprehensive answer to this question necessitates further study and a more in-depth investigation. Qualitative research delves into the subjective dimensions of individuals' experiences, emphasizing comprehensive, dynamic aspects, and human experiences within the context of the conditions and from the perspective of those who have lived through them, offering profound insights.^[16] Therefore, this qualitative study aimed to explore factors affecting MNCs based on the experiences of nurses and patients in cardiac care units.

Materials and Methods

This qualitative study was part of a Ph.D. dissertation in nursing conducted between December 2021 and September 2022 using conventional content analysis. The participants included nurses working in cardiac care units, nursing managers, and patients hospitalized in cardiac care units (comprising two CCUs, one ICU, emergency, and five medical-surgical units) at Heshmat Educational and Subspecialty Heart Center in Rasht, Iran. Sampling was conducted using a purpose-based method without any restrictions in terms of maximum diversity (age, sex, clinical experience, type of employment, type of unit, and work shift) until data richness. Inclusion criteria for nurses and nursing managers required a minimum of 6 months of work experience in the cardiac care unit in either nursing or managerial roles and at least a bachelor's degree in nursing. For patients, inclusion criteria involved previous hospitalization in the cardiac care unit, the ability to express themselves, and share information. The exclusion criterion was voluntary withdrawal from the study.

Data were gathered through in-depth, face-to-face, and semi-structured interviews. Each interview commenced with an open-ended question such as "Please describe the care you provide for your patient during a shift?" and continued with questions such as "Based on your own experience, have you ever forgotten or delayed care, and how did that happen?" and "In your experience, how did you prevent this from happening again, and what factors were beyond your control?" Objective follow-up questions such as "Can you elaborate further?" or "Can you clarify this point?" were also asked. Interviews were recorded with participants' consent and ranged in duration from 15 to 65 min. Field notes supplemented the interviews, and data collection spanned over 10 months. Data saturation was achieved when codes were repeated, and no new codes emerged.

The five-step method proposed by Graneheim and Lundman *et al.*^[17] was employed for data analysis. This method involved transcribing interview content verbatim after each session, followed by multiple readings to comprehend participant statements in line with the research objectives. Primary codes were then extracted, and these primary codes were subsequently merged to form subcategories. Subcategories were compared based on similarities and differences, leading to the creation of categories. In forming these categories, efforts were made to maximize homogeneity within categories and heterogeneity among them. Ultimately, the main themes were determined. MAXQDA 2020 software facilitated data management.

Lincoln and Guba's four criteria of validity, reliability, transferability, and verifiability were used to establish trustworthiness.^[18] Validity was increased by the researcher's long-term presence in the research locations (10 months) and maintaining continuous communication with interviewees. Some interview texts, codes, and extracted data classes were reviewed not only by the research team but also by several faculty members, and consensus was reached on the final texts. Reliability was assured through peer checking and multiple meetings with research team members to assess work quality and results. To meet the criterion of transferability, purposive sampling was conducted among nurses with diverse backgrounds, including those in managerial and executive positions. To fulfill the verifiability criterion, the researcher meticulously documented all activities, decisions, collected data, observations, and the data analysis process from the outset to be made available to the audience if necessary.

Ethical considerations

Ethical considerations were adhered to, with research approval obtained under ethics ID: IR.GUMS.REC.1400.005. Before participating in the research, the researcher provided explanations regarding research objectives, information confidentiality, and voluntary participation. Informed consent was duly obtained from all participants.

Results

In this research, 11 face-to-face interviews were conducted with eight nurses, two nursing managers, and one patient. Participant characteristics are summarized in Table 1. Data analysis revealed 33 subcategories, 15 categories, and 5 main themes, including nurse job characteristics, work-life conflict, nurse professional competence, cardiac work environment atmosphere, and organizational management [Table 2].

1. **Nurse's job characteristics:** This theme explores personal aspects related to nursing and comprises two levels: Employee profile and professional experience of the nurse.
 - 1.1. **Employee profile:** These characteristics include items such as nurses' age, gender, educational level,

Table 1: Participants characteristics

Participant (position)	n	Gender		Work experience (years)	Academic degree	
		Female	Male		Bachelor	Masters
Nurse	8	7	1	2.6-7	5	3
Nursing manager	2	2	----	19-25	1	1
Patient	1	----	1	-----	1	-----

Table 2: Subcategories, categories, and main themes of factors affecting MNC

Themes	Categories	Subcategories
Nurse's job characteristics work-life conflict	Employee profile	
	Professional experience	
	Roles and responsibilities	
	Personal life problems	
Nurse's professional competence	Behavioral characteristics	
	Professional commitment	Interest in work Responsibility
	scientific and practical competence	Nurse's knowledge of cardiac care Clinical skills communication skill Spiritual care
	Empowering the patient's self-care	Patient education Involving the patient and family in care Patient learning needs assessment
Cardiac work environment atmosphere	Management atmosphere	Human resources productivity Quality of control and supervision Supporting the personnel Manager's knowledge and ability
	Caring atmosphere	Priority and urgency in providing care Mental stress caused by the cardiac attack Nurse's workload Patient-centered care Medical team performance The nature of the unit
	Professional communication	Personnel and management communication Intra-professional communication of nurses Inter-professional communications
	Recruiting and organizing human resource	Number of staff Recruitment and distribution of human resources Determining roles and responsibilities Development of care policies
Organizational management	Supplying and organizing the facilities	Medicine, facilities, and equipment accessibility Physical space
	Education	Academic education quality Quality of in-service training
	Satisfaction	Job security Organizational justice Job burnout

and employment type. One male nurse discussed the impact of gender on physical abilities, stating, "Physical problems are happening to me because of this (change of position), think that I am a man and have the physical ability. But women do not have the physical ability for this change" (P10-Nurse). Participants also highlighted

the influence of nurses' educational level on motivation and knowledge-based performance, suggesting that nurses with postgraduate education in their field are less likely to miss nursing care. "I was very motivated when I studied the intensive care course to do what I have to do more correctly" (P11-Nurse).

- 1.2. Professional experience:** Most participants believed that nurses with greater experience in caring for cardiac patients are less likely to miss required nursing care. *“A nurse with more experience is less likely to miss nursing care” (P7-Nurse)*. Experienced nurses, based on their knowledge gained through years of practice, can anticipate and diagnose problems, care needs, and emergencies for patients more swiftly and manage critical situations more effectively. *“Many times, due to working with heart patients, one gets that intuition. For example, when our patient is in pre-pulmonary edema phase and has not yet progressed to pulmonary edema, I can prevent it” (P11-Nurse)*.
- 2. Work–life conflict:** This theme relates to the balance and overlap of job and family roles, encompassing roles and responsibilities, personal life problems, and behavioral characteristics of the nurse.
- 2.1. Roles and Responsibilities:** Most participants mentioned the conflict between the maternal and professional roles of nurses, making it challenging to balance these roles and potentially leading to MNC. *“For example, when a nurse leaves her feverish child at home and heads to work in the morning, it becomes a problem directly related to her work” (P8-Manager)*. The availability of holidays and opportunities for recreation and rest can also impact nurse performance and the likelihood of care being missed. *“Nurses are always busy with work and have little leisure time, which affects their performance” (P2-Nurse)*.
- 2.2. Personal life problems:** Physical and financial issues and multiple life responsibilities can reduce a nurse’s physical capabilities or disrupt their focus, potentially leading to MNC. *“My colleague has back pain and can’t take sick leave, so what happens? She comes to work but can’t complete all her tasks, leading to potential missed care” (P10-Nurse)*.
- 2.3. Behavioral characteristics:** Certain moral qualities can enhance a nurse’s commitment and efficiency in their role, affecting their work output. These qualities include a spirit of sacrifice: *“Many times we have to sacrifice ourselves just so that no problem happens to the patient” (P1-Nurse)*; accuracy and concentration: *“Someone, for example, is a good person doing his/her job, but he/she is distracted. I have to remind him/her of his/her work” (P5-Manager)*; patience, conscientiousness, and adaptability to challenging situations.
- 3. Nurse’s professional competence:** This theme focuses on a nurse’s ability and skill in effectively performing their job duties, encompassing professional commitment, scientific and practical competence, and empowering patients’ self-care.
- 3.1. Professional commitment:** Some nurses noted that a desire for job security has led individuals to enter the nursing profession without genuine interest, potentially resulting in MNC. *“Many times, MNC occurs because some nurses lack genuine interest in nursing, choosing it solely because of job availability” (P11-Nurse)*. Participants also mentioned a perceived lack of responsibility among some nurses, affecting the quality of care. *“Despite our best efforts, there may be neglect in medication administration or vital sign monitoring” (P7-Nurse)*.
- 3.2. Scientific and practical Competence:** Nurses with a strong knowledge base can better assess symptoms and take timely action. Practical skills and scientific knowledge are essential for optimal care provision. Speed of action: *“The CCU nurse in CPR must make decisions and must have a speed of action” (P8-Manager)*, specialization and independent professional performance: *“Nursing doesn’t do anything independently at all. We have some nurses who are waiting to see what the doctor wrote and execute it, even if it’s wrong” (P11-Nurse)*; and effective patient communication: *“We have nurses who know the medicine and complications very well, they even know arrhythmias better than doctors, but their communication with the patients is very weak” (P8-Manager)* are critical components of nursing competence.
- 3.3. Empowering the patient’s self-care:** Enhancing cardiac patients’ self-care involves patient education, engagement of the patient and their family in care, and assessing the patient’s learning needs. *“For patients after surgery, the most important thing is to teach them: How to get up? What to eat? What should they do to make their cough less? How to reduce their pain? How to take care of the sternum wound?” (P2-Nurse)*. Empowering patients and their families in the treatment process can serve as a reminder for nurses to provide care and prevent missed care instances. *“Usually, we tell the patient: be careful before you eat, even if I wasn’t there, give me a message to come and check your blood sugar” (P1-Nurse)*.
- 4. Cardiac work environment atmosphere:** This theme encompasses the conditions within the clinical work environment and consists of three categories: managerial atmosphere, caring atmosphere, and professional communication.
- 4.1. Management atmosphere:** Ensuring control and supervision of nurses’ performance, particularly less experienced nurses, is essential

for guaranteeing the quality of care and reducing MNC. *“Sometimes supervisors randomly check nurses’ performance in administering medication or taking patient blood pressure. This keeps nursing staff more focused” (P6-Nurse).* Some nurses also highlighted shortcomings in leadership and support, which led to feelings of not being understood and coping with personal and work-related problems alone. This situation could contribute to increased MNC. *“Physical issues among nurses are often overlooked. We have a colleague with diabetes, but her condition is ignored. This leads to her missing some care tasks when her blood sugar levels fluctuate” (P10-Nurse).*

4.2. Caring atmosphere: Caring for cardiac patients, given their urgency and sensitivity, creates a stressful atmosphere for nurses, potentially disrupting their performance and resulting in MNC. *“Cardiac patients are highly sensitive. The stress level here is higher, and we’re expected not to make any mistakes easily” (P11-Nurse).* Additionally, the high volume of tasks exerts dual pressure on nurses, causing them to prioritize care due to time constraints. *“For a patient with heart failure, the nurse administers Lasix and a nitroglycerin drip, provides oxygen, and catheterizes the patient. Missing any of these tasks can be critical. However, after completing them, the nurse sits down to document, neglecting to monitor the patient, which can lead to a deterioration in the patient’s condition” (P5-Manager).* Furthermore, the quality of the medical team’s performance, including visits, consultations, operating room schedules, and patient communication, significantly influences MNC. *“Sometimes doctors don’t arrive on time, causing delays in administering necessary medications” (P7-Nurse).*

4.3. Professional communication: Effective communication between staff and management is one of the most critical factors influencing MNC. A nursing manager highlighted her successful relationship with nurses, saying, *“Young nurses make mistakes, but I call and warn them. They trust me because they know me. I have a good rapport with them” (P5-Manager).* Moreover, fostering proper cooperation, coordination, and teamwork spirit is crucial. According to one nurse, *“Besides cooperation, coordination is also vital. Aligning on what needs to be done and what has been done can significantly reduce errors” (P11-Nurse).* Reminders from colleagues also play a controlling role in reducing MNC. *“During shifts, we remind each other whether we’ve completed our tasks or not. These reminders can be helpful” (P1-Nurse).* Participants also emphasized the importance of

cooperation between nurses and other clinical teams, with one nurse sharing an experience. *“At the end of the shift, I noticed in the patient’s record that the attending physician had added a new order without informing us two hours earlier” (P3-Nurse).*

5. Organizational management: This theme refers to the performance of managers in relation to the nursing workforce and includes the recruiting and organizing of human resources, supplying and organizing the facilities, education, and job satisfaction.

5.1. Recruiting and organizing human resources: Most participants emphasized the insufficient number of personnel especially the shortage of nurses, as the primary factor influencing MNC.

“If there were more nurses, each nurse would have fewer patients to attend to. Honestly, a nurse could provide better care” (P6-Nurse).

“With more staff, nurses would have more time and could educate patients” (P7-Nurse).

Correctly defining roles and responsibilities was also recognized as a factor affecting MNC.

“Assigning tasks that aren’t traditionally a nurse’s responsibility makes it challenging for nurses to focus on patient care” (P8-Manager).

5.2. Supplying and organizing the facilities:

Participants highlighted the importance of providing an adequate and timely supply of facilities, equipment, and medications to facilitate nurses’ performance and reduce MNC.

“Sometimes, the medication I need to administer isn’t available on time. For example, clexane, which we should administer at 10 o’clock, sometimes arrives at 11:30” (P1-Nurse).

“Without suitable pressure-relief mattresses, preventing bedsores becomes challenging” (P4-Nurse).

5.3. Education: Some participants identified poor academic education as a significant factor in MNC, citing a mismatch between the topics taught in university courses and the practical needs of students. *“What’s taught at university during a semester is entirely different from what students have to do in real clinical settings” (P10-Nurse).* Additionally, participants found in-service training to be ineffective due to impractical and outdated topics, a lack of expert instructors, and scheduling conflicts with nurses’ shifts.

“After a night shift, nurses are expected to attend training classes, but they’re exhausted” (P8-Manager).

“Many courses are available, but they often lack practical relevance. There’s also a shortage of qualified instructors” (P4-Nurse).

5.4. Satisfaction: Job security emerged as a key motivator for work and, consequently, for reducing

MNC. *“Some nursing personnel have contracts for just 89 days, which is disrespectful. They lack job security, and the hospital offers a fixed salary for their workload. Consequently, personnel see these conditions, and many leave their jobs” (P1-Nurse).* Participants also noted dissatisfaction with the disparity between workload and salary as a factor affecting motivation. *“One reason for nurses’ low motivation is their low income, considering the demanding work they do” (P8-Manager).* The participants further highlighted the impact of nurse fatigue and burnout on MNC, citing factors like tight shift schedules, insufficient intervals between shifts, and nurses holding multiple jobs. *“Tight shifts can leave nurses fatigued and sleep-deprived” (P2-Nurse).* Another nurse added, *“Performing CPR is physically demanding and exhausting, which contributes to fatigue” (P10-Nurse).* Some participants indicated that nurses often work multiple jobs due to income considerations, leading to increased fatigue. *“[Most nurses] have to work two jobs and get tired. they have to because of income” (P2-Nurse).*

Discussion

This study was conducted to explore factors affecting MNCs based on the experiences of nurses and patients in cardiac care units. Participants identified various factors contributing to MNCs, including nurses’ job characteristics, work–life conflict, professional competence, cardiac work environment, and organizational management.

The participants highlighted the significance of nurse job characteristics in MNC occurrence, including age, gender, marital status, education level, type of shift, and clinical work experience. These findings align with a study by Du (2020), which indicated that factors such as not having children, higher education, holding a managerial position, full-time employment, and working night shifts were associated with reduced MNC.^[13] Additionally, experienced nurses were less prone to confusion due to their familiarity with work routines and better time management. This is consistent with Vatankhah’s study (2020),^[19] which showed that MNC decreases with increasing work experience and age of clinical staff.

Work–life conflict emerged as a significant challenge for nurses, impacting their performance and contributing to MNC. Factors such as variable work shifts, rotation, and discrepancies between nurses’ work holidays and official calendar holidays posed challenges, particularly for married nurses with children. Eyni’s study (2021)^[20] found that rotational and variable nursing schedules can lead to more family functioning issues and work-related stress compared to other professions. Additionally, participants noted that individual behavioral characteristics, specifically conscientiousness, played a vital role in reducing MNC.

This finding is consistent with Allahyari Bayatiani’s study (2015),^[21] which highlighted that conscientious nurses demonstrate a strong commitment to their profession, effectively completing their duties both quantitatively and qualitatively.

Professional competence was identified as another key factor influencing MNCs. Participants believed that a nurse’s performance reflects their knowledge, practical skills, and communication abilities. Nobahar (2014)^[22] also reported that nurses’ ability to diagnose patient deterioration, diagnose arrhythmias, and operate medical devices are critical for quality cardiac care. She also concluded that establishing communication between the patient and the nurse reduces the patient’s anxiety level and helps stabilize the hemodynamic status of the heart patient.

The atmosphere of the cardiac work environment was expressed as the most prominent factor affecting the incidence of MNC. In the specialized cardiac hospital, due to the type of patients, the kind of treatment, and the care they need, there is a different care-treatment atmosphere, which affects the nurse’s performance and the amount of MNC. The participants stated that the sensitivity and urgency in dealing with cardiac patients and the large amount of care they need leads to the prioritization of care by the nurse, which in many cases leads to MNC. In this regard, Carthon (2015)^[23] also reported that aspects of nursing care that may be considered a lower immediate priority are more likely to be missed, such as comforting and talking to patients, completing care plans, teaching the patient, and documenting. According to the participants’ experience, a factor preventing the occurrence of MNC is the existence of good cooperation and communication between nurses and teamwork. The findings of Yaghoubi’s research (2019)^[12] showed a significant negative relationship between MNC and teamwork. Therefore, with increased collaboration, the probability of MNC decreases.

Organizational management was described as a significant factor affecting MNCs. The ability of nursing managers, leadership, and support for nurses was deemed crucial. Effective management and leadership were seen as increasing nurse participation in care and reducing MNC, aligning with Kim’s (2018) findings.^[24] Najafi Ghezalje (2021)^[25] similarly emphasized the importance of nursing managers’ support and proper monitoring of nurses’ performance in reducing MNC. Nurse job satisfaction also emerged as an influencing factor in MNC, with factors such as high workload, staffing shortages, and low salaries contributing to nurse dissatisfaction. This finding is consistent with Janatolmakan’s study (2022).^[26]

This qualitative study provided an in-depth understanding of MNC factors. However, it was conducted in a single public heart center in the north of Iran, and hence, its findings may have limited generalizability to other settings.

Conclusion

In conclusion, this study revealed that factors influencing MNC in cardiac care units encompass nurses' job characteristics, work–life conflict, professional competence, the cardiac care environment, and organizational management. Addressing these factors is crucial for controlling MNC in cardiac care units. Authorities should consider the personal and occupational characteristics of nurses, seek solutions to reduce work–life conflict, enhance the professional competence of nurses in cardiac care units, improve the working environment, and develop the skills of organizational managers to mitigate MNCs.

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Understanding the Effect of Virtual Reality on Anxiety and Pain Due to Intrauterine Device Insertion

Abstract

Background: Virtual Reality (VR) can provide more interruption as it inundates the patient in a different universe and connects with numerous faculties. VR has been utilized to deal with the pain and stress associated with various painful medical procedures. **Materials and Methods:** This multi-method study was conducted on 60 women in an Intrauterine Device (IUD) acceptor. This research occurred in the independent practice of midwifery in the great region of Yogyakarta, Indonesia, in 2020. **Results:** The study found that the things that make respondents anxious in the face of this IUD insertion are experience, information, knowledge, and family support. The quantitative analysis found different pain levels in the VR and non-VR groups ($t_{118} = 1,65, p < 0,001$). **Conclusions:** VR can be used as a method to distract clients during IUD insertion.

Keywords: Anxiety, intra uterine device, pain, virtual reality

Introduction

Women worldwide have used the Intrauterine Device (IUD) as a method of contraception for more than 30 years. IUD insertion is related to high nervousness in the vast majority, and uneasiness and dread can cause inconvenience during IUD insertion.^[1]

Virtual Reality (VR) is a modern innovation that permits an individual to be brought into the virtual world. The discoveries of the meta-analysis propose that virtual reality distraction is a potent pain intervention. Previous research on VR interventions for managing procedural pain and anxiety in IUD acceptors has been limited. Cost savings, the availability of high-quality standard technology, and numerous VR environments have made it increasingly possible to integrate VR systems into clinical practice, but staff training and supervision are needed to operate VR devices. Strict and vigilant hygiene procedures based on hospital standards for infectious diseases, powering equipment, and regular updates of operating systems and software. Misuse or improper management of VR equipment can lead to ineffective and problematic use. Positive results have been reported for VR interventions for treating acute procedural pain over the last two

decades due to cost, hardware and software availability, and a lack of resources to perform these interventions.^[2]

Combining innovation with scientific rigor, it is difficult to systematically assess the use of VR interventions and solve difficult health problems. However, the successful integration of these two areas is painful, and procedural interventions may significantly improve non-pharmacological interventions for anxiety and stress. Many academic and private organizations focus on developing hardware and software for VR and other digital therapies for implementation in medical facilities.^[3,4] This study aims to understand the effect of VR on anxiety and pain due to IUD insertion.

Materials and Methods

This multi-method study was conducted on 60 women in IUD acceptor. This research took place in the midwifery office in the extraordinary region of Yogyakarta, Indonesia, from September 2020 to December 2020. Our research steps were: the client came to the Independent Practice Midwife; we gave the serial number; and we asked for the client's consent to be the research subject.

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We used a simple random sampling technique by drawing many respondents based on serial numbers. We assessed the degree of pain during IUD insertion. We considered anxiety just before and shortly after IUD insertion. We conducted semi-structured and in-depth interviews to get to know the client’s feelings in more detail. Our interviews were conducted in a closed room before the intervention. Interviews were recorded on a smartphone with patient consent and fully transcribed. For respondents who said they were anxious about the IUD insertion, we included them in the study sample. One respondent said she had high anxiety about the IUD insertion, so she did not use the IUD. The researcher asked what caused the respondents to feel anxious when facing the IUD insertion for 10–15 minutes. Our respondents’ answers were anonymous, and we kept them confidential.

Before going to the gynecology table, our clients in the intervention group put on glasses and a VR headset that provided underwater scenery, roller coaster rides, museums, and overseas trips, while in the control group, there was no VR. After the patient was immersed in the virtual world, we inserted the IUD. At the installation time, we assessed the patient’s facial expressions and response using VR. The instrument used to assess pain was a visual analog scale (range 0–10). The visual analog scale (VAS) was self-finished by the respondent (mm). The respondent was approached to put a line opposite the VAS line at the point that addressed their pain intensity scoring. Utilizing a ruler, the score was controlled by estimating the distance (mm) on the 10-cm line between the “no pain” anchor and the patient’s imprint, giving a range of scores from 0 to 100. A higher score showed greater pain intensity.

Based on the distribution of pain VAS scores in postsurgical patients (knee replacement, hysterectomy, or laparoscopic myomectomy) who depicted their postoperative pain intensity as none, gentle, moderate, or severe, the following cut points on the pain VAS were recommended: no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm). Measurements using VAS were done after the patient climbed the gynecology table and used VR glasses.

We used VR treatment for respondents in the intervention group and standard care in the control group. After the patient was immersed in the virtual world, we inserted the IUD. At the installation time, we assessed the patient’s facial expressions and response using VR. We conducted semi-structured and in-depth interviews to get to know the client’s feelings in more detail. Our interviews were conducted in a closed room after the intervention. Interviews were recorded on a smartphone with patient consent and fully transcribed.

The researcher asked whether VR could help respondents reduce anxiety and pain. What things about VR helped respondents deal with stress and pain? Rest assured that

all views expressed would be anonymous, and their participation would be kept confidential from practice. We gave these two questions for 10–15 minutes. We conducted semi-structured in-depth interviews in a closed room after the intervention, using interview guidelines and keeping the respondents’ identities anonymous. Qualitative data analysis was manually performed according to traditional content analysis using code development scheme in an organized and comprehensive framework, and categories were developed into topics.

Ethical considerations

This study was approved by the University of Respati Yogyakarta Ethics Committee, code no. 212.3/FIKES/PL/X/2020. The participants were aware of the research objectives, and informed consent was obtained from all of them. They were assured that their information would remain confidential.

Results

In this study, the characteristics of the respondents were presented in Table 1, which included the type of action in the IUD, the level of pain experienced by the respondent, and age. The quantitative analysis found different pain levels in the VR and non-VR groups ($t_{118} = 1,65$, $p < 0,001$) [Table 2]. Qualitative studies before intervention showed that the things that made respondents anxious in the face of this IUD insertion were unpleasant or harmful past experiences, untrue information and myths about the IUD, a lack of knowledge, and worrying about their husband’s response [Table 3]. A qualitative study after intervention showed three functions of VR to reduce anxiety. First, VR created an uncomfortable environment. Secondly, VR content had a distracting effect. Lastly, VR created an immersive function that brought people from the real world to the virtual world [Table 4].

Table 1: Respondent characteristics

Characteristics	Mean (SD)	Category	n (%)
Type of action in IUD*	1.67 (1.23)	Insertion	26 (43.33)
		Insertion and removal	20 (33.33)
		Removal	14 (23.33)
Level of pain of the respondent	1.57 (0.50)	No hurt	13 (21.66)
		Hurt a little bit	41 (68.33)
		Hurt a little more	6 (10.00)
Age	0.87 (0.76)	<35 years old	26 (43.33)
		>35 years old	34 (56.66)

*Intrauterine Device

Table 2: Different tests for the level of pain in the VR* and non VR groups

Level of pain	n (%)	Mean (SD)	p
VR Group	30 (50)	1.13 (1,08)	<0.001
Non-VR Group	30 (50)	2.40 (0.81)	

*Virtual Reality

Table 3: Results of interview data analysis before intervention

Open codes	Categories	Theme
Unpleasant or bad past experiences	Past experience	The things that make the respondent anxious in the face of this IUD insertion
Untrue information and myths about the IUD	Information	
Lack of knowledge	Knowledge	
Worrying about husband's response	Family support	

Table 4: Results of interview data analysis after intervention

Open codes	Categories	Theme
Managing an uncomfortable environment	Functions of VR* glasses	VR effect of reducing anxiety
Functions of VR content	Distraction Function	
How VR works	Immersive Function	

*Virtual Reality

Discussion

Quantitative results showed significant differences between respondents who received VR and non-VR treatments. The results of this study provided evidence for using VR to reduce levels of apathy for older adults in residential care.^[5] First, we found that a lack of knowledge and negative perceptions about the IUD also affected pain and anxiety during insertion. This was in line with the research, which said that erroneous information about IUDs, having heard negative tales about IUDs, and legends and misperceptions associated with pain concerning IUDs might have influenced anticipated pain and actual perceived pain.^[6]

Secondly, we found that a lack of information and myths about IUDs could affect anxiety. Previous research has also revealed myths about IUDs, including that they can cause abortion.^[7] Thirdly, we found she was anxious about her husband's response if the IUD strings caused pain during intercourse. This finding aligned with previous research, which stated that spousal support was characterized as the husband's assistance with choosing an IUD regarding information, judgment, instrumentality, and feeling.^[8]

Fourth, using VR glasses also made respondents unable to see the tools that the midwife placed near them to reduce respondents' anxiety. Some clients were afraid to see the medical equipment and the appearance of the midwife. This finding was in line with previous research showing that the distracting effect of VR could be used to manage several painful experiences in children, including punctures, changing dressings, cleaning and draping burns, and the

management of chronic and acute pain.^[8] This study's limitation was that the anxiety level did not differ between patients who first inserted the IUD, removed the IUD, or removed the IUD.

Conclusion

The VR scenery can shift respondents' focus to the anxiety and pain they experience, so it can be concluded that virtual reality technology can reduce anxiety and pain during IUD insertion. The development of VR content that functions to structure cognition is also necessary, considering that VR content currently mainly functions as a diversion.

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Conflicts of interest

Nothing to declare.

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Breaking Bad News to Pregnant Mothers Experiencing Stillbirth: Reporting a Gap in Practice

Dear Editor,

Human beings have always expected good news upon the pregnancy of a dear member of their family, together with both midwives and physicians. Unfortunately, not all pregnancies lead to good news, such as a normal childbirth or the birth of a healthy baby. Stillbirth gives rise to social, psychological, and physical challenges.^[1] Both parents often experience grief, anxiety, fear, and suffering. Tolerance of bad news may be less agonizing if, thanks to ultrasound technology, fetal abnormalities are detected before childbirth and even during the early phases of gestation; timely interventions and treatment can then be conducted.^[2] Among the undesirable news such as genetic defects, abnormalities, and abortion, the most painful and unexpected news may be the stillbirth, particularly a late stillbirth or a term stillbirth. Therefore, breaking the news of fetal death requires a sensitive approach and empathetic communication toward the affected parents.^[3]

The way mothers respond to these events and the loss of their babies can be a function of how nurses, midwives, and obstetricians/gynecologists treat the stillbirth. Maternal responses may vary from severe (but short-lived shocking) reactions to long periods of depression, all requiring trained and highly skillful personnel to take interventional measures before breaking the painfully unexpected news. Reports from diverse centers suggest that despite studies on breaking bad news and relevant consequences, training the target group of healthcare providers has received less attention and that practical steps are required to provide psychiatric counseling to mothers experiencing stillbirth. The training may be conceived of two stages: a course for the healthcare providers for their presence in labor, delivery, and recovery and another course for post-op counselors who are expected to follow-up with the mourning mother after recovery. Various protocols including Spikes, Breaks, ABCD, Connect, and Sunburn can be widely used to break bad news.

To sum up, preparation for a secure, convenient, and relaxing environment, concentration on what the mourning mother may wish to express, breaking the bad news into smaller fragments, responding to their feelings, and relying on empathy rather than sympathy are some practical pieces of advice. Training the human elements and research on preservice and in-service training may enrich our corpus of case studies. The role of the family is also very important. Family members are in a better position to judge and make decisions, and it is easier for physicians to communicate with them.

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