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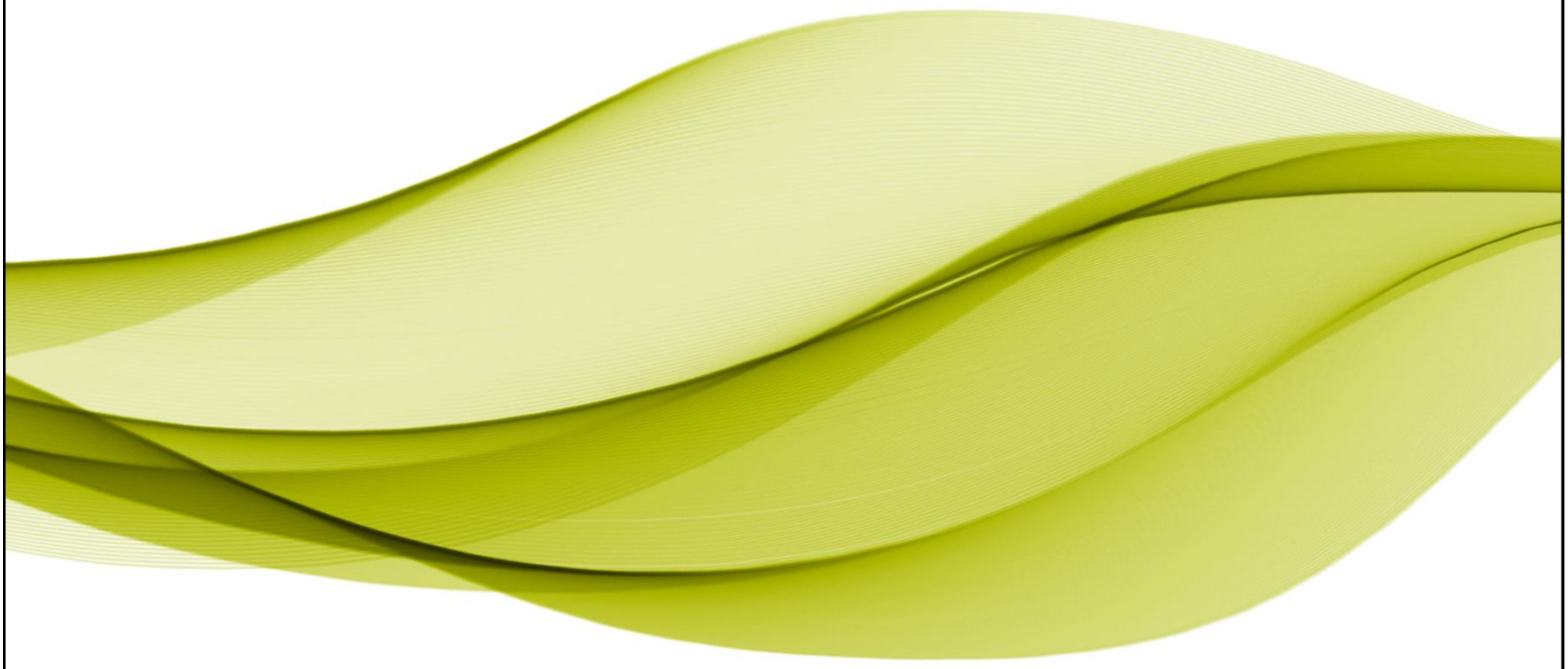

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Health Services Students' Knowledge of Sexually Transmitted Diseases

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Health Services Students' Knowledge of Sexually Transmitted Diseases

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Abstract

Background: The rising incidence of sexually transmitted diseases (STDs) among young people is a significant public health issue. This study aims to assess the level of knowledge of sexually transmitted diseases among students at a vocational health school.

Methods: A descriptive study was conducted at a university in eastern Turkey from January to June 2024. The sample consisted of 621 students who agreed to participate. Data were collected from a sociodemographic form and the Sexually Transmitted Diseases Knowledge Questionnaire.

Results: Knowledge was higher among males, second-year students, those in the emergency and disaster management program, those with previous education about STDs, and those familiar with prevention methods ($p < 0.05$). Human immunodeficiency virus/AIDS was the most commonly recognized disease (64.3%), and 61% of students reported having received information about sexually transmitted diseases at school.

Conclusion: The mean total score of the students was 7.11 ± 5.94. The level of knowledge of sexually transmitted diseases is low. Effective educational interventions are essential for future healthcare providers to improve health education and implement preventive measures.

Keywords: level of knowledge, sexually transmitted diseases, students, Türkiye

INTRODUCTION

Sexually transmitted diseases (STDs) cause significant public health problems worldwide, placing a significant burden on health services. According to the World Health Organization (WHO), 376 million STDs are recorded worldwide each year.[1,2] Bacteria, viruses, and fungi can cause these infections. The most common are chlamydia, gonorrhea, genital herpes, human papilloma virus (HPV), syphilis, and human immunodeficiency virus (HIV).

Worldwide, STDs are on the rise among young adults, which is a cause for concern. The effects of STDs on young people and their tendency to spread create significant burdens on health systems and societies.[3] Young adults are exposed to environments in which they can engage in risky sexual behaviors because of the normal process of psychosexual development and the influence of peers and digital culture. This makes them more vulnerable to STDs than the elderly population.[4,5] Young people aged 15–24 are the most at risk.[6,7] The period of university education coincides with this age group. In this process, significant sociocultural changes in the lifestyles of students and the impact of these changes make them more susceptible to risky sexual behaviors and the risks this entails.[8–11] In this sexually active period, not having enough information about STDs and not getting information from the right sources create misunderstandings among young people and difficulties in the fight against these diseases.[12,13] Considering the results of many international studies, the WHO states that there is a lack of education and awareness about STDs.[1] In this context, emphasizing the prevalence of STDs is critical to raising awareness among young adults. Young people's knowledge of this issue can enable them to play an active role in prevention and treatment processes.[3] Studies have reported that most university students have low levels of knowledge about STDs.[13–15] The situation is similar in Turkey. In a systematic review investigating university students' level of knowledge about STDs, it was reported that the level of knowledge among the majority of students was insufficient.[16] In order to prevent STDs, it is important to provide comprehensive education and information about the types of infections, the diseases they cause, their signs and symptoms, and the fact that some types may be asymptomatic. It is also important to prioritize health promotion programs in this regard.[1,17]

Tackling STDs in young adults is a daunting task for health professionals in most countries. If future health care providers are not well equipped with sound knowledge,

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good attitudes, and good practices, it will be more difficult to solve STD-related medical and social problems. University students, especially medical and health science-oriented students, are recognized as future healthcare providers who may be in a position to promote health education about STDs and implement appropriate preventive measures for the general public.[18] The aim of this study is to determine the level of knowledge about sexually transmitted diseases among students at a vocational health school to provide solutions based on the results.

METHODS

The population of this descriptive study consisted of students (N = 1040) enrolled at the Erzincan Binali Yıldırım University Vocational School of Health Services in the eastern region of Turkey during the spring semester of academic year 2023–2024. No sampling was used in the study as the objective was to reach all the students. The study concluded with 621 (59.71%) students who volunteered to participate and completed the data collection instruments. The data were collected by the researchers between January and June 2024.

Approval was obtained from the Erzincan Binali Yıldırım University Human Research, Health, and Sports Sciences Ethics Committee on December 29, 2023, registered under number E-88012460-050.04-332980-12/04. Permission was obtained from both the institution where the research was conducted and the authors of the scale. Students were informed about the research and gave their written consent to the use of their answers for the purposes of the study.

The data for the study were collected using a sociodemographic form and the Sexually Transmitted Diseases Knowledge Questionnaire (STD-KQ). The sociodemographic form was developed by the researchers. It consisted of 10 questions about age, sex, educational program, type of school completed, longest place of residence, education about STDs, knowledge of STD prevention methods, knowledge of STDs, and sources of information. The STD-KQ was developed by Jaworski and Carey in 2007. This scale measures and assesses young adults' knowledge of the six STDs (chlamydia, genital herpes, gonorrhea, hepatitis B, HIV, and HPV) that pose the greatest health threat to the population.[19] The test of the scale for Turkish validity and reliability was conducted by Dilcen *et al*. It was reported that the total Cronbach's alpha coefficient of this scale was 0.843, which indicates high reliability, and that it was valid and reliable according to Turkish culture for assessing individuals' knowledge and awareness of STDs.[20] The scale consisted of 25 items and six subscales (general knowledge, treatment and protection, transmission and protection, agent, symptom, cause and effect). The possible responses to the items were "true," "false," and "don't know." "Correct" answers to each item in the scale were worth 1 point, and "incorrect" or "don't know" answers were worth 0 points. The highest possible score that could be obtained from the scale is 25 and the lowest is 0. The items with correct answers when the "correct" option was selected in the scale were 2, 3, 5, 7, 8, 10, 11, 12, and 25. The items with correct answers when the "wrong" option was selected were 1, 4, 6, 9, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, and 24. In this study, Cronbach's alpha was 0.902.

Statistical Package Social Sciences for Windows (SPSS) 22 was used to evaluate the data. The suitability of the data for normal distribution was determined by the Kolmogorov–Smirnov test. The descriptive data of the study were expressed as number (n), percentage (%), mean, and standard deviation (SD). The Mann–Whitney U and Kruskal–Wallis tests were used to compare variables that did not fit the normal distribution. $p < 0.05$ was accepted as the threshold of statistical significance.

RESULTS

Table 1 shows the mean age of the students was 20.35 ± 2.57 (minimum: 18, maximum: 44), 76.3% were female, 15.3% were studying in a first and emergency aid program, 52.8% were first-year students, 78.4% graduated from a high school other than a health vocational high school, and 48.1% lived mostly in the provinces. It was found that 59.3% of the students did not receive any education about STDs, 57.5% of them knew the methods of protection from STDs, 64.3% of them reported that the STD they were most familiar with was HIV/AIDS, and 61.0% reported that their source of information about STDs was school.

Table 2 shows the mean scores of the STD-KQ and its subscales. When the mean scores of the STD-KQ and its subscales were analyzed, it was found that the mean score of general knowledge was 1.44 ± 1.61, the mean score of treatment and protection was 1.37 ± 1.26, the mean score of transmission and protection was 0.76 ± 0.94, the mean score of agent was 1.14 ± 0.98, the mean score of symptom was 1.01 ± 1.21, the mean score of cause and effect was 0.54 ± 0.80, and the mean score of the total score was 7.11 ± 5.94.

Table 3 shows the total mean scores of the STD-KQ compared by students' sociodemographic characteristics. A statistically significant difference ($p < 0.05$) was found between the total mean score of the STDs knowledge scale and students' sex, study program, year, type of high school completed, status of receiving education about STDs, and knowledge of STD prevention methods.

TABLE 1. Sociodemographic characteristics of students (N = 621)

Variable	N	%
Sex		
Female	474	76.3
Male	147	23.7
Grade		
1st Grade	328	52.8
2nd Grade	293	47.2
Training program		
First and Emergency Aid	95	15.3
Anesthesia	84	13.5
Emergency and Disaster Management	71	11.4
Oral and Dental Health	56	9.0
Child Development	45	7.2
Home Care Services	74	11.9
Medical Imaging Techniques	63	10.1
Medical Documentation and Secretariat	78	12.6
Pharmacy Services	55	8.9
Type of high school graduated		
Health High School	134	21.6
Other	487	78.4
Place of longest residence		
Village	158	25.4
District	164	26.4
Province	299	48.1
Training in STDs		
Yes	253	40.7
No	368	59.3
Knows STDs prevention methods		
Yes	357	57.5
No	264	42.5
Information about STDs*		
HIV/AIDS	399	64.3
Gonorrhea	112	18.0
Frengi	28	4.5
HPV	26	4.2
Hepatitis	84	13.5
Genital Herpes	63	10.1
STDs information sources*		
School	379	61.0
Family	140	22.5
Friends	231	37.2
Health personnel	142	22.9
Internet	370	59.6
Television	91	14.7
Social media	280	45.1
Book/magazine	90	14.5

*Participants gave more than one answer

DISCUSSION

STDs are a major health problem affecting young people in both developed and developing countries such as Turkey. The group most vulnerable to these infections are young adults because of lack of knowledge and risky practices. Information on this topic is very important for preventing negative outcomes in reproductive health of young adults. The WHO states that studies on STDs show that there is a lack of education and awareness in this area.[13] This study provides information to determine the level of knowledge about STDs among health services students and offers solutions in line with the results.

TABLE 2. Mean scores of students' STD-KQ knowledge scale and subscales

Scale	Med (Min–Max)	Mean ± SD
Total score of STD-KQ	6.00 (0–25)	7.11 ± 5.94
General Information	1.00 (0–6)	1.44 ± 1.61
Handling and protection	1.00 (0–4)	1.37 ± 1.26
Contamination and protection	0.00 (0–3)	0.76 ± 0.94
Agent	1.00 (0–3)	1.14 ± 0.98
Symptom	1.00 (0–4)	1.01 ± 1.21
Cause and effect	0.00 (0–3)	0.54 ± 0.80

Med: Median; Min: Minimum; Max: Maximum; SD: Standard Deviation

In the study, the total STD-KQ score of the students was 7.11 ± 5.94, and their level of knowledge was low. Previous studies have reported that university students have low levels of knowledge about STDs.[13-16] This situation can be explained by the lack or inadequacy of awareness about STDs and training programs at universities. It is believed that students have a low level of knowledge despite receiving health education that effective educational interventions need to be developed, that information about STDs is important for preventing their spread, and that more research on this topic is needed. Training should be provided on the types, symptoms, risk factors, routes of transmission, prevention methods, and treatment methods of STDs. It should also include information on healthy sexual behavior. For this purpose, training programs supported by group discussions, role plays, case studies, videos, animations, and visual materials should be used. Training materials should be constantly renewed to keep up with current information. Questionnaires, tests, and feedback methods should be organized to evaluate the effectiveness of the training. Training programs should be improved. In addition, students should be informed about clinics and counseling lines where more information and support can be obtained. Continuity of trainings should be ensured. Informative materials in schools, seminars, and informative content services on social media and other digital platforms are also important in this regard.

This study found that male students had a higher level of knowledge about STDs than female students. Similar to these results, another study reported that males had better knowledge of STDs.[13] Another study found that females had a higher level of knowledge than males,[18] while a third study found that the sex of the respondent did not affect the level of knowledge about STDs.[21] In our society, boys are raised more freely than women in terms of sexuality, while girls are generally under pressure and

TABLE 3. STD-KQ mean scores by student sociodemographic characteristics

Variable	Mean ± SD	*p*
Sex		
Female	6.75 ± 5.75	0.015*
Male	8.25 ± 6.40	
Grade		
1st Grade	5.73 ± 5.44	0.000*
2nd Grade	8.65 ± 6.11	
Training program		
First and Emergency Aid	7.02 ± 6.30	0.000*
Anesthesia	8.32 ± 6.46	
Emergency and Disaster Management	9.52 ± 5.17	
Oral and Dental Health	8.71 ± 5.99	
Child Development	2.77 ± 4.12	
Home Care Services	7.60 ± 4.92	
Medical Imaging Techniques	6.74 ± 6.78	
Medical Documentation and Secretariat	5.48 ± 4.97	
Pharmacy Services	6.27 ± 5.76	
Type of high school graduated		
Health High School	8.97 ± 5.79	0.000*
Other	6.59 ± 5.89	
Place of longest residence		
Village	7.04 ± 6.12	0.818
District	6.84 ± 5.58	
Province	7.29 ± 6.05	
Training in STDs		
Yes	10.10 ± 5.68	0.000*
No	5.05 ± 5.20	
Knows STDs prevention methods		
Yes	9.31 ± 5.73	0.000*
No	4.12 ± 4.81	

*p< 0.05; SD: Standard Deviation; Mann–Whitney U test and Kruskal–Wallis test were used accordingly.

control and are raised according to more conservative and traditional expectations.[22] Analyzing the cultural or social factors that affect this situation will be useful in this sense.

This research found that the level of knowledge about STDs was higher among second-year students. Another study reported that first-year university students had insufficient knowledge of STDs and their prevention.[23] Other studies have reported that students have better knowledge about STDs as their years of study increase.[13,18] This study found that students trained in emergency and disaster management had higher levels of knowledge about STDs than students trained in other programs. This can be explained by the fact that students' course content on infectious diseases is more extensive than in other programs.

The study found that levels of knowledge about STDs were higher among students who had graduated from a health school. Previous studies have reported that students who graduated from health science colleges had higher levels of knowledge about STDs and infections[24] and that health science students had higher levels of knowledge about STDs than students who graduated from non-health science colleges.[7,18] In the present study, the level of knowledge about STDs was higher among students who had received education about STDs and among students who knew about prevention methods. Another study reported that having received SRH education at school was an important factor that influences knowledge of STDs.[14] In this regard, it is clear that the inclusion of topics on infectious diseases, including STDs, in educational curricula and the provision of education on these topics are effective in influencing these outcomes.

The study found that HIV/AIDS was the STD most commonly known by students (64.3%). Previous studies have also shown that HIV is the most common STD.[14,18] In this regard, current sex education programs could be strengthened by providing more information about not only HIV but also other STDs.

The study found that students get most of their information about sexuality from school (61%), followed by the Internet (59.6%) and social media (45.1%). With regard to sources of information in the studies, it was reported that the Internet was the main source of information for students (77.3%) and that more than half of the students obtained this information through the faculty curriculum.[18] In another study, it was reported that students obtained information from three main sources:

the Internet (41.3%), courses at school or university (27.8%), and health professionals (16.7%).[14] Health education and easy access to health educators, the Internet, and social media are important means for raising awareness among the masses. However, the reliability of these sources and their impact on the quality of information should be assessed. The spread of misinformation from Internet sources and the timeliness of materials are important factors that affect the quality of information. In future research, studies should be carried out to assess the reliability and impact of these sources. The results of the research are not representative of the general student population as they reflect only the level of knowledge of the students who agreed to participate.

CONCLUSIONS

This research reveals that the level of knowledge of students who receive education in the field of health is low. In this regard, there is a critical need to reevaluate the current sexual education program content and teaching methods. STDs training for students should be increased, and health screenings and treatment at universities should be made available for students. It is thought that these steps will also affect awareness and knowledge in other university programs that do not include health education. Without these actions, it will be difficult to train good healthcare providers in STDs in the future. Future research could be conducted with larger sample groups and focus on areas such as changes in knowledge over time or the effectiveness of specific training programs.

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest.

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Unraveling the Multilevel Dynamics of Water, Sanitation, and Child Anthropometry in Indonesia

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Unraveling the Multilevel Dynamics of Water, Sanitation, and Child Anthropometry in Indonesia

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Abstract

Background: Anthropometrics, reflecting nutritional status, growth, and development, are crucial elements that can predict a person's health and well-being. However, low anthropometric measures among children under 5 years remain a significant issue in Indonesia, often influenced by various factors at the household and community levels. Access to clean water and adequate sanitation has been identified as major determinants of these adverse health outcomes. This study analyzes the relationship between anthropometric measures and access to water and sanitation at household and community levels using a multilevel analysis approach.

Methods: The study employs cross-sectional data from the Indonesian Family Life Survey (IFLS) waves 4 (2007) and 5 (2014), comprising a combined sample of 7,583 children. Furthermore, height-for-age z-scores (HAZ) and weight-for-height z-scores (WHZ) serve as the dependent variables, while improved water and sanitation access are the main independent variables. To account for the hierarchical nature of the data, a multilevel linear regression model is employed, clustering individuals, households, and communities at various levels.

Results: The results indicate that improved sanitation at the household level and water coverage at the community level are significantly associated with higher HAZ, increasing the scores by 0.171 standard deviation (SD) ($p < 0.01$) and 0.004 SD ($p < 0.1$), respectively. However, the water and sanitation variables do not reveal a significant association with WHZ.

Conclusions: The results of the study emphasize the importance of household-level sanitation and community-level water sources in influencing children's health. Effective interventions must target improvements in water and sanitation facilities at household and community levels simultaneously to enhance children's health and well-being. Recognizing and addressing the contextual factors at multiple levels is crucial for developing comprehensive health strategies.

Keywords: anthropometry, child, Indonesia, sanitation, water

INTRODUCTION

In 2022, approximately 2.2 billion people, or 27% of the global population, faced challenges in accessing safely managed water.[1] This predicament was marked by reliance on basic and limited services, unimproved sources, and surface water for drinking purposes. Furthermore, 3.4 billion individuals lacked access to adequately managed sanitation facilities, including those with basic, limited, or unimproved facilities, in addition to those practicing open defecation.[1] These issues are particularly severe in rural areas lacking even basic facilities,[1] and they commonly occur in developing countries, including Indonesia.[1]

In 2022, 94% and 88% of the Indonesian population had access to at least basic drinking water sources and basic sanitation, respectively.[1] However, these percentages vary across provinces, revealing regional disparities in access to clean water and sanitation.[2] Moreover, approximately 4% of the population still practices open defecation.[1] The persistence of these issues underscores the ongoing challenge of inadequate water, sanitation, and hygiene (WASH) services.

The lack of safe WASH access can lead to diseases such as diarrhea, intestinal worm infection, and environmental enteropathy,[3] significantly disrupting children's nutrient absorption and protein utilization.[3] Further, these conditions contribute to poor anthropometric measures, including height-for-age (HAZ, stunting), weight-for-height (WHZ, wasting), and weight-for-age (WAZ, underweight).[4] Undernutrition, indicated by low anthropometrics, affects children's cognitive abilities[5] and long-term health and stature.[6] Body measurements, reflecting health status, dietary intake, growth, and development, are crucial indicators in this context.[7]

Undernutrition remains a pressing issue in Indonesia, as revealed by Indonesia Nutrition Status Survey (SSGI) 2022. The survey underscored stunting, wasting, and underweight prevalence rates of 21.6%, 7.7%, and 17.1%, respectively.[8] Furthermore, these rates are notably higher in lower-income regions.[9] As inadequate access to improved water and sanitation is recognized as a contributing factor to low anthropometrics,[10–12] investigating this issue further is imperative, especially in Indonesia.

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Distinguishing between household and community-level access is crucial, as these factors can impact children's health differently.[13,14] This is especially relevant in hierarchical data structures, where individuals with similar backgrounds tend to share similar characteristics.[15] Therefore, it is essential to account for these differences at each level through data clustering. In addition, the study focuses on early childhood because it is a critical period for development, as growth failure due to poor nutrition and infection is more likely to happen at this time.[16]

This paper analyzes the relationship between access to water and sanitation and anthropometric measures among children under 5 years in Indonesia, considering household- and community-level factors. By employing multilevel estimation techniques, we offer a comprehensive understanding of the issue and increasingly reliable estimates.

METHODS

Data source

This study used cross-sectional secondary data from the Indonesian Family Life Survey (IFLS) waves 4 and 5. The IFLS data was collected by the Research and Development Corporation in collaboration with research centers, such as Survey METRE, and universities, such as the University of Indonesia and University of Gadjah Mada. The IFLS comprises a longitudinal survey spanning five waves, which were conducted in 1993, 1997, 2000, 2007, and 2014. Moreover, it represents approximately 83% of the country's population, covering 13 of 27 provinces.[17] IFLS 4 and 5 were conducted from 2007 to 2008 and from 2014 to 2015, respectively.[17] By using data from waves 4 and 5, the study captures a broad picture of the situation across different years, thus enhancing the findings' robustness and reliability.

The study focused on children under 5 years. Out of 10,744 children, only 7,583 were eligible for the sample after excluding cases with missing data on outcome variables (N = 914) and predictors (N = 2,247). The eligibility criteria included having complete data for the anthropometric measures and key predictors of interest. Ethical approval of the survey and its procedures was obtained from institutional review boards in the United States and the University of Gadjah Mada in Indonesia before the commencement of fieldwork.[17]

Outcome variables

While WAZ could be beneficial for assessing underweight, the result might be influenced by stunting, wasting, or both, making the interpretation increasingly complicated.[18] Therefore, HAZ and WHZ were chosen as the dependent variables. HAZ reflects a long period of nutrient intake, and low HAZ (below −2 SD) indicates stunting (typically due to insufficient nutrients or repeated illness).[18] Meanwhile, WHZ implies recent dietary intake, where low WHZ (below −2 SD) suggests wasting (usually resulting from extreme food shortages or diseases that drastically reduce weight), and high WHZ (above 2 SD) indicates excessive weight.[18] These indicators were calculated according to the World Health Organization (WHO) Child Growth Standards.[18] The z-score denotes how far the measurement deviates from average values or, in other terms, how many SDs the score is below or above the mean value. In addition, a higher z-score indicates a greater deviation of the anthropometric value from the population average.

Individual-level variables

Control variables at the individual level included child-level factors such as age in months, gender (1 = girl, 0 = boy), birth weight in kilograms, and full immunization status (1 = yes, 0 = no). Full immunization was defined as having received one dose of BCG and measles, four doses of Polio, and three doses of DPT and Hepatitis B for 9-month-old children and older, adjusting the required injections and doses according to age for children younger than 9 months old, based on the Decree of the Minister of Health No 1611/MENKES/SK/XI/2005.[19,20]

Household-level variables

The main predictor variables at the household level included improved water and sanitation. Improved water was defined as mineral water, piped water, well/pump, well water, spring water, and rainwater, while unimproved water sources were rivers/creeks, ponds/fishponds, water collection basins, and others. Moreover, improved sanitation was defined as households' using private toilets with septic tanks, while unimproved sanitation included toilets without septic tanks, shared toilets, public toilets, creeks/rivers/ditches without toilets, yards/fields without toilets, sewers, ponds/fishponds, animal stables, seas/lakes, and others. Household-level control variables comprised the routine boiling of water (1 = yes, 0 = no), years of schooling completed by the child's mother, the mother's body mass index category (−1 = underweight, 0 = healthy weight, 1 = overweight, 2 = obesity), and the natural logarithm of per capita expenditure (calculated by dividing the total monthly expenditure of the household by the number of people in the household).

Community-level variables

Community-level WASH variables comprised the proportion of households using improved water and sanitation in the community, expressed as a percentage. Moreover, control variables at this level included the natural logarithm of community per capita expenditure (calculated by dividing the total monthly expenditure of people in the community by the number of people in the community), average number of years of schooling for individuals aged 15 and above, and urban/rural residency (1 = urban, 0 = rural).

Statistical analysis

Descriptive statistics were first used to summarize the key characteristics of the data sample. This offered an overview of the demographic, household, and community variables. Following the descriptive analysis, a random intercept multilevel linear model was employed to investigate the relationship between the anthropometric features of children under 5 years and access to water and sanitation. This multilevel model was chosen to account for the hierarchical nature of the data, [15] which was structured at three levels, namely, individual, household, and community (sub-districts). The hierarchical structure within the data necessitated a nuanced approach beyond traditional linear regression, as this structure could signify influences exerted by the group or generated by individual members within the group.[15] Further, this effect, often referred to as a contextual effect, cannot be separated from the individuals within the group.[21]

The study set the levels of statistical significance at 0.10, 0.05, and 0.01. The likelihood ratio (LR) test was used to assess whether the data exhibited a hierarchical structure. This test compared the intercept-only model (without explanatory variables) with the complete model (with all explanatory variables). A significant LR test indicated that the multilevel model was appropriate, signifying that the null model was nested within the complete model.[22] Confidence intervals were reported at 99%, 95%, and 90% levels to provide a range of estimates for the parameters. The statistical analysis software that will be used is Stata version 17.

RESULTS

Overall, the data from both IFLS waves suggest a high usage of improved water sources and sanitation facilities among children's households. Table 1 provides an overview of the statistics summary of the data, revealing that children's households predominantly use improved water sources (>96%) and sanitation facilities (>69%) and adopt the practice of boiling water before consumption (>54%). The mean number of years of schooling attained by the children's mothers ranges from 9 to 10, and more than half of the sample comprises mothers with a healthy weight. Moreover, at the community level, the mean coverage for improved water exceeds 96% in both IFLS waves, while improved sanitation coverage stands at 68.5% (wave 4) and 74.3% (wave 5). The average educational attainment for individuals aged 15 and above in the community is over 8 years.

Table 1 also provides information on children's nutritional status, indicating a decreasing trend in malnutrition across all three indices (stunting, wasting, and overweight) in the two datasets. Stunting is the most prevalent of the three malnutrition conditions, affecting over 34% of the children sampled.

Table 2 presents the results of the multilevel linear regression for HAZ and WHZ. Two LR tests were conducted: one that compares the multilevel regression model with the ordinary linear model and another that compares the full model with the null model. For HAZ, the first LR test showed that the multilevel model provided a better fit than the simple linear model (LR $\chi^2 = 46.3$, $p < 0.001$). The second LR test, which compares the full model with the null model, also indicated a significant improvement in fit (LR $\chi^2 = 489.66$, $p < 0.001$). For WHZ, the first LR test similarly demonstrated that the multilevel model was superior to the simple linear model (LR $\chi^2 = 63.62$, $p < 0.001$). The second LR test confirmed that the three-level model was a better fit than the single-level model (LR $\chi^2 = 229.57$, $p < 0.001$). These results suggest that the multilevel model significantly outperforms both the ordinary least squares and intercept-only models, which indicates a better fit with the data.

The results demonstrate that children who reside in households with improved sanitation exhibit a height advantage of 0.17 SD ($p < 0.01$) compared with those without improved sanitation. Furthermore, a 1% increase in improved water coverage at the community level correlates with an increase of 0.004 SD ($p < 0.1$) in children's average height-for-age Z-scores (HAZ). Conversely, improved water and sanitation at the household and community levels, respectively, show no significant association with HAZ, and none of the WASH variables at any level demonstrate significance for weight-for-height Z-scores (WHZ).

Of the control variables at the individual level, birth weight is positively significant with HAZ and WHZ. When the child's age increased by one month, HAZ and WHZ scores decreased, by −0.01 SD and −0.007 SD, respectively. The results indicate that full immunization status is not significantly associated with anthropometry. Of the control variables at the household level, boiling water and per capita expenditure exhibit a positive correlation with HAZ. Meanwhile, underweight mothers demonstrate a negative association with WHZ and HAZ, while overweight and obese mothers are associated with higher WHZ in their children. As expected, higher education levels attained by mothers correlate with higher anthropometric features. At the community level, only community education ($p < 0.1$) and urban residency ($p < 0.05$) variables are significant for HAZ. Finally, the year 2014 variable is significant only for children's WHZ.

Multiple linear regression is performed as a robustness check and presented in Table 3. While the estimates are only marginally different from the multilevel model, the standard error of the OLS model is lower. Some differences in p-values are observed, where improved water coverage, boiling water, the mother's BMI (underweight), and the urban variable show a stronger relationship with HAZ than indicated by the multilevel results. These findings were anticipated as the LR test establishes data clustering, rendering the use of OLS a

TABLE 1. Statistics summary

Variable	IFLS 4		IFLS 5	
	N (%)	Mean ± SD	N (%)	Mean ± SD
Child characteristics				
HAZ		−1.44 ± 1.57		−1.39 ± 1.47
WHZ		−0.17 ± 1.51		−0.26 ± 1.43
Age		28.87 ± 17.17		28.86 ± 17.10
Gender				
Girl	1,665 (48.26)		1,978 (47.86)	
Boy	1,785 (51.74)		2,155 (52.14)	
Birth weight		3.20 ± 0.60		3.16 ± 0.62
Fully immunized				
Yes	1,016 (29.45)		1,353 (32.74)	
No	2,434 (70.55)		2,780 (67.26)	
Household factors				
Water source type				
Improved water	3,366 (97.57)		4,006 (96.93)	
Unimproved water	84 (2.43)		127 (3.07)	
Sanitation type				
Improved sanitation	2,399 (69.54)		3,114 (75.34)	
Unimproved sanitation	1,051 (30.46)		1,019 (24.66)	
Boiling water				
Yes	2,745 (79.57)		2,265 (54.80)	
No	705 (20.43)		1,868 (45.20)	
Mother's education		9.63 ± 3.64		10.27 ± 3.50
Mother's BMI				
Underweight	342 (9.91)		292 (7.07)	
Healthy weight	2,105 (61.01)		2,225 (53.83)	
Overweight	752 (21.80)		1,124 (27.20)	
Obesity	251 (7.28)		492 (11.90)	
Per capita expenditure		809,858 ± 3,124,493		1,018,314 ± 1,416,838
Community factors				
Improved water coverage		96.96 ± 11.66		97.21 ± 9.03
Improved sanitation coverage		68.50 ± 27.79		74.29 ± 24.05
Community education		8.51 ± 2.25		8.91 ± 2.05
Community per capita expenditure		1,096,559 ± 2,280,421		1,176,104 ± 1,408,741
Community area				
Urban	1,998 (57.91)		2,442 (59.09)	
Rural	1,452 (42.09)		1,691 (40.91)	
Children malnutrition status				
Stunting	1247 (36.14)		1429 (34.58)	
Wasting	339 (9.83)		368 (8.9)	
Overweight	270 (7.83)		271 (6.56)	
Total observations		3,450		4,133
Total households		3,097		3,740
Total communities		928		1,094

HAZ: height-for-age; WHZ: weight-for-height; BMI: body mass index; N: number of observations; SD: standard deviation

TABLE 2. Association between access to water and sanitation and children's height-for-age (HAZ) and weight-for-height (WHZ) scores: Multilevel linear regression analysis

Variable	HAZ		WHZ	
	β (SE)	CI (95%)	β (SE)	CI (95%)
WASH Variables				
Improved water[Ref: Unimproved]	0.123 (0.136)	−0.143 – 0.389	−0.124 (0.133)	−0.386 – 0.137
Improved sanitation[Ref: Unimproved]	0.169 (0.048)***	0.074 – 0.263	−0.053 (0.047)	−0.146 – 0.040
Improved water coverage (%)	0.004 (0.002)*	0.000 – 0.009	0.002 (0.002)	−0.003 – 0.006
Improved sanitation coverage (%)	0.000 (0.001)	−0.002 – 0.002	0.001 (0.001)	−0.001 – 0.003
Individual Level				
Age (Years)	−0.010 (0.001)***	−0.012 – −0.008	−0.007 (0.001)***	−0.009 – −0.005
Girl[Ref: Boy]	0.099 (0.034)***	0.033 – 0.165	−0.005 (0.033)	−0.070 – 0.060
Birth weight (Kilograms)	0.343 (0.028)***	0.288 – 0.398	0.218 (0.028)***	0.164 – 0.272
Full immunization[Ref: Not full]	0.045 (0.037)	−0.027 – 0.118	−0.001 (0.037)	−0.072 – 0.071
Household Level				
Boil water[Ref: Not boil]	0.097 (0.040)**	0.019 – 0.175	−0.009 (0.039)	−0.087 – 0.068
Mother's education (Years)	0.030 (0.006)***	0.018 – 0.042	0.012 (0.006)**	0.000 – 0.023
Mother's BMI: underweight[Ref: Normal weight]	−0.124 (0.063)*	−0.248 – 0.000	−0.233 (0.062)***	−0.355 – −0.111
Mother's BMI: overweight[Ref: Normal weight]	−0.003 (0.041)	−0.084 – 0.078	0.189 (0.041)***	0.110 – 0.269
Mother's BMI: obesity[Ref: Normal weight]	0.043 (0.060)	−0.074 – 0.160	0.339 (0.059)***	0.223 – 0.454
Per capita expenditure (ln)	0.146 (0.028)***	0.090 – 0.202	0.068 (0.028)**	0.013 – 0.123
Community Level				
Community education (Years)	0.022 (0.012)*	−0.002 – 0.045	0.010 (0.012)	−0.013 – 0.034
Community per capita expenditure (ln)	0.015 (0.035)	−0.053 – 0.083	0.026 (0.035)	−0.043 – 0.094
Urban[Ref: Rural]	0.089 (0.045)**	0.001 – 0.177	−0.003 (0.046)	−0.093 – 0.086
Year 2014[Ref: year 2007]	−0.008 (0.006)	−0.020 – 0.004	−0.023 (0.006)***	−0.035 – −0.011
Constant	9.839 (12.07)	−13.81 – 33.49	43.783 (12.30)***	19.671 – 67.900
Observations	7,583		7,583	
Number of groups (community)	2,022		2,022	
Number of groups (household)	6,837		6,837	
LR test vs. linear model	46.30		63.62	
Prob > chi2	(0.000)		(0.000)	
LR test vs. null model	489.66		229.57	
Prob > chi2	(0.000)		(0.000)	

HAZ and WHZ scores are measured in β: regression coefficients; SE: standard error; Ref: reference category; WASH: water, sanitation, and hygiene; BMI: body mass index; ln: natural logarithm; and LR: likelihood ratio. *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$

violation of the assumption of data independence, which results in erroneous standard errors and significance tests.[22]

DISCUSSION

This study determines that some of the WASH variables are associated with children's health, specifically the HAZ score. Improved sanitation at the household level is significantly associated with higher HAZ scores, demonstrating its role in preventing diseases that impair nutritional growth. However, no significant association was identified between WASH variables and WHZ scores, implying that WASH impacts may manifest more in long-term than short-term health outcomes. implying that WASH impacts may manifest more in long-term than short-term health outcomes.

The findings align with previous observations, indicating a significant association between improved sanitation at the household level and children's HAZ.[10,23] Moreover, improved sanitation prevents diarrhea, active trachoma, certain soil-transmitted helminth infections, and schistosomiasis,[24] which are pathways that can lead to disturbed nutritional growth.[3] Prior research in the WASH-health domain often emphasized the impact of community-level sanitation on community-level water sources.[23,25,26]

However, our study reveals that improved water coverage, rather than improved sanitation coverage, is significantly positively correlated with children's height. This finding is consistent with other studies,[27,28] suggesting positive externalities generated by improved water sources. As improved water coverage increases, overall community pathogen levels may decrease, thus reducing contamination.[27] Study of Reese *et al*. in India determined that the influence of improved water coverage extends to children's anthropometry through household sanitation.[26]

TABLE 3. Association between access to water and sanitation and children's height-for-age (HAZ) and weight-for-height (WHZ) scores: Ordinary least squares regression analysis

Variables	HAZ	WHZ
	β (SE)	β (SE)
Improved water[Ref: Unimproved]	0.119 (0.134)	−0.092 (0.132)
Improved sanitation[Ref: Unimproved]	0.168 (0.048)***	−0.045 (0.047)
Improved water coverage (%)	0.005 (0.002)**	0.002 (0.002)
Improved sanitation coverage (%)	0.000 (0.001)	0.001 (0.001)
Age (Years)	−0.010 (0.001)***	−0.007 (0.001)***
Girl[Ref: Boy]	0.097 (0.034)***	0.004 (0.033)
Birth weight (Kilograms)	0.347 (0.028)***	0.217 (0.028)***
Full immunization[Ref: Not full]	0.051 (0.037)	0.014 (0.036)
Boil water[Ref: Not boil]	0.101 (0.038)***	0.007 (0.038)
Mother's education (Years)	0.031 (0.006)***	0.012 (0.006)**
Mother's BMI: underweight[Ref: Normal weight]	−0.123 (0.063)**	−0.255 (0.062)***
Mother's BMI: overweight[Ref: Normal weight]	−0.002 (0.041)	0.184 (0.040)***
Mother's BMI: obesity[Ref: Normal weight]	0.049 (0.059)	0.337 (0.058)***
Per capita expenditure (ln)	0.148 (0.028)***	0.066 (0.028)**
Community education (Years)	0.020 (0.011)	0.011 (0.011)
Community per capita expenditure (ln)	0.022 (0.032)	0.024 (0.032)
Urban[Ref: Rural]	0.078 (0.040)*	−0.002 (0.040)
Year 2014[Ref: year 2007]	−0.009 (0.006)	−0.025 (0.005)***
Constant	11.584 (10.93)	47.244 (10.78)***
Observations	7,583	7,583
R-squared	0.069	0.029

HAZ and WHZ scores are measured in β: regression coefficients; SE: standard error; Ref: reference category; WASH: water, sanitation, and hygiene; BMI: body mass index; and ln: natural logarithm. *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$

By contrast, none of the WASH variables are significantly related to WHZ. This result aligns with previous studies[29,30] and might indicate that WASH variables affect children's health more on the long-term [31] rather than a short-term basis, as reflected by WHZ.[32] However, caution is warranted, as research in sub-Saharan Africa[33] and Cambodia[34] identified a significant relation between WHZ and WASH interventions. This discrepancy implies that our study might be overlooking certain confounding variables, such as children's dietary intake or personal hygiene, or that the outcome result might be underestimated.

According to Richard and others, decreases in HAZ and WHZ overall distribution among children as they get older suggests that they are not growing to their full capability, as is often the case for children in developing countries.[35] Furthermore, the study underscores the strong association between birth weight and children's anthropometrics (i.e, HAZ and WHZ), echoing earlier findings.[36] The prenatal environment, as represented by birth weight, emerges as a pivotal predictor of children's nutrition.[36] Another significant individual factor is the child's gender, as girls are generally taller than boys. This finding supports Thurstan and others' claim that boys are relatively more vulnerable to undernutrition than girls.[37] Moreover, children who reside in urban areas are reportedly taller than those who live in rural areas. Similarly, as the average educational attainment in the community increases, so does the children's height.

The household practice of boiling water to treat contaminated water is significantly related to HAZ, which aligns with findings from Cousens' study of Sri Lanka.[38] The mother's education also is crucial to children's anthropometry. This supports Glewwe's work and suggests that education contributes to the mother's knowledge of health and indirectly influences the child's nutritional status. The effect of the mother's BMI on the child's health, expected because of its representation of genetic factors and household lifestyle, is significant for WHZ. This association is highly linked to dietary intake and recurrent disease episodes.[35] The relationship indicates that when the mother is underweight, the WHZ of her children is lower than that of children whose mothers have a healthy weight. The coefficient increases as the mother's weight category inclines toward overweight and obese. However, the year 2014 variable shows that children's WHZ in 2014 were lower than children's WHZ in 2007. While it might indicate possible infectious diseases and a persistent lack of nutritional intake,[40] the variable also suggests that there are differences between the two-time frames of the data, which might be a result of natural changes in the circumstances over time.

However, this study encountered some limitations. First, one of the WASH components, personal hygiene, had to be left out because of the limitation of the IFLS. Including it would have further substantiated the association between WASH and nutrition. Second, apart from personal hygiene, this research might be overlooking some noteworthy determinants of children's anthropometrics, for instance, dietary intake, which might result in an underestimated outcome. Third, this study is cross-sectional, so a causal relationship between the outcome and the explanatory variables cannot be inferred. Finally, the datasets were constructed in 2007 and 2014, which might reflect a circumstance different from the current situation, especially after the COVID-19 pandemic.

Multilevel interventions targeting specific audiences are crucial, and promoting education, especially for women, fosters better child nutrition practices. Future research could use panel data to explore the causal relationships between WASH variables and children's anthropometry to enhance the understanding of their causality. Comprehensive inclusion of WASH variables, such as hygiene practices, is essential for a comprehensive exploration of this subject.

CONCLUSIONS

This study contributes to explaining the urgency of access to improved water and sanitation, especially at different levels (individual, household, and community) in Indonesia. The findings of this study fill a research gap in children's anthropometrics by adjusting the individual, household, and community-level factors in Indonesia, which might open new avenues for future research. Moreover, this study underscores the need for governments to prioritize improving water sources and sanitation facilities to alleviate the health burden of inadequate drinking water and sanitation. Furthermore, exploring the implications of our findings in the current situation, particularly in the post-COVID-19 era, is essential for informing policy decisions and interventions to address the health challenges that children face.

CONFLICT OF INTEREST

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Exploring Overactive Bladder Symptoms in Premenopausal and Postmenopausal Women: A Comparative Cross-Sectional Study

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Exploring Overactive Bladder Symptoms in Premenopausal and Postmenopausal Women: A Comparative Cross-Sectional Study

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Abstract

Background: Overactive bladder syndrome affects millions globally. It can intermittently cause urinary incontinence, which can significantly diminish the quality of life. This study investigated overactive bladder symptoms in premenopausal and postmenopausal individuals by analyzing the influence of demographic, gynecological, and obstetric factors.

Methods: This single-center prospective cross-sectional study was conducted between September 1 and November 1, 2023, among premenopausal and postmenopausal women. In total, 244 patients meeting the inclusion criteria were selected using a simple random method. Participants were asked to complete an information collection form, and the Turkish version of the Overactive Bladder-V8 questionnaire was administered. A significance level of $p < 0.05$ was considered.

Results: Individuals with an overactive bladder were older (mean age, 46.14 ± 14.56) and had a higher body mass index (mean, 28.47 ± 6.02) than healthy individuals ($p = 0.013$, $p < 0.001$, respectively). No significant difference in menopausal status was found ($p = 0.091$). Urinary incontinence was significantly higher in the overactive bladder group (63.6% vs. 17.4%, $p < 0.001$). The number of vaginal deliveries and prior gynecologic surgeries differed significantly between the groups ($p = 0.030$, $p = 0.001$, respectively).

Conclusions: Age, higher body mass index, vaginal childbirth, and history of gynecological surgeries are associated with overactive bladder frequency, whereas menopausal status did not exert a significant effect.

Keywords: menopause, postmenopause, premenopause, urinary bladder, urinary incontinence

INTRODUCTION

Overactive bladder (OAB), as defined by the International Continence Society (ICS), is characterized by symptoms such as frequent urination, nocturia, and a sudden urge to urinate in the absence of an underlying infection or pathological cause. It can intermittently lead to symptoms such as urinary incontinence (UI), negatively affecting the quality of life.[1] OAB has affected millions of people worldwide.[2,3] One of the largest population-based studies on lower urinary tract symptoms (LUTS) and OAB, conducted in five countries with over 19,000 participants, revealed an overall prevalence of OAB symptoms of 11.8% (men, 10.8%; women, 12.8%).[3]The consequences of OAB, including UI, negatively affect the quality of life for affected individuals.[4] Despite the limited number of studies on OAB prevalence in Turkey, one study reported a prevalence of 20.6% of OAB in women. The same study identified age and parity as risk factors for OAB.[5]

Although distinguishing between the effects of aging and declining estrogen levels during menopause poses a challenge, pelvic organs and their supportive muscular and connective tissues respond to estrogen. Epidemiological studies underscore menopause as a critical risk factor for the development of pelvic floor disorders, with urinary symptoms and their severity markedly increasing post-menopause.[6] Furthermore, postmenopausal women frequently exhibit decreased bladder capacity, weakened detrusor muscle function, and slower urine flow rates.[7] Nevertheless, research on the effect of menopause on OAB yields varying results. Zhu *et al*. suggested a close association between menopausal symptoms and OAB, proposing a higher prevalence of OAB in women experiencing severe menopausal symptoms.[8] However, a meta-analysis of risk factors for OAB concluded that menopause did not affect the OAB risk.[9]

In this study, we aimed to investigate OAB symptoms in both premenopausal and postmenopausal individuals

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and assess demographic, gynecological, and obstetric factors influencing these symptoms.

METHODS

This single-center prospective cross-sectional study was conducted between September 1, 2023, and November 1, 2023, among premenopausal and postmenopausal women presenting for any reason to the gynecology and obstetrics outpatient clinic of a training and research hospital. The study received ethical approval from the University Hospital's Medical Ethics Committee on July 21, 2023 (Decision no. 2023/14–13) and was conducted in accordance with the principles outlined in the Declaration of Helsinki.

Of the 600 patients attending the gynecology and obstetrics outpatient clinic over 2 months, a minimum sample size of 235 individuals was determined for the study population for a 95% confidence level with a confidence interval of α = 0.05. In total, 244 patients meeting the inclusion criteria were selected using a simple random method, provided with information about the study, and included after obtaining verbal and written consent. In this study, women still experiencing menstrual cycles were classified as premenopausal, whereas women who had been amenorrheic for a minimum of 12 months without psychological or pathological reasons were considered postmenopausal.[8] This study was conducted on volunteer women who applied for any reason to the gynecology and obstetrics outpatient clinic. The exclusion criteria were as follows: malignancies, dementia, pregnancy, illiteracy, inability to speak the Turkish language, diuretics, and anticholinergic drugs. Women who had a history of urogynecologic surgery such as pelvic organ prolapse surgery and anti-incontinence procedures were also excluded.

Participants were asked to fill out an information collection form, which included questions about age, marital status, educational background, obstetric and gynecological characteristics, chronic diseases, and smoking status. Subsequently, the Turkish version of the Overactive Bladder-V8 (OAB-V8) questionnaire was administered. The OAB-q, developed by Coyne *et al*., is designed to assess individuals' OAB symptoms.[10] Subsequently, in later research, a shorter form called OAB-V8 was developed.[11] Tarcan *et al*. conducted a Turkish validation and reliability study for OAB-V8. The OAB-V8 questionnaire consists of eight questions, allowing patients to rate the severity of their complaints as follows: none = 0, very little = 1, a little = 2, quite a bit = 3, a lot = 4, and very much = 5. The total score can range from 0 to 40. Individuals scoring >11 points may be indicative of OAB.[12]

Demographic information questions such as marital status, smoking habits, and body mass index (BMI) classification, along with responses to these questions, are depicted using numerical (n) and percentage (%) values to illustrate the distribution of individuals. In this study, continuous variables' normal distribution suitability was assessed graphically and through the Shapiro–Wilk test. None of the continuous variables followed a normal distribution. Descriptive statistics for the variables were presented as means ± standard deviations (SD) and median (minimum–maximum) values. The Mann–Whitney U test was employed for the comparison of age, BMI, total number of pregnancies, total number of deliveries, number of vaginal deliveries, number of cesarean deliveries, number of pregnancies resulting in miscarriage, and number of induced abortion cases according to the OAB-V8 classification. According to the OAB-V8 classification, cross-tabulations were created for the comparison of categorical variables, providing the number (n), percentage (%), and chi-square (χ^2) test statistics. IBM SPSS Statistics for Windows version 21.0 (IBM Corp., Armonk, NY, USA) and MS Excel 2007 were utilized for statistical analyses and calculations. A $p < 0.05$ was considered significant.

RESULTS

The mean age of the participants was 43.04 ± 13.84 years (minimum and maximum of 18.0 and 75.0, respectively). The average BMI was 26.27 ± 5.47 kg/m². Regarding BMI classification, 4.1% (N = 10) of the participants were underweight, 38.1% (N = 93) were normal weight, 34.4% (N = 84) were overweight, and 23.4% (N = 57) were obese. Regarding marital status, 63.9% (N = 156) of participants were married, 23.4% (N = 57) were single, and 12.7% (N = 31) were widowed/divorced.

According to the Turkish version of the OAB-V8, individuals scoring >11 points are classified as having OAB, whereas those scoring ≤11 points are categorized as normal. According to the OAB-V8 classification, the average age of the normal group was 41.61 ± 13.29 years, whereas the OAB group had an average age of 46.14 ± 14.56 years. A significant difference in age values was found between the normal and OAB groups ($p = 0.013$). The average BMI of the normal group was 25.26 ± 4.88, whereas that of the OAB group was 28.47 ± 6.02 ($p < 0.001$). The comparison of participants' demographic data according to the OAB-V8 classification is shown in Table 1. Based on the OAB-V8 classification, no significant differences were identified concerning menopausal status ($p = 0.091$). The comparison of participants' menopausal statuses according to the OAB-V8 classification is presented in Table 1.

According to the OAB-V8 classification, 17.4% of the participants who had normal OAB scores (N = 29) had complaints of UI, and 63.6% who had high OAB scores (N = 49) had complaints of UI. A significant difference has been observed in the distribution of responses to the

question, "Do you have complaints of urinary incontinence?" (p < 0.001). Table 2 presents the comparison of participants' gynecological and UI-related characteristics according to the OAB-V8 classification.

In the OAB-V8 classification, the normal group exhibited a median value of 0.0 for the number of vaginal deliveries, whereas the OAB group had a median of 1.0. A significant difference in terms of the number of vaginal deliveries has been detected based on the OAB-V8 classification (z = 2.169, p = 0.030). In addition, a significant difference has been noted in the number of pregnancies resulting in miscarriage according to the OAB-V8 classification (z = 1.986, p = 0.047). The median value for pregnancies resulting in miscarriage was 0.0 for both normal and OAB groups, with a range of 0–4 in the normal group and 0–3 in the OAB group. Table 3 displays the comparison of participants' obstetric histories in accordance with the OAB-V8 classification.

DISCUSSION

Awareness of the effect of OAB on the quality of life is crucial to understanding the necessity of appropriate healthcare services. Despite significantly affecting their quality of life, many individuals do not seek treatment for OAB.[13] Considering the millions of people worldwide suffering from OAB[3], further research is needed on OAB and the factors influencing it. Various opinions have been presented regarding the prevalence of OAB in women. Inthe study by Sheikh *et al*. study in Pakistan, the OAB prevalence was 10.2%,[14] whereas in the study by Tikkinen *et al*. in Finland, it was 9.3%.[15] Safarinejad *et al*. reported a prevalence of 18.2% in their study conducted in Iran.[16]

TABLE 1. Comparison of the demographic data of participants and participants' menopausal status according to the Overactive Bladder-V8 classification

Variable	Total participants (N = 244)	Normal group (N = 167)	OAB group (N = 77)	p
	N (%)	N (%)	N (%)	
Age (years)				
Mean ± SD	43.04 ± 13.84	41.61 ± 13.29	46.14 ± 14.56	0.013*
Median (min–max)	44.0 (18–75)	42.0 (18–75)	48.0 (20–73)	
BMI (kg/m^2)				
Mean ± SD	26.27 ± 5.47	25.26 ± 4.88	28.47 ± 6.02	<0.001*
Median (min–max)	25.6 (16.6–42.2)	25.0 (16.6–40.0)	27.5 (18.3–42.2)	
BMI Classification				
Underweight	10 (4.1)	9 (5.4)	1 (1.2)	0.002*
Normal	93 (38.1)	74 (44.3)	19 (24.7)	
Pre-obese	84 (34.4)	54 (32.3)	30 (39.0)	
Obese	57 (23.4)	30 (18.0)	27 (35.1)	
Marital status				
Married	156 (63.9)	107 (64.1)	49 (63.6)	0.048*
Single	57 (23.4)	44 (26.3)	13 (16.9)	
Widowed/divorced	31 (12.7)	16 (9.6)	15 (19.5)	
Chronic disease				
No	157 (64.3)	125 (74.9)	32 (41.6)	<0.001*
Diabetes mellitus	21 (8.6)	10 (6.0)	11 (14.3)	
Hypertension	24 (9.8)	13 (7.8)	11 (14.3)	
Endocrine diseases	15 (6.1)	8 (4.8)	7 (9.1)	
Asthma/COPD	8 (3.3)	2 (1.2)	6 (7.7)	
Others	19 (7.8)	9 (5.3)	10 (13.0)	
Smoking				
No	146 (59.8)	100 (59.9)	46 (59.7)	0.322
Yes	81 (33.2)	58 (34.7)	23 (29.9)	
Quit	17 (7.0)	9 (5.4)	8 (10.4)	
Menopause				
No	164 (67.2)	118 (70.7)	46 (59.7)	0.091
Yes	80 (32.8)	49 (29.3)	31 (40.3)	
If yes, how many years have you been in menopause?				
Mean ± SD	9.50 ± 8.62	8.77 ± 8.23	10.59 ± 9.19	0.391
Median (min–max)	6.0 (0.0–30.0)	5.5 (1.0–30.0)	6.5 (0.0–29.0)	

Mann–Whitney U test statistics and Chi-square test statistics were employed accordingly. *p < 0.05
BMI: body mass index; COPD: chronic obstructive pulmonary disease.

TABLE 2. Comparison of participants' urinary incontinence and gynecological features according to the Overactive Bladder-V8 classification

Participants' urinary incontinence and gynecological features	Total participants (N = 244)	Normal group (N = 167)	OAB group (N = 77)	*p*
	N (%)	N (%)	N (%)	
Do you have a history of hysterectomy or gynecologic surgery				
No	198 (81.1)	145 (86.8)	53 (68.8)	0.001*
Yes	46 (18.9)	22 (13.2)	24 (31.2)	
Do you have complaints of uterine prolapse?				
No	232 (95.1)	163 (97.6)	69 (89.6)	0.011*
Yes	12 (4.9)	4 (2.4)	8 (10.4)	
Do you have complaints of urinary incontinence?				
No	166 (68.0)	138 (82.6)	28 (36.4)	<0.001*
Yes	78 (32.0)	29 (17.4)	49 (63.6)	
If you experience urinary incontinence, how does it happen?				
Coughing, sneezing, lifting heavy objects (stress incontinence)	32 (41.0)	17 (58.6)	15 (30.6)	
Sudden urge to urinate and cannot reach the toilet in time (urge incontinence)	12 (15.4)	4 (13.8)	8 (16.3)	0.043*
I experience urinary incontinence in both ways (mixed incontinence)	34 (43.6)	8 (27.6)	26 (53.1)	
Do you urinate at night?				
No	88 (36.1)	78 (46.7)	10 (13.0)	
I urinate once at night	92 (37.7)	67 (40.1)	25 (32.5)	<0.001*
I urinate twice at night	44 (18.0)	20 (12.0)	24 (31.2)	
I urinate three or more times at night	20 (8.2)	2 (1.2)	18 (23.3)	
Have you consulted a doctor for complaints of urinary incontinence before?				
No	216 (88.5)	164 (98.2)	52 (67.5)	<0.001*
Yes	28 (11.5)	3 (1.8)	25 (32.5)	
Have you experienced urinary incontinence during sexual intercourse?				
No	235 (96.3)	165 (98.8)	70 (90.9)	0.005*
Yes	9 (3.7)	2 (1.2)	7 (9.1)	
Have you been diagnosed with an overactive bladder before?				
No	230 (94.3)	165 (98.8)	65 (84.4)	<0.001*
Yes	14 (5.7)	2 (1.2)	12 (15.6)	
Do you have a history of difficult births?				
No	206 (84.4)	151 (90.4)	55 (71.4)	<0.001*
Yes	38 (15.6)	16 (9.6)	22 (28.6)	
Do you have a history of bladder prolapse?				
No	233 (95.5)	163 (97.6)	70 (90.9)	0.026*
Yes	11 (4.5)	4 (2.4)	7 (9.1)	

Mann–Whitney U test statistics and Chi-square test statistics were employed accordingly. *p <0.05.

According to the study by Al Edwan *et al*. in different countries, approximately 50% of women aged >40 years exhibited OAB symptoms.[17] In the present study, the prevalence of OAB was 31.5%, and the difference from other studies may be attributed to variations in the ages of participants, racial differences, or application method of the survey.[18] In addition, 84.4% of the individuals in the OAB group, according to the OAB-V8 classification, were not previously diagnosed with OAB. This highlights a lack of awareness regarding OAB, a condition that significantly affects the quality of life.

The relationship between age and OAB showed variations in studies available in the literature. Wen *et al*. demonstrated an increase in OAB prevalence with age in their studies.[19] According to the results of a meta-analysis conducted by Zhu *et al*., an increase in age was associated with increased OAB risk.[9] In contrast, in the study by Lingping Zhu *et al*., no significant difference in age was found between individuals with and without OAB.[8] In the present study, a significant age difference was found between individuals with and without OAB. Owing to changes in the pelvic floor and bladder associated with aging,[20] an increase in OAB with age was plausible. Wen *et al*. demonstrated a higher prevalence of OAB in individuals with BMI >29 kg/m^2.[19] In the study by Yang *et al*., the prevalence of OAB associated with UI in middle-aged women with a BMI of ≥27 kg/m^2 was 1.5 times higher

TABLE 3. Comparison of participants' obstetric histories according to the Overactive Bladder-V8 classification

Participants' obstetric histories	Total participants (N = 244)	Normal group (N = 167)	OAB group (N = 77)	*p*
Total number of pregnancies				
Mean ± SD	1.97 ± 3.26	1.91 ± 1.88	2.09 ± 1.64	0.229
Median (min–max)	2.0 (0.0–11.0)	2.0 (0.0–11.0)	2.0 (0.0–7.0)	
Total number of deliveries				
Mean ± SD	1.61 ± 1.48	1.54 ± 1.53	1.78 ± 1.38	0.083
Median (min–max)	2.0 (0.0–11.0)	2.0 (0.0–11.0)	2.0 (0.0–6.0)	
Number of vaginal deliveries				
Mean ± SD	1.23 ± 1.51	1.12 ± 1.53	1.47 ± 1.45	0.030
Median (min–max)	1.0 (0.0–11.0)	0.0 (0.0–11.0)	1.0 (0.0–6.0)	
Number of cesarean Section deliveries				
Mean ± SD	0.39 ± 0.76	0.42 ± 0.77	0.31 ± 0.73	0.191
Median (min–max)	0.0 (0.0–3.0)	0.0 (0.0–3.0)	0.0 (0.0–3.0)	
Number of pregnancies resulting in miscarriage				
Mean ± SD	0.25 ± 0.61	0.29 ± 0.64	0.17 ± 0.55	0.047
Median (min–max)	0.0 (0.0–4.0)	0.0 (0.0–4.0)	0.0 (0.0–3.0)	
Number of induced abortions				
Mean ± SD	0.11 ± 0.39	0.08 ± 0.34	0.17 ± 0.49	0.167
Median (min–max)	0.0 (0.0–2.0)	0.0 (0.0–2.0)	0.0 (0.0–2.0)	

Mann–Whitney U test statistics was employed. *p <0.05.

than those with BMI <24 kg/m^2.[18] In contrast, Lingping Zhu *et al*. did not find an association between BMI and OAB.[8] Our results align with the findings of Wen and Yang, as we observed a significantly higher BMI in the OAB group.

In a meta-analysis, Zhu *et al*. found that OAB symptoms were not influenced by marital status.[9] In contrast, Safarinejad indicated that being married was associated with OAB symptoms.[16] Yang observed that having a partner with OAB with UI was associated with developing OAB with UI.[18] Although we found a higher prevalence of OAB among married participants than single ones, the lack of partner inquiries in our study may be considered a limitation.

Brown *et al*. revealed that chronic conditions such as chronic obstructive pulmonary disease (COPD), a history of stroke, and diabetes mellitus (DM) are associated with UI.[21] Similarly, Kim *et al*. demonstrated that conditions such as DM, hypertension, and hyperlipidemia increase the prevalence of OAB.[22] In this study, a significant difference was identified in the distribution of chronic diseases according to the OAB-V8 classification. Upon examining the source of significance with post-hoc tests, the higher rates of DM, asthma/COPD, and other chronic diseases in the OAB group contributed to this significance compared with the normal group. Bladder ischemia and structural changes resulting from chronic diseases[23] might lead to OAB.

Kawahara *et al*. identified smoking as a risk factor for LUTS in their study, and quitting smoking led to improvement in urinary symptoms, particularly in younger participants.[24] In contrast, Zhu *et al*. did not consider smoking as a risk factor for OAB.[9] Our finding of the lack of significant difference between smoking status and OAB is consistent with the findings of Zhu *et al*.

Genitourinary menopause syndrome is a new terminology used for vulvovaginal atrophy and urinary symptoms that can occur together or independently.[25] A study conducted in Iran indicated a positive correlation between menopause and OAB.[16] In a study conducted in China, symptoms of menopause such as sexual problems, mood changes, and melancholy were associated with OAB; however, these issues may not solely be attributed to menopause.[8] Nagai *et al*. identified a relationship between postmenopausal status and OAB; however, in more comprehensive studies, a definitive link has not been established between postmenopausal status and OAB.[9] Although the prevalence of OAB in postmenopausal women was higher in the present study, no significant difference in OAB was observed between premenopausal and postmenopausal women. Vaginal estrogen therapy was found to be effective in improving urinary symptoms.[27] Baruch *et al*. demonstrated that improvement in symptoms with vaginal estrogen therapy was significantly higher in women who develop OAB symptoms after menopause than in those who had symptoms before menopause.[28]

Ninomiya *et al*. demonstrated that vaginal birth and cesarean section were risk factors for stress UI but were not risk factors for OAB.[29] In a review study, cesarean delivery was found to be associated with reduced risk of UI compared with vaginal delivery,[30] and another study argued that having ≥4 births increases UI symptoms[31]

Studies have suggested that cesarean delivery is more related to risk reduction for both stress incontinence and OAB than vaginal birth.[32] A meta-analysis examining OAB risk factors did not find a relationship between the number of pregnancies and vaginal deliveries with OAB.[9] In this study, a significant difference was found between number of vaginal deliveries and pregnancies resulting in miscarriage, according to the OAB-V8 classification, among groups with normal and OAB. However, no significant differences were found in the number of cesarean deliveries and total number of deliveries in both groups.

Brown *et al*. analyzed 7900 individuals and found that a history of hysterectomy was associated with UI[21], whereas Yang *et al*. revealed that a history of hysterectomy or oophorectomy was not associated with OAB.[18] In the present study, the OAB rate was higher in participants who answered affirmatively to the question, "Do you have a history of hysterectomy or gynecological surgery?" In this respect, our findings were consistent with those of Brown *et al*. Notably, the lack of inquiry into the vaginal component of surgery, both in the present study and in other studies, may be considered a limitation.

OAB occurring in conjunction with UI is referred to as "OAB_{wet}," and in the absence of UI, it is termed "OAB_{dry}."[33] In this study, of the 77 individuals classified as having OAB, 63.6% were considered to have OAB_{wet}, and 36.4% were evaluated as having OAB_{dry}. Irwin *et al*. demonstrated that approximately half of women exhibiting OAB symptoms experience some form of UI.[3]

Tikkinen *et al*. found urge UI in 27% of women with OAB,[15] whereas Sarici *et al*. reported that stress UI was more common in this study population.[5] In the present study, a significant difference was detected in the distribution of responses to the UI-type inquiry according to the OAB-V8 classification. When the source of significance was examined with post-hoc tests, mixed UI was found to be more prevalent in the OAB group than in the normal group, whereas stress UI was more common in the normal group.

Nocturia is cited as the most troubling symptom in the older population.[34] In the study by Irwin *et al*., in which nocturia was defined as voiding two or more times at night, the prevalence of nocturia in women was 24.0%.[3] Sheikh *et al*. reported that 27.6% of their patients voided two or more times at night.[14] Similarly, in the present study, 26.2% of the participants voided two or more times at night, similar to both studies. A significant difference was found in the distribution of responses to the question, "Do you urinate at night?" according to the OAB-V8 classification. In the analysis of significance with posthoc tests, the higher prevalence of individuals in the OAB group who responded, "I urinate twice at night" and "I urinate three or more times at night," contributed to the significance when compared with the normal group.

A study conducted in Poland found a low rate of seeking treatment for OAB and LUTS, and the possible reason could be shame or perception that this condition is a natural process that occurs with age. [35] In the present study, a significant difference was found in the distribution of responses to the question, "Do you have complaints of urinary incontinence?" However, only 35.9% (28/78) of the participants who reported experiencing UI had previously sought medical help for it. Participants might not have consulted a doctor because of common reactions to LUTS, such as embarrassment, discomfort, perceiving LUTS as a natural outcome of aging,[35] or the depression caused by LUTS.[36,37]

The main limitation of this study was the use of only the OAB-V8 questionnaire for the diagnosis of OAB. Studies diagnosing OAB based on urodynamic assessments could provide additional insights. Moreover, this was a single-center study with a small sample size. Despite these limitations, this study had some strengths. The results are supported by a comprehensive literature review, and detailed demographic, gynecological, and obstetric information about the participants has been collected. Considering the limited number of studies involving the Turkish population, the results of this study will guide future studies on the relationship between menopausal status and OAB.

CONCLUSIONS

The older and obese populations are increasing worldwide. In the coming years, urogynecological problems may emerge as a serious public health problem. Considering the scarcity of studies on the prevalence of OAB in our country, these studies may guide future health policies. According to the results of this study, menopausal status was not associated with the prevalence of OAB. However, this study found that OAB was associated with advanced age, increased BMI, parity, number of vaginal deliveries, and comorbidities. The awareness of OAB, which affects millions of women worldwide, and the development of new treatment strategies are of significant social and economic importance. More large-scale studies on the Turkish population are needed.

CONFLICT OF INTEREST

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Correlation Between Chemotherapy-Induced Nausea and Vomiting with Quality of Life in Patients with Ovarian Cancer at Dr. Cipto Mangunkusumo Hospital

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Correlation Between Chemotherapy-Induced Nausea and Vomiting with Quality of Life in Patients with Ovarian Cancer at Dr. Cipto Mangunkusumo Hospital

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Abstract

Introduction: Nausea and vomiting (NV) remain as side effects of chemotherapy, which has a detrimental effect on patients' quality of life (QOL) and treatment adherence. This study aimed to determine the effect of chemotherapy-induced NV (CINV) on the QOL of patients with ovarian cancer treated with chemotherapy at Dr. Cipto Mangunkusumo Hospital (CMH).

Methods: We conducted a cross-sectional study in patients with ovarian cancer receiving first-line chemotherapy regimens of carboplatin and paclitaxel. The European Organisation for Research and Treatment helped translate the Quality-of-Life Questionnaire-OV28 (QLQ-OV28) into Indonesian and tested it in a preliminary study. The approved Indonesian version of the QLQ-OV28, with the Quality-of-Life Questionnaire-C30 (QLQ-C30), was then used to evaluate QOL before and 1 week after chemotherapy.

Results: Several symptom scales increased, whereas function scales decreased. Moreover, 72.5% had an increase in the NV symptom scale, whereas 67.5% had a decrease in patients' scale after chemotherapy. CINV had a significant partial effect on reducing QOL (p = 0.047 and y = 12.208–0.432).

Conclusions: CINV has a significant influence on lowering the QOL of patients with ovarian cancer undergoing first-line chemotherapy regimens with carboplatin and paclitaxel in CMH.

Keywords: chemotherapy, Indonesia, ovarian neoplasms, quality of life

INTRODUCTION

In the 21st century, cancer is expected to be the primary factor responsible for mortality and presents as an essential obstacle to improving life expectancy.[1] In 2018, ovarian cancer was the seventh most common cancer in women, accounting for 295,414 cases (3.4% of all cancer diagnoses in women) and 184,799 deaths (4.4% of all women's cancer-related deaths). Among Southeast Asian countries, Indonesia accounts for approximately 50% of the incidence and mortality.[1] Despite these, various studies have shown a reduction in mortality and morbidity rates and improved quality of life (QOL) due to factors such as the approach of cytoreductive surgery followed by chemotherapy, an increase in the proportion of patients who received definitive treatment, use of less toxic analogs of platinum-based therapy (carboplatin), and adoption of targeted therapy in advanced-stage ovarian cancer.[2] In Dr. Cipto Mangunkusumo Hospital (CMH), 1,062 chemotherapy sessions were performed for patients with ovarian cancer who received adjuvant chemotherapy between November 2018 and November 2019.[3] Chemotherapy uses chemicals or cytotoxic drugs to stop the proliferation of rapidly dividing cells (e.g., cancer cells) to halt its growth and prevent its spread.[4] However, cytotoxic drugs in patients with ovarian cancer, such as carboplatin and paclitaxel, have severe side effects because of their effects on healthy cells, such as blood components, gastrointestinal (GI) mucosa, and hair roots.[3,5] Carboplatin is a cytotoxic drug with hematological side effects in thrombocytopenia (16%) and leukopenia (10%). In addition, it has non-hematological side effects such as nausea and vomiting (NV, 9%) and alopecia (4%). Meanwhile, paclitaxel exerts hematological side effects, such as granulocytopenia (96%), and non-hematological side effects, such as NV (10%).[6]

GI side effects have been a significant problem because chemotherapy is first used to treat cancer.[7] The symptoms of GI toxicity include NV, constipation, diarrhea, abdominal pain, bloating, and weight loss.[8] Approximately 60%–100% of patients on high-dose chemotherapy will experience GI side effects.[8] Abola *et al*.[9]

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emphasized the importance of the GI toxicity effect of chemotherapy by treating 10% of the GI toxicity effect, resulting in an increase in progression-free survival by 3.4% (p = 0.007) but not in overall survival. GI toxicity also affects QOL. Börjeson *et al*.[10] found that the intensity and duration of NV disrupt patients' QOL. The study also revealed that a simple drug such as ondansetron has been proven to reduce the incidence and intensity of acute nausea. Still, it cannot reduce the duration of NV.[10] The side effects of chemotherapy-related NV are known as chemotherapy-induced NV (CINV).[7] CINV can reduce QOL, disrupt treatment schedules, reduce adherence rates, and cause medical complications. Bezjak *et al*.[11] described impaired QOL by CINV using the Quality of Life Questionnaire-C30 (QLQ-C30) issued by the European Organization for Research and Treatment of Cancer (EORTC). The study revealed that the QOL decreased by 9.3 points in the cyclophosphamide plus cisplatin (CP) group and 9.8 points in the paclitaxel plus cisplatin (TP) group since the first cycle along with the highest increase in the incidence of NV from the baseline compared with subsequent cycles (24.8 points for the CP group and 22.4 points for the TP group). Haiderali *et al*.[12] used the Functional Living Index-emesis and found that 37.2% of patients reported a reduction in daily functioning and 90% of those with inadequate CINV management reported a significant reduction in daily functioning.

The EORTC QLQ-C30, a widely utilized questionnaire for assessing the QOL of patients with cancer, examines functional domains (such as physical, emotional, and role functioning) and cancer-related symptoms (including NV, pain, and fatigue).[13] The EORTC QLQ-OV28 is designed to complement the QLQ-C30 as an additional module to increase the sensitivity of the health-related QOL assessment for patients with ovarian cancer.[14] The QLQ-C30 has been validated in Indonesian.[15] However, the QLQ-OV28 has not been validated in Indonesian.

Although newer antiemetic drugs are available, CMH continues to administer basic antiemetics such as ondansetron, ranitidine, dexamethasone, and diphenhydramine since the inception of its chemotherapy services for ovarian cancer. This protocol persists owing to the limited drug options covered by the Indonesian Social Security Agency. Currently, data on the QOL of patients with ovarian cancer receiving adjuvant chemotherapy and those experiencing CINV in CMH and across Indonesia are insufficient. Consequently, evaluating and comparing these protocols with others is challenging. Thus, this study aimed to assess the effect of CINV on the QOL of patients with ovarian cancer undergoing chemotherapy at CMH and validate the Indonesian version of the EORTC QLQ-OV28.

METHODS

Ethical approval

The ethical approval to conduct this study was obtained from the Faculty of Medicine, Universitas Indonesia Health Research Ethics Committee (4428.UN2.F1/ETIK/PPM.00.02/2021).

Development of the Indonesian version of QLQ-OV28

The translation of the QLQ-OV28 took place from February to April 2021, which consisted of its translation from English to Indonesian and pilot testing.

The translation process for the new language version of the EORTC QLQ-OV28 began with an application to the EORTC Translation Unit (TU) in Belgium. The TU confirmed that no questionnaires existed or is being developed and prepared a translation package. Two native speakers of the target language translated the English version, and a reconciled translation was created. The EORTC reviewed and combined the translations for accuracy.[16]

Two native speakers translated the English questionnaire into Indonesian, and a reconciled translation was created from these versions. The EORTC reviewed and combined the translations for the best version based on accuracy and wording. Then, two translators with excellent English skills retranslated the reconciled version into English. All processes (forward translation, reconciliation, and backward translation) were reported to the TU, including comments on the reconciliation.[16]

The report was reviewed, issues resolved, and the initial translation was proofread by an external proofreader. All suggestions were discussed until a consensus was reached. Then, the translated version was subjected to linguistic validation through pilot testing, in which the translated EORTC OV-28 questionnaire was tested on 10 patients, who provided feedback on their understanding. All comments were summarized in a pilot testing report submitted to the TU. The TU then finalized the translation and closed the process.[16] The characteristics of the phase 1 sample are provided in Supplementary Table 1. The preliminary study indicated that items related to "sex activity," "passing gas," and "weakness in arms and legs" needed adjustments. These issues were resolved in the post-study discussion. In accordance with the EORTC translation protocol, a retest was not conducted because the post-study discussion resulted in unanimous understanding among all 10 patients.

Implementation of questionnaire

Data collection, data analysis, and statistical analysis were conducted from May to November 2021. Data were collected on the Indonesian EORTC OV-28 questionnaire from 40 patients with ovarian cancer before chemotherapy, excluding the 10 patients in the pilot test. Patients with ovarian cancer undergoing first-line

SUPPLEMENTARY TABLE 1. Phase 1 sample characteristics (N = 10)

Characteristics	N (%)
Age, mean (SD) years	49.9 (9.02)
Stage	
Early (1-II), n (%)	3 (30)
Advanced (III-IV), n (%)	7 (70)
History of surgery	
No history of surgery	1 (10)
Undergone surgery once	6 (60)
Undergone surgery twice	3 (30)
Undergone surgery more than two times	0 (0)
Performance Status (ECOG)	
0	10 (100)
1	0 (0)
2	0 (0)
3	0 (0)
Occupation	
Homemaker	7 (70)
Private employee	2 (20)
Researcher	1 (10)
Metastasis	
to upper gastrointestinal tract	0 (0)
to lungs	0 (0)
to brain	0 (0)
History of nausea and vomiting	
Yes	0 (0)
No	10 (100)

carboplatin and paclitaxel chemotherapy at CMH were included. Patients with chronic diseases, mental illness, psychotropic medication, and previously treated GI disease were included. A thorough history, physical examination, and laboratory tests ensured criteria fulfillment. The Indonesian version of the QLQ-C30[15] and QLQ-OV28 were completed before and 1 week after chemotherapy during control visits at the Gynaecologic Oncology Clinic.

The questionnaires were collected, and raw scores (RS) and scale scores (S) were calculated using EORTC QLQ-C30 and QLQ-OV28 formulas, values before and after chemotherapy were compared. The RS, an average of each item contributing to the scale, was calculated first. This RS was then used in the linear transformation of the functional scale, item scale/symptoms, and global health status/QOL. These calculations were performed to descriptively analyze function, symptom, and QOL scales.

RS was calculated with the following formula:

$$\text{Raw score} = RS = (I1 + I2 + I3 + .In)/n \quad (1)$$

I = value for each question item; n = number of question items.

The second stage involved linear transformation of the functional scale, item/symptom scale, and global health status/QOL. It was standardized for hospitals; thus, the scale score range ranged from 0 to 100. The three equations used for each scale are as follows.

Scoring system for the EORTC QLQ-C30:

Raw score

$$RS = \left\{\frac{(I_1 + I_2 + \ldots + I_n)}{n}\right\} \quad (2)$$

Linear transformation

Functional scales:

$$S = \left\{1 - \frac{(RS - 1)}{range}\right\} \times 100 \quad (3)$$

Symptom scale/items:

$$S = \left\{\frac{(RS - 1)}{range}\right\} \times 100 \quad (4)$$

Global health status/QOL:

$$S = \left\{\frac{(RS - 1)}{range}\right\} \times 100 \quad (5)$$

Scoring system at the EORTC QLQ-OV28:

Raw score

$$RS = \left\{\frac{(I_1 + I_2 + \ldots + I_n)}{n}\right\} \quad (6)$$

Linear transformation

Symptom scale/items:

$$S = \left\{\frac{(RS - 1)}{range}\right\} \times 100 \quad (7)$$

Statistical analysis

Statistical validity and reliability tests of the Indonesian version of the EORTC QLQ-OV28 filled before chemotherapy were performed using Pearson's and Cronbach's alpha. The questionnaire results were also analyzed using a simple linear regression test on all symptom and functional scales. A simple linear regression test for bivariate analysis was performed, followed by multivariate analysis using a multiple regression test. Statistical analysis was performed using IBM SPSS Statistics for Windows version 24.0. If the regression significance value is <0.05 and the t-count value >t-table (0.026), a significant relationship exists between the variables and QOL. The sample set for validity and reliability tests will be the same for the bivariate and multivariate analyses.

RESULTS

Sample characteristics

Between May and November 2021, 40 patient responses were received. The questionnaires were self-administered with a 100% response rate. Patients were free to ask questions if they did not understand. Moreover, 97.5% of the patients had an educational background, with the majority having graduated from senior high school (47.5%, N = 19), and one patient (2.5%) had no educational background but was literate. Most patients (85%, N = 34) have undergone at least one surgery for the primary treatment of ovarian cancer, whereas no patients underwent more than two surgeries, and 87.5% (N = 35) had an Eastern Cooperative Oncology Group (ECOG) status of 0, which indicated that most patients were fully active and could perform all activities before disease without restriction. An ECOG status of 1 (7.5%, N = 3) indicates the inability to perform strenuous activities but is still ambulatory, whereas an ECOG status of 2 (5%, N = 2) indicates that the patient is capable of self-care and ambulation but is incapable of performing any work activities.[17] No patients had an ECOG status >2. GI metastases were found in 10% (N = 4) of the cases, and a history of NV was found in 52.5% (N = 21). The characteristics of the phase 2 sample are shown in Table 1.

TABLE 1. Phase 2 sample characteristics (N = 40)

Characteristics	N (%)
Age, mean ± SD years	50 ±11
Stage	
Early (1–II)	5 (12.5)
Advanced (III–IV)	35 (87.5)
History of surgery	
No history of surgery	6 (15.0)
Undergone surgery once	27 (67.5)
Undergone surgery twice	7 (17.5)
Undergone surgery more than two times	0 (0)
Performance status (ECOG)	
0	35 (87.5)
1	3 (7.5)
2	2 (5)
3	0 (0)
Occupation	
Homemaker	25 (62.8)
Private employee	7 (17.5)
Pharmacist	1 (2.5)
Nurse	1 (2.5)
Retiree	4 (10.0)
Teacher	2 (5.0)
Metastasis	
to the upper gastrointestinal tract	4 (10.0)
to the lungs	5 (12.5)
to the brain	0 (0)
History of nausea and vomiting	
Yes	21 (52.5)
No	19 (48.5)

Validity and reliability test

For the 28 questions and answers of the EORTC QLQ-OV28 before chemotherapy, statistical validity and reliability tests were performed using Pearson's and Cronbach's alpha tests. Of the 28 questions, 25 were valid ($p < 0.05$ and R count > R table), whereas three questions (question nos. 38, 57, and 58 about symptoms of hair loss and sexual activity) were not valid ($p > 0$, 05 and R count < R table). This may be due to the small number of participants in this validity test, and 65.5% of the patients with ovarian cancer were not sexually active. Based on brief interviews, this occurred because of feelings of fear in 28% (N = 7), 24% were not interested in sex because of age factor (N = 6), and 48% were not married/divorced (N = 12). The results of the validity test are shown in Table 2. Good consistency was obtained with Cronbach's alpha of 0.881.

Results of EORTC QLQ C-30 and OV28

Tables 3 and 4 compare the symptom scale, function scale, and QOL before and after chemotherapy using the EORTC QLQ-C30 and EORTC QLQ-OV28. The GI symptom scale has the largest proportion (80%), followed by the NV symptom scale (72.5%). The largest proportion of changes in patients' QOL after chemotherapy is a decrease in QOL by 68%.

Bivariate and multivariate analysis

The results of a simple linear regression test between function and symptom scales on QOL are presented in Table 5. Based on Table 5, all symptom and function scales on the EORTC QLQ-C30 and EORTC QLQ-OV28 demonstrated a significant effect on QOL, except for symptoms of dyspnea, social function, symptoms of peripheral neuropathy, and sexual symptoms.

The relationship between CINV and QOL is significant based on a simple linear regression test ($p < 0.0001$, R square = 0.382 and y = 11.492–0.703x) and multiple linear regression test ($p < 0.047$ and y = 12.208–0.432). Because all symptom and function scales were significantly related with QOL, we determined which relationship partially affected QOL ($p < 0.05$). The partial relationship between the symptom and function scales on QOL is provided in Table 6. As shown in Table 6, NV, other chemotherapy side effects, and hormonal/menopausal symptoms have a significant partial effect on the QOL of the patients.

DISCUSSION

The cytotoxic effect of chemotherapy agents is caused by the stimulation of enteroendocrine cells in the GI mucosa that releases prostaglandins, 5-hydroxytryptamine (5-HT), cholecystokinin, and substance P, stimulating the vagal afferents to trigger emesis.[18] Antiemetics are used prophylactically to reduce the duration of NV.[10] In this study, patients were given 20 mg dexamethasone, 8 mg

ondansetron, and 150 mg ranitidine intravenously during chemotherapy, followed by 3 x 8 mg ondansetron and 2 x 150 mg ranitidine orally after chemotherapy session and returning home. Based on the results, 17.5% (N = 7) of the patients did not experience NV after chemotherapy. However, most patients (72.5%, N = 29) still experienced NV despite having been given prophylaxis.

Newer antiemetics, such as second-generation 5-HT3 receptor antagonists, D2/3 receptor antagonists, and NK-1 receptor antagonists, have shown advantages over existing antiemetic options and should be considered CINV prophylaxis.[19] Ondansetron, as a 5-HT3 receptor antagonist, was an effective antiemetic in patients receiving a cisplatin-based regimen and further

TABLE 2. Validity of EORTC QLQ-OV28

Item number	R Value	R table 5%	*p*	Criteria
31 - Abdominal pain	0.666	0.312	0.000	Valid
32 - Feeling bloated	0.615	0.312	0.000	Valid
33 - Clothes feeling tight	0.326	0.312	0.040	Valid
34 - Change in bowel habits	0.400	0.312	0.011	Valid
35 - Trouble with flatulence	0.579	0.312	0.000	Valid
36 - Feeling full too quickly	0.449	0.312	0.004	Valid
37 - Indigestion/heartburn	0.597	0.312	0.000	Valid
38 - Hair loss	0.292	0.312	0.067	Not yet valid
39 - Upset with hair loss	0.600	0.312	0.000	Valid
40 - Taste change	0.606	0.312	0.000	Valid
41 - Tingling hands or feet	0.459	0.312	0.003	Valid
42 - Finger or toe numbness	0.352	0.312	0.026	Valid
43 - Arms or legs weakness	0.524	0.312	0.001	Valid
44 - Muscle or joint aches/pains	0.536	0.312	0.000	Valid
45 - Hearing problem	0.429	0.312	0.006	Valid
46 - Frequent urination	0.431	0.312	0.005	Valid
47 - Skin problem	0.506	0.312	0.001	Valid
48 - Hot flushes	0.470	0.312	0.002	Valid
49 - Night sweats	0.398	0.312	0.011	Valid
50 - Physically feel less attractive	0.643	0.312	0.000	Valid
51 - Dissatisfied with body	0.415	0.312	0.008	Valid
52 - Disease burden	0.469	0.312	0.002	Valid
53 - Treatment burden	0.594	0.312	0.000	Valid
54 - Worry about future health	0.667	0.312	0.000	Valid
55 - Interest in sex	0.387	0.312	0.014	Valid
56 - Sexual activity	0.344	0.312	0.030	Valid
57 - Enjoyment of sex	0.264	0.312	0.100	Not yet valid
58 - Vagina	0.237	0.312	0.142	Not yet valid

TABLE 3. Comparison of the symptom scale, functional scale, and quality of life before and after chemotherapy using EORTC QLQ C-30

Item	No changes, N (%)	Scale degression, N (%)	Scale up, N (%)
Quality of life	10 (25.0)	27 (67.5)	3 (7.5)
Physical functioning	9 (22.5)	22 (55.0)	9 (22.5)
Role functioning	12 (30.0)	20 (50.0)	7 (17.5)
Emotional functioning	11 (27.5)	17 (42.5)	12 (30.0)
Cognitive functioning	17 (42.5)	15 (37.5)	8 (20.0)
Social functioning	15 (37.5)	20 (50.0)	5 (12.5)
Fatigue	4 (10.0)	9 (22.5)	27 (67.5)
Nausea and vomiting	7 (17.5)	4 (10.0)	29 (72.5)
Pain	10 (25.0)	7 (17.5)	23 (57.5)
Dyspnea	25 (62.5)	6 (15.0)	9 (22.5)
Insomnia	19 (47.5)	7 (17.5)	14 (35.0)
Appetite loss	11 (27.5)	6 (15.0)	23 (57.5)
Constipation	21 (52.5)	7 (17.5)	12 (30.0)
Diarrhea	25 (62.5)	6 (15.0)	9 (22.5)
Financial difficulties	20 (50.0)	7 (17.5)	13 (32.5)

TABLE 4. Results of EORTC QLQ-OV28

Item	No changes, N (%)	Scale degression, N (%)	Scale up, N (%)
Gastrointestinal	2 (5.0)	6 (15.0)	32 (80.0)
Peripheral neuropathy	9 (22.5)	7 (17.5)	24 (60.0)
Chemotherapy side effects	4 (10.0)	11 (27.5)	25 (62.5)
Hormonal	13 (32.5)	13 (32.5)	14 (35.0)
Body image	13 (32.5)	11 (27.5)	16 (40.0)
Attitude to disease/treatment	8 (20.0)	14 (35.0)	18 (45.0)
Sexuality	20 (50.0)	17 (42.5)	3 (7.5)

TABLE 5. Correlation between symptom scales and functional scales with the quality of life

Functional/symptom scales with QOL	T	*p*	R square
Fatigue	5.185	<0.001**	0.414
Nausea and vomiting	4.845	<0.001**	0.382
Pain	4.015	<0.001**	0.298
Dyspnea	1.337	0.189	0.045
Insomnia	3.878	<0.001**	0.284
Appetite loss	4.327	<0.001**	0.330
Constipation	2.494	0.017*	0.141
Diarrhea	2.047	0.048	0.099
Financial difficulties	3.273	0.002*	0.220
Physical functioning	2.762	0.009*	0.167
Role functioning	4.779	<0.001**	0.375
Emotional functioning	2.931	0.006*	0.184
Cognitive functioning	0.971	0.005*	0.188
Social functioning	1.633	0.111	0.066
Abdominal/GI symptoms	6.310	<0.001**	0.512
Peripheral neuropathy	1.602	0.117	0.063
Other chemotherapy side effects	2.441	0.019*	0.136
Hormonal/menopausal symptoms	3.104	0.004*	0.202
Body image	4.033	<0.001**	0.300
Attitude to disease/treatment	3.887	<0.001**	0.284
Sexuality	0.440	0.662	0.050

*$p < 0.05$; **$p < 0.001$

TABLE 6. Multivariate analysis of the symptom and function scales of EORTC QLQ-C30 and OV28

Functional/symptom scales with QOL	T	*p*
Physical functioning	1.805	0.085
Role functioning	0.057	0.955
Emotional functioning	1.560	0.133
Cognitive functioning	−1.348	0.191
Fatigue	−0.091	0.928
Nausea and vomiting	−2.100	0.047*
Pain	−0.227	0.823
Insomnia	−0.456	0.653
Appetite loss	−0.787	0.440
Constipation	−0.315	0.756
Diarrhea	−0.906	0.375
Financial difficulties	−0.951	0.352
Abdominal/GI symptoms	−1.878	0.074
Other chemotherapy side effects	2.734	0.012*
Hormonal/ menopausal symptoms	−2.358	0.028*
Body image	−1.034	0.312
Attitude to disease/treatment	−0.505	0.618

*$p < 0.05$, **$p < 0.001$

demonstrated that ondansetron was superior to metoclopramide in patients receiving both cisplatin and non-cisplatin regimens. These agents are believed to prevent CINV as a 5-HT3 receptor antagonist through the peripheral of the vagal nerve terminals and the center of the chemoreceptor trigger zone. Since its introduction, the 5-HT receptor antagonist has become part of the foundation for preventing CINV because of its effectiveness and well-tolerated side effects.[20]

Corticosteroids are beneficial when used alone to prevent NV in patients receiving low emetogenic chemotherapy and increase efficacy when combined with 5-HT3 receptor antagonists in those receiving moderate or high-emetogenicity chemotherapy. The latest guidelines recommend dexamethasone, although no studies have compared available corticosteroids. Tolerability to corticosteroids is of concern because when used to prevent delayed-type NV, common side effects include insomnia, epigastric discomfort, agitation, weight gain, and hyperglycemia.[20]

QOL is a multidimensional construct that includes physical functioning, which comprises physical well-being, mobility, ability to care for oneself, physical activity, self-activity, appetite, fatigue/sleep, and side effect symptoms; cognitive and psychological functioning, which covers emotional well-being, anxiety, depression, coping, perceptions, experiences, enjoyment, and optimism; social functioning, which comprises family interactions, time with friends, and leisure activities; symptoms of illness and treatment; spiritual or existential problems; sexual function; patient satisfaction with healthcare; and disease control.

Many instruments have been developed and validated to measure QOL issues in patients with cancer, the most commonly used instruments are the EORTC QLQ-C30 and the Functional Assessment of Cancer Therapy – General.[10] Ovarian cancer and its management significantly affect the overall QOL. Issues such as disease burden and long-term treatment effects also influence the quality of care for these patients. Modern ovarian cancer treatments increasingly aim to enhance QOL alongside survival rates and acceptable toxicity levels. To address these concerns, the EORTC QLQ-OV28 was created to complement the EORTC QLQ-C30, ensuring comprehensive assessment and documentation of ovarian cancer-specific disease and management issues. To our knowledge, this is the first study to utilize the EORTC QLQ-OV28 in Indonesian.[10]

EORTC QLQ-C30 and OV28 were used to assess patients' QOL, NV, and GI symptoms, followed by a linear regression analysis. The resulting scales were interpreted with a score range of 0–100. For the QLQ-C30, a high score on the functional scale indicates a high level of functioning, and a high score on the global health status indicates a high QOL. However, the higher the symptom scale, the more severe the symptoms.[21] For the QLQ-OV28, each symptom scale is scored separately, with each scale consisting of several or a single item. A higher score on the symptom scale indicates a severe symptom. A higher score for the functional scale, such as body image and sexual function, means a higher QOL.[10,22] Based on the results of this study, after the first-line chemotherapy regimen of carboplatin and paclitaxel, patients experienced an increase in CINV symptoms by 72.5%, an increase in GI symptoms by 80%, and a decrease in QOL by 62.5%.

The regression test on NV symptoms and QOL showed a significant effect between NV symptoms and QOL, where the regression equation for the effect of NV on QOL was 11.492–0.703x, which means that if the symptoms of NV increased by one unit, the patient's QOL after chemotherapy decreased by 0.703 units. The contribution of the NV scale in reducing the patient's QOL was 38.2% (R square = 0.382). The regression test results on symptoms and functions found in the EORTC QOL-C30 and EORTC QOL-OV28 showed that NV still affected patients' QOL after chemotherapy.

The impaired QOL by CINV, described by Bezjak *et al*.[11] using the EORTC QLQ-C30 questionnaire, decreased in patients receiving chemotherapy since the first cycle started. These results are consistent with the present study, which showed that CINV developed in 72.5% of the patients who received the first chemotherapy. Based on the multivariate test results, only the variables of NV, other chemotherapy side effects, and hormonal/menopausal symptoms demonstrated a significant partial effect on patients' QOL. These results are consistent with a study conducted by Börjeson *et al*.,[10] who studied 162 patients with ovarian cancer receiving combination chemotherapy, including cisplatin 50 mg/m^2. This study showed that NV significantly decreased the physical condition and QOL of patients, even with the administration of prophylactic antiemetics (ondansetron, dexamethasone, and metoclopramide).

Based on these results, the scale scores of GI symptoms increased (80%), which is greater than the CINV symptom scale (72.5%) and the QOL symptom reduction score (67.5%). Meanwhile, multivariate test results showed that the CINV symptom scale significantly reduced QOL, whereas GI symptoms did not. This can occur, considering other variables such as physical function, role function, emotional function, cognitive function, fatigue symptoms, pain, insomnia, decreased appetite, constipation, diarrhea, financial difficulties, other side effects of chemotherapy, hormonal/menopausal symptoms, body image, attitude toward disease/treatment, which affect the QOL as well, causing GI symptoms to have less effect in the multivariate analysis. Despite this, the QLQ-OV28 module is still necessary when evaluating the QOL of patients with ovarian cancer because it assesses a unique

set of QOL domains that are not covered by the QLQ-C30. A validation study of the QLQ-OV28 by Paradowski *et al*.[23] showed that the scales of the QLQ-OV28 demonstrated weak correlation with the scales of the QLQ-C30 (r < 0.3). The discrepancy between the CINV and GI scales can be explained by both scales assessing different symptom domains, with the GI scale evaluating abdominal pain, bloating, tightness of clothing, change in bowel habits, flatulence, and heartburn.

In this study, financial difficulty significantly affected QOL. A study of 3,670 patients with cancer by Perrone *et al*. using the EORTC QLQ-C30 revealed that patients who reported financial difficulties had worse QOL at baseline. During treatment, 74.5% of the patients who developed financial toxicity had significantly higher risk of death (HR 1.20, 95% CI 1.05–1.37, p = 0.007).[24] Although not objectively evaluated in the present study, financial difficulties in patients with cancer may have been caused by changes in their capability to work and unemployment caused by disease or treatment.[25]

In this study, sexuality was found not to have significantly affected QOL. Kim *et al*.[25] and Chie *et al*.[26] reported similar results. Sexual function may be impaired because of decreased estrogen and androgen production, increased fatigue, psychological factors such as depression and anxiety, and abdominal scarring due to surgery. This discrepancy may have been caused by not separating patients by early-stage and advanced-stage disease. Second, the culture in Indonesia, whether a serious disease affects the tendency to conduct sexual activity, was not thoroughly explored. Chie *et al*.[26] mentioned the possibility that unaffected sexual activity might have been caused by the discouragement of sexual activity during or after a serious disease.

Ovarian cancer management aims to increase survival and enhance overall QOL. Evaluating patients' QOL at various treatment stages has been crucial in refining treatment strategies. To address the needs of the Indonesian population, the EORTC QLQ-OV28 tool was translated into Indonesian. Our version is reliable and valid for assessing the QOL of patients with ovarian cancer and can be used in clinical or epidemiological studies involving Indonesian-speaking patients.

Although this study provides valuable insights into the effect of CIMV on QOL, several limitations should be acknowledged. First, the self-reporting nature of questionnaires introduced the potential for response and recall bias. Second, the questionnaire format may be prohibitive to obtain deeper information than a qualitative study. A qualitative study may provide data based on participants' perspectives and interpretations, which might otherwise have been missed in a quantitative study.

CONCLUSIONS

This study provides an Indonesian version of the EORTC QLQ-OV-28. The QLQ-C30 and QLQ-OV28 as a complementary module can be used as measuring tools to evaluate the QOL of patients with ovarian cancer. In conclusion, the presence of CINV can reduce the QOL of patients with ovarian cancer undergoing first-line chemotherapy containing carboplatin and paclitaxel (p < 0.047 and y = 12.208–0.432).

CONFLICT OF INTEREST

The authors hereby declare that there is no conflict of interest.

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Analysis of Fluid Intake During Pregnancy

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Analysis of Fluid Intake During Pregnancy

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Abstract

Background: Pregnancy is an important process that affects the body's daily water requirements through various mechanisms. Adequate fluid intake also plays a critical role in pregnancy. This research aimed to determine levels of water/fluid intake and influencing factors among pregnant women presenting to a university hospital in Trabzon, Türkiye.

Methods: A total of 1,082 pregnant women were included in this cross-sectional research. A questionnaire was used during the face-to-face interviews to collect data. SPSS version 23.0 software was employed during data analysis, and logistic regression was applied to identify factors that affect adequate daily fluid intake.

Results: The pregnant women in this study consumed a daily mean amount of water amounting to 1.8 ± 0.9 liters and had a mean fluid intake of 2.3 ± 0.9 liters. Results showed that daily fluid intake was inadequate in 557 (51.5%) participants. At the same time, logistic regression analysis revealed higher rates of sufficient daily fluid intake among pregnant women who were informed about water intake by their physicians and women with higher total monthly household incomes.

Conclusions: Fluid intake was lower than the recommended amount for pregnant women in approximately half of the study's participants. High levels of education, household income, and information about water intake provided by a physician were identified as important factors related to adequate daily fluid intake.

Keywords: fluid intake, pregnancy, Turkey

INTRODUCTION

Water is essential for the maintenance of life and the body's physiological functions.[1,2] Given that the body cannot produce its own water, this has to be taken in from the outside; furthermore, water lost through various mechanisms during the day must be replaced.[3] The body's water requirements are affected by several factors, including physical activity, health status, diet, and environmental conditions.[2]

Meanwhile, pregnancy is a highly important process that affects the body's daily water requirements through various mechanisms. Due to their increased weight and energy intake, pregnant women are advised to raise their daily water intake by 300–450 mL.[4] Sufficient fluid intake plays a critical role in pregnancy in terms of increasing blood volume via neuroendocrine mechanisms, which, in turn, ensures adequate uteroplacental perfusion.[5,6] In addition, proper fluid intake enables the mother to maintain sufficient reserves to tolerate fluid loss during childbirth.[5] Sufficient fluid intake is also required for the optimal absorbance of water-dissolved vitamins (e.g., ascorbic acid, nicotinic acid, riboflavin, B12 [thiamine], and B6 pyridoxine]) that are essential for maternal and fetal health. This factor also plays a role in ameliorating constipation, which is experienced by one in three women during pregnancy, and in treating urinary tract infections that can lead to complications. One case control study conducted in the framework of the National Birth Defects Prevention study in the USA reported a decrease in congenital defects, including neural type birth defects (spina bifida), orofacial clefts (cleft lip), congenital heart defects (including various cardiac anomalies such as hypoplastic left heart syndrome, right-side obstructions, and pulmonary valve stenosis), and musculoskeletal defects (gastroschisis and extremity deficiencies) as a result of increased water intake among pregnant women.[7]

Studies have also reported that inadequate fluid intake during pregnancy may cause health risks in terms of fetal development and maternal health. Plasma volume throughout pregnancy is associated with the infant's

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birth weight and low plasma volume, which increase the risk of fetal developmental delay.[8] In addition, dehydration has been associated with adverse fetal outcomes, such as preterm labor, because it leads to premature contractions, preeclampsia, and curettage.[6,9]

While the National Academy of Medicine (NAM) recommends a minimum daily fluid intake of 2.3 L, including water, the Turkish Nutrition and Health Survey published in 2019 reported an average daily water intake of 1,205 mL for pregnant women in Turkey.[10,11] This worrying value warrants further investigation and assessment of the daily water intake of pregnant women in Turkey.

Thus far, current studies have largely focused on determining the amount of fluid intake among pregnant women, the content distribution of their fluid intake (water, beverages, and foods), and the effect of water intake and fluid content on maternal/fetal health.[6,7,12–17] In comparison, only a limited number of studies have addressed the factors affecting the water intake levels of pregnant women.[6,13,18] The results of these studies are also inconsistent. For example, a study of pregnant women in China reported a total fluid intake of approximately 1.4 L/day, while a study from Mexico cited 2.6 L/day. Similar variations in the content distribution of daily fluid intake have been reported.[6,12] For instance, a study of pregnant women in Indonesia reported that plain water accounted for 72% of total fluid intake, while a study from Mexico reported a figure of 33.2%.[12,18] These results indicate wide intersocietal differences in the water/liquid consumption behaviors of pregnant women. Therefore, it is important for each community to conduct its own studies to assess the distinct populations of pregnant women.

In line with the abovementioned research gap, the purpose of the present research was to determine levels of water/fluid intake among pregnant women presenting to the Department of Obstetrics and Gynecology pregnancy clinic of a university hospital located in Trabzon, Türkiye and the factors affecting such intake.

METHODS

Ethical approval

Approval for the research was granted by the Karadeniz Technical University Medical Faculty Ethical Committee (No. 24237859-342, dated 25.05.2018). During the data collection stage, we explained the study to women presenting to the pregnancy clinic, and verbal consent was obtained from those who agreed to participate.

Study design

This study was performed with a cross-sectional design. Pregnant women who agreed to participate were administered a questionnaire during the face-to-face interviews, which were conducted to collect data.

Settings

The research population consisted of pregnant women presenting to the pregnancy clinic of a public university hospital in Trabzon, Türkiye. The study was conducted in the pregnancy clinic within the hospital's Gynecology and Obstetrics Department. All pregnant women presenting to the clinic during the recruitment period, which lasted from March to August 2018, were invited to participate.

Participants

The eligibility criteria for the selection of pregnant women for inclusion in the study were as follows: age over 18 years, willingness to participate, pregnancy persisting at the time of the research, evaluation of a single presentation in case of multiple presentations, and absence of risky pregnancy. Women with any condition that might hinder verbal communication were excluded from the study.

Variables

The questionnaire developed by the researchers following a literature review consisted of three sections:

Section 1: Sociodemographic and individual characteristics. This section included closed-ended questions on the participants' educational level (illiterate, literate, elementary school graduate, middle school graduate, high school graduate, and university graduate), profession and working status (yes/no), and presence of chronic disease/drug use before pregnancy (yes/no). Questions regarding the participant's age, total monthly household income, and number of family members were open-ended. The questions on the participants' age, total monthly household income, and number of family members were categorized to be used in the analyses. Age was classified according to mean values and categorized as 30 years or under and over 30 years. Monthly household income was determined in Turkish lira and converted into dollars to ensure that it could be assessed using international values. Monthly household income was classified based on the mean value and categorized as ≤ 780 dollars ($) and >780 $. The number of individuals in the household was classified according to mean values and categorized as 3 persons or fewer and more than 3 persons.

Section 2: Pregnancy-related characteristics. This section included closed-ended questions on pregnancy-related health problems/drug use for the current pregnancy (yes/no), the institution where regular monitoring took place (university/public/private hospital), and regular monitoring by health personnel during pregnancy (yes/no). It also included open-ended questions on the most recent menstrual cycle and total number of pregnancies, as well as information of any pregnancy-

related health problem. The trimesters of pregnant women were determined based on their most recent menstrual cycle dates. In addition, the number of pregnancies was categorized based on whether the current pregnancy was the first or not, as this indicated the experience of the woman concerned.

Section 3: Characteristics related to water and fluid intake in pregnancy. This section investigated characteristics, such as information about water intake provided by a physician, changes in the amounts of daily water intake compared to prepregnancy levels, amounts of daily intake of water and other fluids (mineral water, tea, coffee, fruit juice, milk and milk products, fruit juices, and soft drinks like fizzy drinks containing sugar or sweetener). In this section, the question about being informed by a physician about water intake is a closed-ended question (yes/no). Alterations in water intake during pregnancy were asked as closed-ended (decreased, unchanged, and increased) based on the participants' self-reports. Two distinct terms, "water intake" and "total fluid intake," were used in the study. Specifically, "water intake" refers to the amount consumed by an individual daily in the form of plain water (tap or bottled water) only. Meanwhile, daily "total fluid intake" represents the sum of all fluids consumed during the day and is categorized as follows: water (tap, bottled, and mineral water), hot drinks (tea and coffee), milk and milk products, soft drinks (fizzy drinks containing sugar or sweetener and fruit juices), and other drinks. A there is no recommended level of daily plain water intake for pregnant women in the literature, we thus applied the 2.3 L fluid intake value recommended by the NAM for calculating the sufficiency of daily beverages and plain water-based fluid intake.[10] Accordingly, fluid intake of 2.3 L or more was regarded as adequate that less than 2.3 L was considered inadequate.

Study size

OpenEpi software was employed for sample calculation. Accordingly, we planned to include at least 1,066 pregnant women at a 95% confidence interval (CI), a 50% frequency with unknown prevalence, and 3% deviation. A total of 1,082 pregnant women who agreed to participate were interviewed in the scope of the study. We subsequently scanned patients presenting to the Gynecology and Obstetrics Department, using ICD10 code "Z33: pregnant state" from the hospital database, to determine the total number of pregnant women presenting to the pregnancy clinic between the study dates. The total number of patients diagnosed with "pregnant state" and presenting to the departmental clinics during the study period was 2,385. This number included pregnant women presenting to the high-risk pregnancy clinic or other clinics with different symptoms. However, the study sample was a comprehensive one.

Statistical analysis

SPSS 23.0 software was used during data analysis. Descriptive statistics were expressed as number (N) and percentage (%) for categorical variables and as mean, standard deviation (SD), minimum, and maximum (min–max) for numerical variables. The number of pregnancies, including the current pregnancy, and the number of individuals in the household were presented with median (25th–75th percentile) values. For questions that were unanswered by the participants, the number of participants who answered these questions was expressed as "N" in the question row. The normal distribution of numerical variables was assessed using the Shapiro Wilk test. The Mann–Whitney U and Kruskal–Wallis tests were used to compare measurement variables between independent groups for data that were not distributed normally. Post hoc Bonferroni correction was used to determine the source of significant differences between groups. Logistic regression was applied to identify factors affecting adequate daily fluid intake. Based on NAM recommendations, water intake of 2.3 L or more a day was considered adequate, while intake less than 2.3 L a day was deemed inadequate (10). Parameters with $p < 0.20$ in previous relevant comparisons and with no mutual interaction (educational level, monthly household income, number of pregnancies, trimester, presence of pregnancy-related health problems, and information about water intake during pregnancy provided by a physician) were included in the model. The statistical alpha significance level was set at $p < 0.05$.

RESULTS

A total of 1,082 pregnant women participated in the study. Given that the data were collected face-to-face, responses were recorded reliably, and no ineligible forms were identified. The mean age of the women was 29.7 ± 5.6 (18–54) years, and the median number of pregnancies, including the current pregnancy, was 2.0 (1.0–3.0), while the mean gestational week for current pregnancies was 23.0 ± 9.8 (3.0–40.6). The median number of individuals in the household was 3 (2–4). Other sociodemographic, individual, and current pregnancy-related characteristics are shown in Table 1.

The participating women's mean water intake was 1.8 ± 0.9 (0.1–5.0) liters (L) daily, and their mean total fluid intake was 2.3 ± 0.9 (0.2–6.0) L/day (Table 2). Based on NAM values for daily fluid intake, 557 (51.5%) participants had inadequate levels of water intake, while 525 (48.5%) reported adequate intake. Plain water represented 78.8% of total fluid intake among the pregnant women in this study, 77.1%, 76.3%, and 78.5% in those in the first, second, and third trimesters, respectively. The different fluid distributions in total fluid intake are shown in Table 3.

Higher levels of daily water and fluid consumption were associated with several factors, namely, a higher

TABLE 1. Pregnant women's descriptive characteristics

Variable	N	%
Education status		
Illiterate	7	0.6
Literate	21	1.9
Elementary school graduate	220	20.3
Middle school graduate	213	19.7
High school graduate	320	29.6
University graduate	301	27.9
Own profession		
Yes	335	31.0
No	747	69.0
Working in income-generating employment		
Yes	299	27.6
No	783	72.4
Monthly household income (N = 1,010)		
≤$780	727	72.0
>$780	283	28.0
Presence of chronic disease before pregnancy		
Yes	238	22.0
No	844	78.0
Regular medicine uses before pregnancy		
Yes	167	15.4
No	915	84.6
Trimester (N = 1,075)		
First	205	19.1
Second	407	37.9
Third	463	43.0
Presence of pregnancy-related health problems		
No	858	79.3
Yes	224	20.7
Gestational diabetes	50	23.4
Thyroid disease	47	22.0
Anemia	28	13.1
Hypertension	27	12.6
Recurrent urinary tract infection	15	7.0
Vitamin/mineral deficiency	12	5.6
Kidney failure	7	3.3
Kidney stone	4	1.9
Other	40	18.7
Medicine use during pregnancy (N = 1,079)		
Yes	933	86.5
No	146	13.5
Regular monitoring by health personnel during pregnancy		
Yes	1,071	99.0
No	11	1.0
Institution where regular monitoring took place[a]		
University hospital	1,001	93.7
Public hospital	386	36.1
Private hospital	279	26.1
Receipt of information from a physician concerning water intake in pregnancy		
Yes	565	52.2
No	517	47.8
Alteration in water intake in pregnancy		
Increased	484	44.7
Unchanged	459	42.4
Decreased	139	12.9

[a]More than one option might be selected

education level, working in an income-generating occupation, greater household income, first pregnancy, advancing trimester, having a pregnancy-related disease, taking medication during pregnancy and being informed about water consumption (Table 4).

Logistic regression analysis revealed that a higher level of education, higher income levels, and being informed about water consumption increased adequate fluid intake (Table 5). In particular, the prevalence of adequate fluid intake among pregnant women educated at the high school level or above was 53.3%, significantly higher than that of women with a below high school educational level (42.1%) (OR = 1.37, 95% CI: 1.03–1.82). The prevalence of adequate fluid intake among the women with monthly total household incomes above the 780$ mark was significantly higher than among those with lower income levels (60.4% vs 45.4%, OR = 1.57, 95% CI: 1.15–2.13). Additionally, the prevalence of adequate fluid intake among women who had been informed about water consumption during pregnancy by a physician was significantly higher than that among women who did not receive such information (54.3% vs 42.2%, OR = 1.42, 95% CI: 1.09–1.84).

DISCUSSION

The mean plain water intake of the women who participated in this research was 1.8 ± 0.9 (0.1–5.0) L/day, and their total fluid intake was 2.3 ± 0.9 (0.2–6.0) L/day. As mentioned previously, a cut-off value for adequate total fluid intake of 2.3 L/day was adopted, and an incidence of inadequate fluid intake of 51.5% was determined. The 2019 TBSA reported a daily plain water intake level of approximately 1.2 L among pregnant women, but this contained no data for total fluid intake.[11] In a study from China, Zhou *et al*. reported a mean plain water intake of 1,160 mL/day among pregnant women and a mean total fluid intake of 1,385 mL/day.[6]

In an Indonesian study, Bardosono *et al*. reported a mean total fluid intake of 2311mL/day and adopted 2.3 L/day as a cut-off value for adequate total fluid intake, yielding an inadequate fluid intake rate of 42%.[18] In Martinez's study of pregnant women in Mexico, mean total fluid intake was 2.6 L/day, and a cut-off value of 2,080 mL/day for adequate fluid intake yielded an inadequate intake prevalence of 41%.[12] The prevalence of inadequate total fluid intake in previous studies is quite high. Furthermore, inadequate total fluid intake levels in the present research were higher than in those two previous studies. Total fluid intake is frequently evaluated, because it is simple to apply in large populations and provides a basic finding concerning sufficient hydration. Therefore, the inadequate fluid consumption rate determined in the current research involving an extensive sample group represents a risk for both maternal and fetal health.

TABLE 2. Levels of water and fluid intake among pregnant women

Variable	Amount of daily fluid intake (L)		Proportion of total fluid intake
	Mean ± SD	Min–Max	%
Water	1.80 ± 0.90	0.1–5.0	78.8
Water-based beverages			
Tea	0.30 ± 0.30	0.0–2.5	11.2
Coffee	0.01 ± 0.05	0.0–0.8	0.5
Milk and milk products			
Ayran	0.10 ± 0.10	0.0–1.5	4.7
Milk	0.02 ± 0.08	0.0–1.0	0.8
Nonalcoholic drinks			
Gaseous drinks	0.02 ± 0.06	0.0–0.8	0.7
Fruit juice	0.05 ± 0.10	0.0–1.5	2.3
Other	0.02 ± 0.07	0.0–1.0	1.0
Total fluid intake	2.30 ± 0.90	0.2–6.0	100

TABLE 3. The contributions of different fluid types to total fluid intake

Fluid types	First trimester (%)	Second trimester (%)	Third trimester (%)	Total (%)
Water	77.1	76.3	78.5	78.8
Hot drinks	12.8	12.8	12.4	11.7
Milk and dairy	5.2	6.3	5.6	5.5
Soft drinks	4.2	3.6	2.4	3.0
Others	0.7	1.0	1.1	1.0

TABLE 4. Amounts of daily water and fluid intake related to various parameters

Variable	Daily water intake (L)	*p*	Daily fluid intake (L)	*p*
Age (years)				
30 or under	2.0 (1.0–2.5)	0.126	2.3 (1.7–2.9)	0.368
Over 30	2.0 (1.0–2.5)		2.2 (1.6–2.8)	
Education level				
Below high school	1.5 (1.0–2.0)	<0.001*	2.1 (1.5–2.8)	0.002*
High school or above	2.0 (1.4–2.5)		2.4 (1.8–2.9)	
Working in income-generating employment				
Yes	2.0 (1.5–2.5)	<0.001*	2.4 (1.9–3.0)	<0.001*
No	1.5 (1.0–2.5)		2.2 (1.5–2.8)	
Monthly household income (N = 1,010)				
≤$780	1.5 (1.0–2.5)	<0.001*	2.2 (1.6–2.8)	<0.001*
>$780	2.0 (1.5–2.5)		2.4 (1.9–3.1)	
Number of individuals in the household				
3 or fewer	2.0 (1.2–2.5)	<0.001*	2.3 (1.7–2.9)	0.019*
More than 3	1.5 (1.0–2.0)		2.1 (1.5–2.8)	
Number of pregnancies				
First pregnancy	2.0 (1.0–2.5)	0.017*	2.3 (1.6–2.9)	0.446
≥ two pregnancies	1.7 (1.0–2.5)		2.2 (1.6–2.8)	
Trimester (N = 1,075)				
First	1.5 (1.0–2.0)	<0.001[a,b]*	2.0 (1.3–2.7)	<0.001[a,b]*
Second	1.6 (1.0–2.5)		2.2 (1.6–2.8)	
Third	2.0 (1.2–2.5)		2.4 (1.8–3.0)	
Presence of a pregnancy-related health problem				
Yes	2.0 (1.2–2.5)	0.021*	2.4 (1.8–3.0)	0.038*
No	2.0 (1.0–2.5)		2.2 (1.6–2.8)	
Medicine use during pregnancy (N = 1,079)				
Vitamins/minerals	2.0 (1.0–2.5)	0.001[c]*	2.2 (1.6–2.9)	0.003[c,d]*
Medicine other than vitamins/minerals	2.0 (1.2–2.5)		2.4 (1.7–2.9)	
None	1.5 (1.0–2.0)		2.0 (1.3–2.6)	
Information about water consumption during pregnancy provided by a physician				
Yes	2.0 (1.3–2.5)	0.001*	2.4 (1.8–3.0)	0.001*
No	1.5 (1.0–2.0)		2.1 (1.5–2.7)	

[a]First trimester vs. second trimester, [b]second trimester vs. third trimester, [c]No vs. nonvitamin/mineral medicine, [d]No vs. vitamin/minerals. $p < 0.05$.

TABLE 5. Factors affecting adequate daily fluid intake among pregnant women

Variable	Inadequate fluid intake		Adequate fluid intake		Odds Ratio (95% CI)
	N	%	N	%	
Education level					
Below high school[ref]	267	57.9	194	42.1	
High school and above	290	46.7	331	53.3	1.37 (1.03–1.82)*
Monthly total household income (N = 1,010)					
≤780$[ref]	397	54.6	330	45.4	
>780$	112	39.6	171	60.4	1.57 (1.15–2.13)*
Number of pregnancies					
First pregnancy	160	49.1	166	50.9	1.06 (0.81–1.39)
≥2[ref]	397	52.5	359	47.5	
Trimester (N = 1,075)					
First[ref]	121	59.0	84	41.0	
Second	218	53.6	189	46.4	1.05 (0.73–1.51)
Third	215	46.4	248	53.6	1.34 (0.94–1.93)
Presence of a pregnancy- related health problem					
No[ref]	459	52.9	409	47.1	
Yes	98	45.8	116	54.2	1.34 (0.98–1.85)
Information about water consumption during pregnancy provided by a physician					
No[ref]	299	57.8	218	42.2	
Yes	258	45.7	307	54.3	1.42 (1.09–1.84)*

The distribution of beverage types that contribute to total fluid intake also has an effect on health. Research among pregnant women shows that three groups, namely, hot beverages, plain water, and drinks containing sugar or sweeteners, represent the largest proportion of daily fluid intake.[9,11] Studies have also revealed a link between high levels of beverages containing sugar or sweeteners in diet during pregnancy and adverse health impacts.[13–17] However, no recommendations have been made concerning the distribution of the fluid types constituting total fluid intake. The proportions of plain water to total fluid intake in pregnant women were reported at 72% in an Indonesian study by Bardosono *et al*., at 33.2% in Mexico by Martinez, and approximately twice that of other fluids in Malisova *et al*.'s study from Greece.[12,18,19] Thus, we regard the fact that plain water comprised the largest component of total fluid intake in pregnant women (78.8%) in the present study as a positive finding.

High levels of education and income have a positive impact on water consumption.[20–22] In their study of pregnant women, Zhou *et al*. determined no association between education level and total water, plain water, or beverage-based water intake.[6] In the present study, a participant's higher level of education was associated with greater daily fluid and water intake, along with a higher rate of adequate fluid intake. This finding therefore indicates that education plays a role in pregnant women's health-related decision-making processes. Brooks *et al*.'s study of adults reported a 20% greater risk of inadequate hydration in those with low income compared to high-income individuals.[21] In Zang *et al*.'s study conducted in urban China, total fluid consumption was reported to be lower in areas characterized by lower socioeconomic status.[22] In the present study, pregnant women coming from households with high total income levels consumed significantly more fluid and water and exhibited higher rates of adequate fluid intake. This relationship between economic status and water and fluid consumption thus requires further investigation to eliminate inequalities in the hydration status of pregnant women.

Since the numbers of pregnancies can alter pregnant women's health-related information acquisition behaviors, they can also play a role in water and fluid intake. In a study of women in the final trimester, Aydin reported higher rates of positive nutritional behaviors during pregnancy among primiparous women compared with multiparous individuals. However, no correlation was found between parity and levels of water intake.[23] In the current research, significantly higher levels of plain water and total fluid intake were observed in women in their first pregnancy compared with their multiparous peers. However, logistic regression analysis revealed that the number of pregnancies had no effect on adequate fluid intake. This finding suggested that although women in their first pregnancies consumed high quantities of water and fluid, due to the effect of other variables, these remained at threshold levels in terms of adequacy.

The amount of water and fluid consumed is generally expected to increase as the trimesters advance.[4] However, previous studies found no statistically significant difference between the trimesters in terms of daily water and fluid intake.[6,13,18] In the present study, levels of water and fluid consumption increased in parallel with the trimesters, while intake of water and fluid was significantly higher in the third trimester. However, logistic regression analysis revealed no significant relationship between trimester and adequate fluid intake. Thus, we

interpreted the trimester-related increase in fluid intake in this study as a positive finding in terms of meeting increased fluid requirements from the second trimester onward, as recommended by the EFSA. Meanwhile, experiencing health problems during pregnancy can increase health awareness and play a decisive role in pregnant women's water and fluid intake. In the present research, daily plain and total water intake were significantly higher among women experiencing health problems during pregnancy and those taking medications. However, no relationship was found between the presence of a health problem during pregnancy and adequate fluid intake.

More studies have addressed nutritional behaviors among pregnant women and the role of healthcare providers than those examining the role of physicians in adequate water/liquid consumption in such women.[24–26] As mentioned earlier, water and fluid intake is also a component of nutrition during pregnancy. For example, in a qualitative study of pregnant women conducted by Bookari *et al*., physicians and obstetricians were identified as the most reliable sources of nutrition advice for pregnant women. Bookari *et al*. also reported that the advice given by the healthcare provider had a positive effect on nutrition.[24] In the current study, being informed about water intake during pregnancy by a physician was linked to an increase in fluid intake and adequate daily fluid consumption. Considering the positive effects of water on the maternal and fetal health, along with the complications that may arise in case of deficiency, the instructional role of physicians can be considered a prime example of preventive medicine initiatives in the field of public health. In this regard, he positive effect of the informative role of physicians on water and fluid consumption in pregnant women requires greater emphasis in light of the prevalence of inadequate fluid consumption.

There are several limitations to this study. First, daily fluid intake was based on participants' self-report and recall, which might have generated recall bias. Furthermore, the study involved pregnant women admitted to a university hospital, which led to a lack of random selection. Therefore, the results cannot be generalized to the entire population. Finally, compared to other studies, the amount of water ingested from food was not calculated in this research. This may have caused some limitations in the discussion of the data.

Despite these limitations, this study also particular strengths. First, while there are some studies in the local literature that investigated water/fluid consumption during pregnancy, to our knowledge, this is the first study from Türkiye to investigate the factors affecting water and fluid intake among pregnant women. Therefore, the data from this study are particularly important. Furthermore, the study was conducted with a relatively large sample size of 1,082 participants. As the data were collected face-to-face, their quality is high, and the incidence of missing data quite low. Finally, the questionnaire employed to determine the parameters affecting water and fluid consumption was a comprehensive one that was produced from an extensive review of the previous literature.

This research also has some important key points. Considering the impact of water on maternal and fetal health, the 51.5% prevalence of inadequate fluid consumption in this study is quite alarming. As such, this research can serve as a useful guide for future studies in terms of conducting in-depth investigations of the variables hereby identified as risk factors for inadequate fluid consumption and in revealing relevant risk profiles. Finally, demonstrating the positive effect of the informative role of physicians on water/liquid intake on pregnant women reveals important opportunities for successful interventions.

CONCLUSIONS

In conclusion, the fact that the daily water intake in this research exceeded the mean daily level of water consumption among pregnant women in Türkiye represents a positive finding. However, daily total fluid intake was lower than that recommended by the NAM in approximately half of our participants. Furthermore, higher levels of education and household income and being informed about water intake during pregnancy by a physician were found to be linked to adequate daily fluid consumption among pregnant women. In addition, our finding that physicians play a determining role in daily water/fluid intake and adequate fluid intake in pregnant women is an important one. Based on this finding, we recommend that physicians evaluate women's daily water and fluid intake at check-ups before, during, and after pregnancy, and that a counseling service concerning daily water intake be made available as a part of the dietary consultancy provided.

CONFLICT OF INTEREST

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The Challenges of Down Syndrome Screening in Primary Healthcare for Pregnant Women in Iran in 2018

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The Challenges of Down Syndrome Screening in Primary Healthcare for Pregnant Women in Iran in 2018

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Abstract

Background: This study aimed to evaluate the various aspects of the implementation phase, including an economic evaluation, of Iran's Down syndrome (DS) screening program.

Methods: Data were collected via phone interviews involving three random sample groups, with each group consisting of 1000 mothers who completed their pregnancies in 2018. To analyze the DS screening program from an economic aspect, we compared the costs related to the care of a DS individual in the country with that of finding and aborting a DS fetus based on the current screening program. In addition, to examine the financial expenses, we assessed the false positive rate (FPR) obtained from the tests and the status of pregnancy outcomes in terms of DS birth and the incidences of abortion complications in the interviewed samples.

Results: A total of 94.5% of pregnant mothers participated in the DS screening program. The calculated FPRs in the screening tests were in the range of 15.3% (95% confidence interval (CI): 12.7%–18.1%) to 16.5% (95% CI: 13.7%–19.5%) for mothers registered in Iran's Health Network and 12.5% (95% CI: 10.2%–15.2%) for all mothers. The results suggest the inefficiency of the current implementation of the DS screening program in Iran from an economic perspective and given the respective side effects, especially fetal loss.

Conclusions: The DS screening program in Iran necessitates urgent review and modification.

Keywords: down syndrome, health policy, Iran, maternal health

INTRODUCTION

Down syndrome (DS), a.k.a. trisomy-21, is the most prevalent nonlethal chromosomal abnormality, with an incidence of 1 out of 800–1200 live births.[1] At the global level, the prevalence of this disease accounts for 1 out of 1000–1100 births.[2] DS screening refers to the process of determining the probability of fetal DS in the first and second trimesters. The screening for DS can be achieved in several ways.[3,4]

Combined screenings in the first trimester, the most widely used screening protocol, combines Nuchal Translucency (NT) measurement and serum levels of human chorionic gonadotropin (hCG) and pregnancy-associated plasma protein A (PAPP-A).[5] Through this protocol, the rate of diagnosis of DS in large prospective trials was in the range of 79%–88%, and that of false positive results was approximately 5%.[6] Mother's age affects combined screening;[7] in women who were older than 35 years at the time of delivery, the rate of diagnosis of DS was 90%–95%, which had a higher rate of false positive rate (FPR) (15%–22%).

Combined screening tests in the second trimester include the measurement of triple markers, including of unconjugated estriol (μE3), alpha-fetoprotein (AFP), and total β hCG, in the mother's serum in weeks 15–17 and Quadruple tests, including those for total β hCG, μE3, AFP, and dimeric inhibin-A (DIA), in weeks 15–17.[8] This triple test can diagnose 61%–70% of DS cases, and the false positive results reach 5%. The amount of the fourth marker, called DIA, increases in DS. The addition of this marker to the previous three markers enables the administration of a quadruple test, which, in the case of trisomy 21, is associated with a diagnosis rate of approximately 80% and an FPR of 5%.

Integrated screening tests, which include the following, increase the power of aneuploidy diagnosis. The integrated screening included NT + PAPP-A tests performed on weeks 11–14. The tests were conducted in consideration of the mother's age, a quadruple test in weeks 15–20, and a calculation of the final risk based on these seven parameters. Integrated screening shows an association with the highest rate of DS diagnosis (95%) and 5% of false positive results.[9] Sequential screening comprises two

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research methods.[3] The first one is Sequential.[10] This method includes the implementation of first-trimester tests and risk calculation. Based on the calculated risk, individuals who are at high risk (risk higher than 1.50) are determined, and counseling and diagnostic tests are suggested. Other lower-risk cases are referred to the quadruple test in the second trimester. The second one is Contingent sequential. This method includes the calculation of the risk of infection after the first trimester tests and allotment of women to three groups: high-, medium-, and low-risk groups. High-risk cases are referred for diagnostic tests. No further action is implemented for low-risk cases, and moderate-risk individuals, who account for 15%–20% of the population, are screened in the second trimester.

Cell-free fetal DNA,[11] extensive parallel sequencing or chromosomal selection sequencing, is used to isolate cell-free fetal DNA from maternal plasma to detect DS and other autosomal trisomies,[12] which can be diagnosed from the 10th week of pregnancy.[13] Recent experiments on high-risk pregnancies revealed a 95% detection rate for trisomies 13, 18, and 21 and a FPR of approximately 5%.[14,15]

In the case of a high-risk screening result, complementary and diagnostic tests are performed to confirm fetal DS. The Iranian Health System directs mothers carrying a DS fetus toward legal abortion. In 2011, Iran's Ministry of Health and Medical Education (MOHME) released a legally binding mandate requiring healthcare service providers to recommend to all pregnant women methods for fetal health diagnosis in terms of abnormalities. However, the latter instruction lacked details. Therefore, the MOHME released another document titled, "The Procedure for Screening and Diagnosis of Fetal Abnormalities" in 2013. This document defines the standards and frameworks for fetal screening. Subsequently, the National DS Screening Program was integrated into the Primary Healthcare Program for Pregnant Women in Iran's Health Network. The document has been revised and updated multiple times since 2013. This study was performed during the validation of the 2015 update titled, The National Guidelines for the Prevention of Fetal Chromosomal Disorders; Down Syndrome.[16]

In general, screening programs for a population are cost-effective only when implemented exclusively for high-risk groups, are optional, without substantial cost, and are conducted with careful continuous monitoring.[14,17] False positives and negatives are inevitable, and thus, screening programs can cause harm to people, specifically when they violate the abovementioned standards. Thus, careful evaluation should be conducted on the implementation phase of a national screening program in terms of costs, benefits, performance indicators of various agents, etc.[18]

Public and private sectors provide health services in Iran. The government renders free primary health care services. However, specialized tests related to prenatal screening are not covered by basic insurance and are mainly paid out of pocket. In Iran, approximately 10% of the gross domestic product (GDP) is allotted for health expenses, and from 2010 to 2018, on average, approximately 50% of health expenses comprised out-of-pocket payments.[19] Furthermore, families must directly shoulder DS screening tests. Moreover, as a legal obligation, all pregnant women are strongly advised to undergo DS screening. Therefore, the implementation of the DS screening program will likely result in adverse consequences.

Therefore, this study aimed to analyze the current DS screening program in Iran from a medical and economic point of view, i.e., to determine the mechanism underlying the program implementation medically and whether it is economically efficient. To attain such a goal, sub-objectives, such as the calculation of the cost burden of the DS screening program, the percentage of pregnant women undergoing such tests were set.

METHODS

This study received ethical approval from the Tehran University of Medical Sciences Research Ethics Board (IR.TUMS.MEDICINE.REC.1397.292). This study was a descriptive-analytical (cross-sectional) study performed in 2018. Research data were collected via phone interviews. The research sample comprised randomly selected pregnant women who had completed their pregnancies during the first quarter of 2018 and were registered in the SIB electronic system (SIB is the name of an integrated electronic health system used in Iran's Health Network). This system accounted for 85% of the country's entire population in 2018. The coverage has risen since 2018. It is almost 100% for villages and small cities but is lower for large cities.

This research included three randomly selected sample groups, with each group comprising 1000 women who had finished their pregnancy in the first quarter of 2018. The recruitment period and contact with samples lasted three months. The three sample groups were selected in accordance with the following logic: The DS screening program in Iran has two versions of declared guidelines which are routine and pilot. The pilot version, which has been implemented since 2014, was communicated to 11 medical science universities (in nine provinces). The routine version has been enforced in other provinces since 2012. Accordingly, two sample groups corresponded to the two versions of declared guidelines. However, these samples excluded mothers not covered by the Health Network during pregnancy.

To compensate for this shortcoming, we selected a third sample group that included mothers who had received vaccinations for their 2-month-old infants in April 2018. Unlike its coverage for pregnancy health services, the SIB contains records of almost 100% of the data regarding

infant vaccination. The selected samples in three separate classes were extracted from the SIB electronic system via simple random sampling. Thus, existing electronic system files were used in the initial selection of three separate groups of mothers based on the research objectives. The samples from each class were selected through simple random sampling. In consideration of the specificity of DS screening tests, this study required a minimum sample size of 245. This calculation used estimates of p = 0.9, d = 0.04, and z = 2.

Prompted by the concerns regard missing data, the researcher decided to increase the sample size to increase the power of the study. As the interviews were conducted through phone communication from the university call center, no substantial cost was incurred for the research team. Therefore, the sample size for each group increased to 1000. The Clopper–Pearson exact method was used to calculate the 95% confidence interval (CI) for the selected proportions.

The interviews were fully structured and based on a predefined questionnaire containing 14–16 questions. The same questionnaire was administered to first and second sample groups, and all screening steps were explored to determine whether each step was undertaken, the outcome of each step, and the due costs the interviewees had paid. The questionnaires also explored the pregnancy outcome determining fetal loss and live birth condition in terms of DS. Each person completed the questionnaire for 15–20 min. The direct costs related to screening were inquired in the interviews, and the expenses related to caring for an affected person in other countries were obtained from the literature.

Two trained medical students performed the interviews, heeding the following points: (1) Interviewees were contacted through phone calls using the 5-digit phone number of the Health Department of Tehran University of Medical Sciences (TUMS), (2) prior to asking questions, the interviewers introduced the organization behind the study and elaborated its objectives, (3) interviewees were informed that participating in the study was optional, moreover, they were excluded if they did not want to participate in the study, and (4) interviewees were informed that in case they forgot any information, they could call back the same number and express the complementary points.

We used the phone numbers registered in the Ministry of Health's SIB system to communicate with the samples. Each number was called up to three times. If we failed to communicate with the person during these three attempts a result of calling the wrong number, changing phone numbers, etc., that participant was removed from our interview list and considered missing data. A period of less than one year elapsed between interviews and screening tests. Thus, the probability of recall bias was low. In addition, in Iran, these tests are unusually expensive and not covered by basic insurance. Therefore, they still pose a concern among people. Notably, recall bias is one of this study's limitations.

IBM SPSS Statistics 21 was used in data analysis, including the calculation of the actual variables of interest, i.e., the false positive value (FPV) and positive predictive value (PPV) of the DS screening system and other variables, such as the sensitivity and specificity ratios, and financial calculations. Economic analysis was performed by comparing the total cost of detecting a DS fetus through the current procedure in Iran with the cost of caring for a DS individual heeding US standards. This step was performed in three different scenarios

RESULTS

Overall, 2,096 individuals out of 3,000 who were eligible participated in the study, i.e., the response rate equaled 69.9%. The remaining 30.1% (those who did not answer) comprised individuals whose phones were switched off (23.4%), those with wrong numbers (4.5%), and individuals who refused to participate in the study (2.2%). Table 1 presents the response rate and age distribution of participants in this study. The average age of the participants was 25 years old, and the overall response rate was 69.9%.

A total of 94.5% of mothers in the third sample underwent DS screening tests (Table 1). The FPRs of DS screening tests were 15.3% (95% CI: 12.7%–18.1%), 16.5% (95% CI: 13.7%–19.5%), and 12.5% (95% CI: 10.2%–15.2%) for the first, second, and third sample groups, respectively.

TABLE 1. Phone interview participation in each sample group and their corresponding age distribution

No.	Description of the Sample Group	Number of Participants	Response Rate	Min. Age	Max. Age	Average Age
1	Pregnant mothers under care in the National Health Network, in the pilot program	719	71.9	16	50	23
2	Pregnant mothers under care in the National Health Network, in the routine program	651	65.1	15	46	24
3	All Pregnant mothers (whether covered by the National Health Network or not)	726	72.6	15	57	29

TABLE 2. Primary description and analysis of data gathered through phone interviews

Sample Group No.	1 (N = 719)	2 (N = 651)	3 (N = 726)
1st Trimester Test	711	557	551
NT Sonography (1st-trimester screening)	690	617	602
Sonography + Test (1st-trimester screening)	714	642	647
Quadri Marker Test (2nd Trimester)	335	242	341
% of Compliance with Screening	100%	100%	94.5%
Amniocentesis or CVS	39	41	32
% of Compliance with Amniocentesis or CVS	5.4%	6.3%	4.4%
NIPT	24	27	27
% of Compliance with NIPT	3.3%	4.1%	3.7%
false positive rate (FPR)	15.3 (110/719)	16.4 (107/651)	12.5 (86/726)
SPE (95% CI)*	84.7 (81.9–87.3)	83.5 (80.6–86.3)	87.5 (85.6–90.4)
PPV	1.79 (0.22–6.30)	Indeterminable	Indeterminable
NPV	99.8	99.8 (99.1–99.9)	-
No. of 2nd Trimester Abortions	19	18	0

* Clopper–Pearson exact method

TABLE 3. Average direct clinical costs corresponding to the current DS screening program (US$) in the 3rd sample group who had undertaken each screening stage

Description	1st trimester screening		2nd trimester screening	Invasive complementary tests		
	Double Marker Test (N = 551)	NT Sonography (N = 602)	Quadri Marker Test (N = 341)	Amniocentesis (N = 32)	NIPT (N = 27)	Total (N = 726)
Mean unit cost	30.68	34.09	38.64	363.64	363.64	-
Total costs	16,906	20,522	13,175	11,636	9,818	**72,058**

TABLE 4. Number and percentage of abortions in the first and second sample groups

Sample group no.	No. of participants	No. of abortions by normal mothers	No. of abortions by high-risk mothers	No. of abortions following amniocentesis	Total 2nd trimester abortions (N)	Total 2nd trimester abortions (%)
1	719	5	13	1	19	2.6
2	651	6	12	0	18	2.7

The percentage of invasive diagnostic tests, including amniocentesis and chorionic villus sampling (CVS) was 5.4% (95% CI: 3.8–7.1%), 6.3% (95% CI: 4.4–8.2%) and 4.4% (95% CI: 2.9%–5.9%) for the first, second, and third sample group, respectively. Moreover, for the 3 sample groups, 3.3% (95% CI: 2.0%–4.7%), 4.1% (95% CI: 2.6%–5.7%), and 3.7% (95% CI: 2.3%–5.1%) of participants went through the complementary genetic test on cell-free DNA. The results indicate that 8%–10% of pregnant women were referred for complementary diagnostic tests, including noninvasive prenatal test (NIPT), amniocentesis, and CVS.

The calculated specificity of DS screening tests in the current program were in the range of 83.5–87.5. In addition, the PPV and NPV were 1.79 (95% CI: 0.22%–6.30 %) and 99.8 (95% CI: 99.1%–99.9%), respectively (Table 2). Table 3 provides the direct clinical costs of various DS screening tests in USD. The raw data were in rial, and the exchange rate at the time of the study was 44,000 rial for 1 USD. The direct clinical cost of DS screening for one pregnant woman was estimated at $99.3. Table 4 presents the abortion statistics, which indicate that 2.6%–2.7% of pregnancies ended in the second trimester.

DISCUSSION

Studies on DS screening experiences in other countries revealed compliance rates considerably lower than 94.5%, e.g., 33.6% in Canada, 33% in Sweden, and 30% in the Netherlands.[15,20,21] This finding was due to the restriction of DS screening of high-risk groups (ages higher than 35–40 in different countries), and honoring the right of mothers to inhibit from undergoing DS screening.[20,22,23]

The FPR of DS screening tests ranges 1.8%–5% in countries with firm standards that set an upper bound for the FPR and implement careful monitoring of the process to minimize fetal loss.[14,24–26] This study revealed a large difference between this rate in Iran (12.5%–16.5% for different samples) and 1.4%–5%.

One of the most important reasons for such differences is the implementation of several screening tests in Iran. In addition, any mother with at least one positive result from each test is considered a "positive" case. Thus, the FPR increases with the use of an "OR" operator between various results. In regard to the low specificity of these

tests in Iran, a sequential algorithm has been suggested for DS screening. However, in practice, complementary screening tests are recommended and performed for most mothers, regardless of the results of previous tests.

The following issues also contribute to the above differences in the FPRs: (1) most physicians and laboratories disobey the standards set by the MOHME. As for the side findings of this work, in a survey that was conducted on 40 subspecialists of perinatology, the Ministry of Health set a 1/250 cutoff for determining high-risk cases for referral to additional tests (including invasive tests or NIPT); however, contrary to the national guidelines, according to more than 75% of these specialists, their experts' opinion was to refer a pregnant mother within a cutoff of 1.1100–1500 for additional tests (mainly invasive tests, such as amniocentesis). At the time of conducting the study, one referral laboratory, which performs approximately 70% of prenatal screening tests in Iran, recommended that mothers with a screening risk of more than 1.2000 be referred for NIPT testing, which is contrary to the standards announced by the Ministry of Health on its official website. This approach was reflected in the screening result report sheet presented to the mothers. (2) DS screening's not being limited to high-risk groups. According to the national guidelines at the time of the conduct of the study, health personnel were required to screen all pregnant mothers of any age, even if they were under 20 years old regardless of a positive family history of DS birth or having insurance to support expensive tests. Screening was seriously recommended in this regard. In addition, if a pregnant mother refuses the test, health personnel are obliged to obtain a written waiver from the mother and indicate in her health care file that "if I give birth to a child with Down syndrome, I will take responsibility for the consequences." (3) Conflict of interest. As the private sector mainly provides these specialized tests, and once this issue becomes clearer, any action aimed at improving the current process and raising it closer to national and international standards will be met with resistance by interested groups. A total of 8%–10% of pregnant women in Iran are referred for complementary diagnostic tests, including NIPT, amniocentesis, and CVS. Moreover, the DS screening tests in the current program in Iran have a specificity of 83.5–87.5. In addition, the PPV and NPV reach 0.017 and 99.8, respectively. Notably, the program lacks acceptable PPV and NPV, which indicates the lack of accurate test quality and high false positive and negative results. This condition implies the need to modify and standardize the program.

As noted previously, complementary diagnostic tests in Iran are not covered by insurance coverage nor provided with another form of financial support. However, some developed countries offer complementary diagnostic tests for pregnant mothers for free.[23] From an economic point of view, we compared the following costs to analyze the DS screening program: how much is the cost burden of caring for a DS individual for the country and how much is the cost burden of finding and aborting a DS fetus for the country based on the current DS screening program.

Regarding the first question, in 2002, the cost of raising a DS individual was $677,692 in the US.[27] Based on the US Consumer Price Index for 2018, the abovementioned cost can be updated to $1,148,745 for the timeframe of this study. The abovementioned cost for Iran can be estimated by multiplying the estimated cost for the US by the ratio of Iran's nominal GDP per capita to that of the US.[28,29] Accordingly, considering the US standards, the cost burden of raising one DS individual in Iran was estimated to be 104,431$ in this study's timeframe.

Regarding the second question, i.e., the cost burden of finding and aborting a DS fetus, at least two types of costs must be considered: 1) the costs of required DS screening tests and 2) costs due fetal loss. For estimation of the first type, the probability of DS occurrence in Iran must be determined. In consideration of the maternal age range of births that occurred in the year of study (the last three quarters of 2017 and the first quarter of 2018) and the corresponding DS risk for each range, the DS occurrence for this study had a probability of 1 out of 885. On the other hand, the direct clinical cost of DS screening tests was 3,180 million rials for the third sample group (726 participants), i.e., 3,870 million rials for a population of 885 participants. Considering the exchange rate of 44,000 rials to 1 US$ in the first quarter of 2018, the total cost of DS screening tests for detecting a DS fetus would be $89,000.

Estimation of the second type of cost necessitated investigation of due abortions. Abortions that occurred in the DS screening process are categorized into the following three groups: 1) DS fetuses discovered during the process and were aborted legally; 2) complications of invasive complementary tests; 3) illegal abortions. The third group of abortions can be attributed to the high FPR of DS screening tests, the unaffordable cost burden of complementary diagnostic tests for an average family in Iran, and the lack of financial support and insurance coverage.

Considering 1.5 million births in Iran during the year of study and the probability of DS occurrence (1 out of 885 pregnancies), we expected to deliver 1,695 DS infants if no screening program were implemented. According to the Iranian Legal Medicine Organization, 1371 pregnant mothers obtained a legal abortion license for their DS fetuses within the abovementioned timeframe.

A considerable portion of abortions in the second trimester are related to non-DS fetuses. Thus, some non-DS fetuses were eliminated to discover one DS fetus. These unwanted abortions fell under two groups: iatrogenic abortions and illegal abortions. Iatrogenic

abortions result from the DS screening procedure. According to the literature on obstetrics and gynecology, invasive diagnostic tests incur a 0.5%–1% probability of abortion.[30–32] This study revealed that 4.4%–6.3% of all pregnant women in Iran are referred for either amniocentesis or CVS. In addition, 94.5% of Iranian mothers underwent DS screening tests. Given this information and considering 1.5 million annual births in the year of study, the number of iatrogenic yearly abortions caused by the DS screening procedure in Iran were either 312–893 or 624–1786, depending on the invasive tests' referral rates (4.4%–6.3%) and the selected probabilities (0.5%–1%). (312 = 1.5 million * 94.5% * 4.4% * 0.5%; and 893 = 1.5 million * 94.5% * 6.3% * 1).

Illegal abortions are induced after DS screening. According to the literature on obstetrics and gynecology, apart from fetal or maternal disorders that result in spontaneous abortions in the second trimester, a considerable and often neglected part of second-trimester abortions is due to screening procedures and aneuploidy diagnosis.[30,31] Spontaneous abortions account for 0.5% of the total pregnancies in Ireland, where no screening program is implemented, and elective-induced abortion is illegal.

A total of 2.1%–2.2% more second-trimester abortions were documented in Iran. As for the reasons, we cannot offer explicit judgment as the differentiation between elective and spontaneous abortions was not possible via interviews due to legal considerations. Therefore, limitations were encountered regarding the estimation of the number of illegal abortions after DS screening tests. However, given the high FPR of the current DS screening program in Iran (12.5%–16.4%), which is higher than the standard threshold in developed countries (2%–5%), and the lack of financial support to the cost burden of complementary diagnostic tests, induced abortion remains the exclusive means for families to terminate a DS fetus.

We can investigate the causes of non-spontaneous abortions in the second trimester in three scenarios. The first one is the best scenario. This scenario indicates the absence of illegal abortions (the second group mentioned above). In this case, 312–1786 iatrogenic abortions occur in the second trimester, i.e., 0.19–1.11 normal fetus abortions for each discovery of one DS fetus. The second one is the intermediate scenario. This scenario entails abortions related to high-risk mothers referred for invasive complementary tests, which all illegal, and subsequent to DS screening. This setting assumes that mothers have opted to abort their fetuses to avoid giving birth to a DS infant before undertaking the complementary tests (probably prompted by due cost burden). In this case, illegally induced abortions after DS screening tests range within 1.3%–1.8% of the annual pregnancies. Two extreme states exist in this scenario: 1) lower bound: all spontaneous abortions are abortions related to high-risk mothers; and 2) upper bound: all abortions related to high-risk mothers are induced and illegal. The ranges are equal to illegal yearly abortions of 19,500–27,000. Iatrogenic abortions shall be also accounted for.

The third one is the worst scenario. All 2.1%–2.2% of abortions that occur in the second trimester (after deducting the 0.5% spontaneous abortions) are illegal abortions subsequent to DS screening, i.e., mothers have selected to abort their DS-suspected fetus. This finding means 31,500–33,000 illegal abortions, i.e., 18.5–19.4 normal fetuses for the discovery of one DS fetus, to which we should add iatrogenic abortions.

Fetal loss due to the current implementation of the DS screening program was determined by estimating an individual's economic production at the time of this study. Such a goal was accomplished based on Iran's Gross National Income per capita in the year of study, i.e., $21,050.[24] Multiplying this number by 50, i.e., an individual's productive life period (15–64 years), we obtained a value of $1,052,500.[33]
Next, we identified the loss incurred in each of the above scenarios by multiplying the individual's economic production during their lifetime by the number of fetal losses in each scenario:

1) Best scenario: Loss is only due to iatrogenic abortions:
$$1{,}052{,}500 \times [0.19, 1.11] = [199{,}975, 1{,}168{,}275]\$$$

2) Intermediate scenario: Loss is due to iatrogenic plus induced abortions, and abortions by high-risk mothers are assumed to be induced:
$$\begin{cases} iatrogenic\ abortion\ loss = [199{,}975, 1{,}168{,}275]\$ \\ induced\ abortion\ loss = 1{,}052{,}500 \times [11.5, 16] = [12{,}103{,}750, 16{,}840{,}00]\$ \\ Total\ loss = [12{,}303{,}725, 18{,}008{,}275]\$ \end{cases}$$

3) Worst scenario: Loss is due to iatrogenic plus induced abortions, and all second-trimester abortions are either iatrogenic or illegally induced ones:
$$\begin{cases} iatrogenic\ abortion\ loss = [199{,}975, 1{,}168{,}275]\$ \\ induced\ abortion\ loss = 1{,}052{,}500 \times [18.5, 19.4] = [19{,}471{,}250, 20{,}418{,}500]\$ \\ Total\ loss = [19{,}671{,}225, 21{,}586{,}775]\$ \end{cases}$$

The above costs were added to the total direct clinical costs of DS screening tests to discover one DS fetus, i.e., $89,000. The total cost of finding one DS fetus in the best scenario was $288,975 – $1,257,275. The total cost of finding one DS fetus in the intermediate scenario was $12,103,750 – $18,097,275. And the total cost of finding one DS fetus in the worst scenario was $19,760,225 – $21,665,250.

A comparison of the costs of raising 1 DS child, i.e., $104,431, with the costs of finding one DS fetus in the current DS screening program in Iran, revealed that none of the three scenarios is economically justified. Therefore, if no DS screening were implemented, and the government accepted all DS children and the costs of caring for them, based on US standards, the expenditures would be reduced by 2.7–12 times in the best scenario, by 118–173 times in the intermediate scenario, and by 189–207 times in the worst scenario, compared with the current situation.

Finally, the most critically problematic factors underlying the implementation of the DS screening program in Iran can be summarized as (1) compelling the public to undergo DS screening tests, merging them into the Primary Healthcare Program for Pregnant Women, minus the differentiation of potentially high- and low-risk individuals in the target population; (2) poor consultation programs for pregnant women inform them properly about the various aspects of the DS screening program, i.e., the aim (determining whether their fetus is a DS fetus and helping them abort it rather than curing the anomaly), steps, the meaning of results, and so on; (3) financial support in the form of insurance coverage for DS screening tests, especially the expensive complementary ones, is lacking; (4) conflicts of interest for DS screening service providers that lead to excessive tests; and (5) weaknesses in monitoring key standard indicators can be used to evaluate the performances of laboratories, gynecologists, and radiologists at various stages of the DS screening program.

The limitations encountered in this work comprise incorrect phone numbers and lack of response, which we attempted to solve by increasing the sample size; the interviewee's lack of trust in the interviewer, whom we contacted by calling the special line phone number of the Health Center of TUMS, which is a well-known phone number, and people trusted it more easily; and noncooperation and consent of interviewees to participate in the interview. We attempted to encourage the interviewees to participate in the discussion by expressing data confidentiality and the importance of this study for the health of mothers and children of the country.

CONCLUSIONS

As observed, the cost of screening and discovering fetuses with DS was costly in any scenario compared with the cost of caring for individuals with DS. Therefore, laboratory tests should be revised and standardized due to their low PPV and high FPV. In addition, as screening of low-risk groups, where the chance of disease occurrence is less than that in false positive tests, is practically useless, mandatory screening should be removed in low-risk groups.

CONFLICT OF INTEREST

None declared.

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Evaluation of the Relationship Between Self-Care and Treatment Compliance in Patients with Type 2 Diabetes: A Cross-Sectional Study from Northeast Türkiye

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Abstract

Background: The study aimed to investigate the connection between self-care behaviors and treatment adherence among individuals with type 2 diabetes.

Methods: This cross-sectional correlational study was conducted between January and May 2022 in a public hospital involving 191 patients diagnosed with type 2 diabetes. Data were collected using the patient information form, the diabetes self-care scale, and the assessment scale for treatment compliance in type 2 diabetes.

Results: The mean self-care score was 84.57 ± 14.46 years, and the mean treatment compliance score was 79.50 ± 11.13 years, with a significant negative correlation between them (r = −0.315, p < 0.001). Factors positively influencing self-care were being female (p < 0.05), unemployed (p < 0.05), farmer or civil servant (p < 0.05), hospitalized in the past year (p < 0.01), and exercising regularly or occasionally (p < 0.001). Treatment compliance was significantly higher in those who did not exercise (p < 0.01). A positive correlation was found between age and treatment compliance (r = 0.152, p < 0.05) but not with BMI or diagnosis duration.

Conclusions: The study revealed that patients exhibited moderate levels of self-care and treatment compliance. Moreover, as self-care improved, treatment compliance tended to decrease.

Keywords: nurse, self-care, treatment compliance, type 2 diabetes

INTRODUCTION

Diabetes is a condition characterized by the insufficient action of the insulin hormone, leading to persistently high blood sugar levels. Insulin is crucial in regulating the body's metabolism and utilization of glucose for energy.[1,2] It represents a significant global health concern, affecting approximately 537 million individuals worldwide. In Turkey, the prevalence of diabetes stands at 14.5%, as reported by the International Diabetes Federation in 2021.[3] Diabetes affects all age groups because of various factors such as aging, imbalanced nutrition, obesity, and a sedentary lifestyle. This condition not only diminishes life expectancy but also imposes a considerable economic burden and necessitates the development of self-care skills.[4,5] Self-care encompasses personalized practices aimed at fostering health promotion and disease prevention. It involves adherence to medications, adoption of appropriate dietary habits, engagement in physical activity, regular monitoring of blood glucose levels, and adherence to prescribed diabetes treatments.[1] Engaging in self-care behaviors has been associated with enhanced glycemic control and decreased risk of diabetes-related complications.[6,7] For instance, a Nigerian study revealed that individuals with high levels of self-care activities exhibited improved glycemic control and reported a higher quality of life.[8] Similarly, a Taiwanese study demonstrated that patients with inadequate glycemic control tended to exhibit lower self-care levels.[9] In addition, a Singaporean study of patients with type 2 diabetes indicated that individuals with insufficient self-monitored blood glucose levels experienced a detrimental effect on their quality of life.[10] The management of type 2 diabetes aims to attain blood glucose normalization and mitigate complications and necessitates lifestyle modifications, medication adherence (including oral hypoglycemic drugs/insulin injections), and adoption of self-care practices.[11] A study conducted in Nicosia reported a treatment non-compliance rate of 4.5% among patients with type 2 diabetes, whereas in Southwest Ethiopia, the non-compliance rate was 24.9%.[12,13] A systematic review revealed that at least 45% of patients with type 2 diabetes failed to achieve adequate glycemic control, with poor treatment adherence being a significant contributing factor. Findings of a study conducted in southwestern Nigeria indicated that poor medication adherence among patients with type 2 diabetes was associated with suboptimal glycemic control.[14] Moreover, non-adherence to treatment in patients with type 2 diabetes correlated with heightened rates of

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hospitalization, inferior health outcomes, increased morbidity and mortality rates, and high healthcare expenditures.[15,16] By actively involving patients in their care, nurses can empower them to fulfill their treatment, care, and informational needs.[5] Treatment compliance denotes the extent to which an individual's behaviors, medication adherence, dietary selections, and lifestyle adjustments conform to the guidance provided by healthcare professionals.[17] Nurses are pivotal in helping patients with diabetes acclimate to their condition, oversee their treatment, embrace healthy dietary practices, participate in consistent physical activity, and mitigate the likelihood of future complications.[12] The literature review identified several studies that evaluated self-care and treatment compliance in Turkish patients diagnosed with type 2 diabetes.[20,21] However, none of these studies investigated both self-care and treatment compliance concurrently. Consequently, this study aimed to identify factors affecting self-care and treatment compliance among patients with type 2 diabetes and analyze the associations between these determinants.

METHODS

Ethical considerations

The study obtained permission from the relevant authors to use the scales. To conduct the study, approval was obtained from the Artvin Çoruh University Ethics Committee on March 10, 2021 (Approval no. E-18457941-050.99-24269). In addition, permission was obtained from the institution where the study took place (Permission no. E-17720518-602.05). Patients with type 2 diabetes who participated in the study were informed about the research, and they provided consent. The study was conducted in accordance with the Declaration of Helsinki.

Type, population, and sample

In this cross-sectional and correlational study, the population consisted of patients with type 2 diabetes who were admitted to the internal medicine outpatient clinic of a state hospital in the northeast of Turkey. The sample included patients who were admitted to the clinic between January and May 2022 and met the inclusion criteria. The inclusion criteria were as follows: age >18 years, diagnosis of type 2 diabetes at least a year ago, lack of verbal communication disability, and willingness to participate in the study. Initially, 228 patients with type 2 diabetes were interviewed for the study. However, the final sample size only included 191 patients because 24 declined to participate and 13 were diagnosed less than a year ago. Based on the post hoc power analysis conducted using the G Power 3.1.9.7 program, which examined the relationship between treatment compliance scale and self-care scale scores ($r = -0.315$), the study obtained a power of 0.99 at a 95% confidence interval and a significance level of $a = 0.05$. These results indicate that the sample size is adequate.[22]

Data collections tools

The following instruments were used: diabetes patient information form, diabetes self-care scale, and the assessment scale for treatment compliance in type 2 diabetes mellitus.

Diabetes Patient Information Form. This researcher-created form is divided into two parts. The first part consists of eight descriptive questions that focus on sociodemographic data, including age, sex, marital status, educational level, and employment status of the patients. The second part contains nine questions that inquire about disease-related factors. These questions cover topics such as illness duration, treatment type, dependence level, and hospitalization status.

Diabetes Self-Care Scale. The Lee and Fisher scale was developed to evaluate diabetes-related self-care activities.[23] Its validity and reliability studies were conducted in Turkish by Karakurt and Kaşıkçı.[24] The Likert structure of the scale was modified to a 4-point Likert-type scale: 1 = never, 2 = sometimes, 3 = often, and 4 = always. The scale ranges from a minimum of 35 to a maximum of 140 points, and a higher score indicates greater engagement in self-care activities. In patients with a total scale score of >66%, their self-care is at an acceptable level. The scale does not have subdimensions or items with reversed scoring. The item–total correlations of the scale ranged from $r = -0.19$ to $r = 0.56$, and the test–retest correlation coefficient was 0.96.[24] The validity and reliability studies reported Cronbach's alpha of 0.81, whereas in the present study, Cronbach's alpha was 0.85.

Assessment Scale for Treatment Compliance in Type 2 Diabetes Mellitus. This assessment scale was developed by Demirtaş and Albayrak to evaluate treatment compliance among individuals with type 2 diabetes in the Turkish population.[25] This scale comprises 30 items and follows a 5-point Likert structure. The scale ranges from 1, indicating "strongly agree," to 5, indicating "strongly disagree." The minimum and maximum possible scores on this scale are 30 and 150, respectively. A lower score indicates higher patient compliance in the treatment of type 2 diabetes. The scale includes 13 and 17 items that measure positive and negative attitudes, respectively. Positive items are scored from 1 to 5, whereas negative items are scored inversely from 5 to 1. The study's KMO test resulted in a score of 0.75, indicating good sampling adequacy. The factor loadings of the items in the scale ranged from 0.30 to 0.77. Furthermore, the test–retest correlation coefficient yielded an impressive result of 0.99.[25] Its Cronbach's alpha was 0.77, whereas in the present study, it was 0.70.

Data collection

Data were collected using the diabetes patient information form, diabetes self-care scale, and assessment scale for treatment compliance in type 2

diabetes mellitus. Patients with type 2 diabetes who were visiting the outpatient clinic of internal medicine were personally informed by the researcher, and their consent was obtained before data collection. The forms took approximately 15–20 min to complete.

Data analysis

The study data were analyzed using IBM SPSS Statistics for Windows version 23 (IBM Corp., Armonk, NY, USA). Significance was determined at a *P*-value of <0.05, with a 95% confidence interval. Data were presented as percentiles and means ± standard deviations (SDs). The normality of data distribution was assessed using skewness and kurtosis analysis. For normally distributed binary variables, the mean scores of self-care and treatment compliance were compared using independent sample t-tests. For more than two normally distributed data, one-way analysis of variance (ANOVA) and post hoc tests were employed. The relationship between continuous variables (such as age and duration of diagnosis) and self-care and treatment compliance was examined using Pearson/Spearman correlation analysis. Furthermore, a multiple linear regression analysis was conducted to assess the relationship between independent variables and the prediction of self-care and treatment adherence scores.

RESULTS

The study involved 191 patients diagnosed with type 2 diabetes. The average age of these patients was 56.06 ± 13.72 years. Among the participants, 46.6% were between the ages of 43 and 61, 55% were female, 88% were married, 40.8% had completed primary school, and 29.8% were employed. In terms of occupation, 42.1% were civil servants. In addition, 36.7% of the patients had lower income than expenses. The average weight of the patients was 80.67 ± 15.09 kg, and the average height was 167.09 ± 8.98 cm. The mean body mass index was 28.99 ± 5.65 kg/m^2 (Table 1).

The mean duration of diagnosis was 9.78 ± 7.69 years. In this study, 77% took oral antidiabetic medications for treatment, 36.1% had diabetes-related complications, 35.1% were hospitalized in the past year because of diabetes or its complications, 25.1% were smokers, 3.7% consumed alcohol, 15.2% engaged in regular exercise, 62.8% had another chronic disease in addition to

TABLE 1. Demographics and clinical characteristics of the sample (N = 191)

Variable	Mean ± SD	Min – Max
Age/years	56.06 ± 13.72	24 – 87
Weight/kg	80.67 ± 15.09	48 – 124
Height/cm	167.09 ± 8.98	145 – 189
BMI (kg/m^2)	28.99 ± 5.65	17.30 – 50.31
Diabetes diagnosis duration (years)	9.78 ± 7.69	1 – 40
Age	N	%
24–42	35	18.3
43–61	89	46.6
62–80	57	29.8
>81	10	5.2
Sex		
Male	86	45.0
Female	105	55.0
Marital status		
Married	168	88.0
Single	23	12.0
Educational status		
Literate	30	15.7
Primary education	78	40.8
Secondary/high school	57	29.8
Undergraduate/ postgraduate	26	13.7
Employment status		
Employed	57	29.8
Unemployed	134	70.2
Profession (N = 57)		
Farmer	11	19.3
Self-employed	22	38.6
Civil servant	24	42.1
Income status		
Income < Expense	70	36.7
Income = Expense	87	45.5
Income > Expense	34	17.8
Type of treatment		
OAD	147	77.0
OAD + Insulin	26	13.6
Insulin	18	9.4
Diabetes-related complication		
Present	69	36.1
Absent	122	63.9
Hospitalization in the last year because of diabetes or its complications		
Yes	67	35.1
No	124	64.9
Smoking status		
Yes	48	25.1
No	143	74.9
Alcohol use		
Yes	7	3.7
No	184	96.3
Exercise status		
Yes	29	15.2
Sometimes	64	33.5
No	98	51.3
Chronic diseases other than diabetes		
Present	120	62.8
Absent	71	37.2
Family member with diabetes		
Present	123	64.4
Absent	68	35.6

OAD, oral antidiabetic drug; SD, standard deviation

TABLE 2. Mean scores of the diabetes self-care scale items of the participants (N = 191)

Item No.	Items	Mean ± SD	Min–max
1	I eat my meals at the same time every day.	2.59 ± 0.97	1–4
2	I always eat my snacks.	2.48 ± 0.96	1–4
3	I keep bound to my diet when I eat out in the restaurants.	2.18 ± 0.98	1–4
4	I stick to my diet when I go to invitations (to others, friends, meetings, etc.).	2.21 ± 0.96	1–4
5	I keep bound to my diet even when the people around me do not know I am diabetic.	2.49 ± 0.98	1–4
6	I do not eat excessively.	2.66 ± 0.94	1–4
7	I do exercise regularly.	2.07 ± 0.97	1–4
8	I do my exercises even when I do not feel like exercising.	1.91 ± 0.97	1–4
9	I do exercise adequately.	1.96 ± 0.99	1–4
10	I measure my blood sugar.	3.18 ± 0.96	0–4
11	I keep records of my blood sugar measurements.	2.45 ± 1.09	1–4
12	I take my oral antidiabetic drugs as recommended.	3.51 ± 0.83	0–4
13	I take my insulin injections as recommended.	0.88 ± 1.54	0–4
14	I adjust my insulin dosage according to my blood sugar measurements.	0.82 ± 1.29	0–4
15	I keep a lump of sugar with me when I am out/away from home.	2.59 ± 1.18	1–4
16	I eat a lump of sugar when my blood sugar drops.	2.71 ± 1.08	1–4
17	I regularly go and see my doctor.	2.96 ± 0.91	1–4
18	I consult my doctor when my blood sugar level is very high.	2.84 ± 0.97	1–4
19	I consult my doctor when my blood sugar level is very low.	2.78 ± 1.03	1–4
20	I regularly check my feet.	2.90 ± 1.04	1–4
21	I always wear shoes, by all means, outside the house.	3.18 ± 1.05	1–4
22	I always wear a slipper or a house shoe when inside.	2.87 ± 1.10	1–4
23	I always wear socks.	3.02 ± 1.00	1–4
24	I keep my toenails short and straight.	3.41 ± 0.83	1–4
25	I routinely take a shower (at least once a week or more).	3.45 ± 0.81	1–4
26	I brush my teeth every day.	3.01 ± 0.97	1–4
27	I carry a diabetes identification card.	2.04 ± 1.16	1–4
28	I talk with the other patients with diabetes about how they care for themselves.	2.42 ± 0.99	1–4
29	I consult nurses, doctors, and other health care providers/specialists about how to prevent complications.	2.63 ± 1.01	1–4
30	I read handouts and brochures about diabetes, when given.	1.99 ± 1.03	1–4
31	I go to the library to get information on diabetes.	1.30 ± 0.69	1–4
32	I attend to a diabetes support group.	1.30 ± 0.70	1–4
33	I am a member of a diabetes journal.	1.25 ± 0.63	1–4
34	I do research on the Internet to find information about diabetes.	1.89 ± 0.97	1–4
35	I use the things I learn to avoid any complications that can occur about diabetes.	2.65 ± 0.96	1–4

TABLE 3. Participants' mean scores on the assessment scale for treatment compliance in type 2 diabetes mellitus items (N = 191)

Item No.	Items	Mean ± SD	Min–max
1	I check my blood sugar regularly.	1.91 ± 1.01	1–5
2	I do not feel like a diabetic.	2.90 ± 1.41	1–5
3	I regularly take my oral antidiabetics/insulin.	1.65 ± 0.97	1–5
4	I believe that my disease will completely cure when my worries or stress is over.	3.09 ± 1.29	1–5
5	I eat the amount of food in the recommended manner as advised by healthcare professionals.	2.60 ± 1.16	1–5
6	I want to manage my disease by making dietary changes rather than using oral antidiabetics or insulin.	2.89 ± 1.29	1–5
7	I think that nothing bad will happen even if my blood sugar is high.	2.27 ± 1.28	1–5
8	I visit the doctor with the recommended frequency.	2.14 ± 1.10	1–5
9	Nothing has changed in my life after I was diagnosed with diabetes mellitus (DM).	2.29 ± 1.21	1–5
10	I get angry with my friends and relatives more easily after my diagnosis.	3.35 ± 1.29	1–5
11	I arrange my oral antidiabetic medication/insulin dose according to my food intake.	3.27 ± 1.31	1–5
12	I am more nervous and furious due to the difficulties of diabetes.	3.43 ± 1.31	1–5
13	I always try to improve my knowledge about DM.	2.61 ± 1.26	1–5
14	I always feel depressed about my future due to my disease.	2.87 ± 1.33	1–5

TABLE 3. Continued

Item No.	Items	Mean ± SD	Min–max
15	I can easily tell everyone that I am a diabetic.	1.74 ± 1.01	1–5
16	After I was diagnosed with DM. I quit my bad habits.	2.58 ± 1.23	1–5
17	I feel when my blood sugar is low.	1.80 ± 1.02	1–5
18	I do not trust the health staff; they do not help me.	1.87 ± 1.27	1–5
19	I regularly exercise in both winter and summer as recommended.	3.30 ± 1.21	1–5
20	I am angry because I have to eat special food and have special needs.	2.99 ± 1.28	1–5
21	I am very angry that I have this disease.	3.03 ± 1.38	1–5
22	I feel anxious when it is medication/insulin time.	2.89 ± 1.34	1–5
23	I can easily live with diabetes by doing everything that is required.	2.69 ± 1.14	1–5
24	I wish there was no special diet for the disease.	3.51 ± 1.24	1–5
25	I feel when my blood sugar is high.	1.81 ± 1.02	1–5
26	I started caring for my feet after I was diagnosed with DM.	2.28 ± 1.28	1–5
27	I usually have a defense for not doing exercises.	2.97 ± 1.39	1–5
28	I am sad because I have to endure my disease.	3.19 ± 1.21	1–5
29	I feel strong enough to fight the disease.	2.45 ±1.23	1–5
30	I believe that my diabetes will cure if I strictly follow to my diet.	3.16 ± 1.32	1–5

TABLE 4. Comparison of patients' descriptive characteristics with their self-care and treatment compliance scores (N = 191)

Variable	Self-care score		Treatment compliance score	
	Mean ± SD	*p*	Mean ± SD	*p*
Age				
24–42	84.62 ± 15.28		76.51 ± 7.68	
43–61	84.03 ± 15.02	0.533	79.82 ± 11.83	0.305
62–80	86.12 ± 13.19		80.33 ± 11.73	
>81	80.40 ± 14.34		82.50 ± 10.88	
Sex				
Male	81.82 ± 14.91	0.017*	81.11 ± 11.50	0.071
Female	86.82 ± 13.74		78.19 ± 10.69	
Marital status				
Married	84.49 ± 14.05	0.833	79.61 ± 10.89	0.710
Single	85.17 ± 17.51		78.69 ± 13.02	
Educational status				
Literate	88.33 ± 12.24		81.90 ± 12.79	
Primary education	84.52 ± 13.93	0.416	80.78 ± 10.15	0.093
Secondary/high school	83.68 ± 18.29		76.56 ± 11.70	
Undergraduate/postgraduate	82.34 ± 14.14		79.38 ± 9.80	
Employment status				
Employed	81.03 ± 16.02	0.027*	81.42 ± 9.65	0.122
Unemployed	86.08 ± 13.53		78.69 ± 11.64	
Profession (N = 57)				
Farmer	88.00 ± 14.51		84.00 ± 10.85	
Self-employed	73.36 ± 11.98	0.012*	82.68 ± 8.12	0.282
Civil servant	84.87 ± 17.52		79.08 ± 10.24	
Income status				
Income < Expense	86.21 ± 13.31		81.01 ± 11.14	
Income = Expense	84.03 ± 16.10	0.438	78.73 ± 11.45	0.361
Income > Expense	82.58 ± 12.51		78.38 ± 10.21	
Type of treatment				
OAD	83.44 ± 14.40		79.14 ± 11.24	
OAD + insulin	86.46 ± 14.03	0.081	79.61 ± 11.28	0.519
Insulin	91.11 ± 14.28		82.33 ± 10.12	
Diabetes-related complication				
Present	85.81 ± 13.63	0.376	79.14 ± 11.89	0.736
Absent	83.87 ± 14.92		79.71 ± 10.72	
Hospitalization in the last year because of diabetes or its complications				
Yes	88.53 ± 13.60	0.005*	80.38 ± 11.97	0.423
No	82.43 ± 14.51		79.03 ± 10.67	

TABLE 4. Continued

Variable	Self-care score		Treatment compliance score	
	Mean ± SD	*p*	Mean ± SD	*p*
Smoking				
Yes	85.04 ± 15.06	0.797	79.00 ± 12.54	0.716
No	84.41 ± 14.30		79.67 ± 10.66	
Alcohol use				
Yes	81.27 ± 10.02	0.541	82.85 ± 11.65	0.419
No	84.70 ± 14.60		79.38 ± 11.12	
Exercise status				
Yes	92.51 ± 15.62		76.86 ± 13.42	
Sometimes	86.98 ± 12.51	0.000*	76.18 ± 9.82	0.001*
No	80.65 ± 14.32		82.45 ± 10.48	
Chronic disease other than diabetes				
Present	84.59 ± 13.85	0.984	79.05 ± 11.40	0.470
Absent	84.54 ± 15.55		80.26 ± 10.70	
Family member with diabetes				
Present	83.20 ± 13.95	0.078	79.78 ± 11.36	0.650
Absent	87.05 ± 15.13		79.01 ± 10.77	
Age/year (min, 24; max, 87)	56.06 ± 13.72	(r = −0.026)		(r = 0.152)*
BMI (kg/m^2) (min,17.30; max, 50.31)	28.99 ± 5.65	(r = −0.040)		(r = −0.057)
Diabetes diagnosis duration/year (min,1; max, 40)	9.78 ± 7.69	(r = −0.031)		(r = −0.098)

SD: standard deviation; r: Pearson correlation analysis; statistical analysis was conducted using independent sample t-test, ANOVA, Pearson correlation, and Spearman correlation as required. *$p < 0.05$.

TABLE 5. Predictors affecting patients' self-care and treatment compliance scores

Independent Variables	β	SE	*p*	Model *p*	R^2
Self-care					
Constant		3.871	0.000*	0.054	0.212
Sex$^{ref = male}$					
Female	0.100	5.327	0.454		
Profession$^{ref = self-employed}$					
Farmer	0.322	6.191	0.041*		
Civil servant	0.284	4.699	0.057		
Hospitalization in the last year because of diabetes or its complications$^{ref = yes}$					
No	−0.060	4.496	0.666		
Exercise status$^{ref = no}$					
Yes	0.162	6.234	0.283		
Sometimes	0.230	4.693	0.106		
Treatment compliance					
Constant		3.531	0.001*	0.001*	0.085
Age	0.101	0.057	0.159		
Exercise status$^{ref = no}$					
Yes	−0.158	2.326	0.037*		
Sometimes	−0.253	1.740	0.001*		

β: standardized regression coefficient; SE: standard error of the coefficient; R^2: proportion of variations in the dependent variable that is explained by the regression model; $p < 0.05$.

diabetes, and 64.4% had a family member with diabetes (Table 1). The patients were found to have a mean self-care score of 84.57 ± 14.46 (min, 52; max, 132).

The mean scores of patients' responses to the self-care scale are presented in Table 2. The mean self-care score of the female patients was significantly higher than that of male patients, ($p < 0.05$, independent sample t-test). Patients had a mean treatment compliance score of 79.50 ± 11.13 (min, 50; max, 102). The mean scores of patients' responses to the treatment compliance scale are presented in Table 3.

Non-working patients had significantly higher self-care scores than working patients ($p < 0.05$). Occupation also influenced the self-care scores of patients ($p < 0.05$, ANOVA test). Farmers and civil servants had higher self-care scores than self-employed individuals, as determined by post hoc analysis (LSD). Furthermore, patients who had been hospitalized for diabetes or its complications in the past year had higher mean self-care scores than those who had not been hospitalized ($p < 0.01$, independent sample t-test). Moreover, a significant difference was found between patients' exercise status and their self-care scores ($p < 0.001$, ANOVA test). Post hoc analysis (LSD) demonstrated that both regular and occasional exercisers had higher self-care scores than non-exercisers (Table 4).

No significant difference was found in the mean self-care score based on the patients' age, marital status, educational level, income status, treatment type, presence of diabetes-related complications, smoking and alcohol use, presence of chronic disease other than diabetes, and presence of a family member with diabetes ($p > 0.05$) (Table 4).

The ANOVA test showed a significant change in the mean treatment compliance score based on exercise status ($p < 0.01$). Further analysis using the LSD method revealed that patients who did not exercise had higher treatment compliance scores than those who exercised occasionally and regularly (Table 4).

In this study, no significant differences in treatment compliance total score based on age, sex, marital status, educational level, employment status, occupation, income status, treatment type, presence of diabetes-related complications, hospitalization in the last year because of diabetes or its complications, smoking and alcohol use, presence of chronic diseases other than diabetes, and having family members with diabetes ($p > 0.05$) (Table 4).

The regression model examining the relationship between participants' sex, occupation, hospitalization because of diabetes and its complications in the last year, exercise status, and self-care score was not significant ($p > 0.05$). On the contrary, the regression model exploring the association between participants' age, exercise status, and treatment compliance score was significant ($p < 0.01$). The model was able to explain 8% of the variance. Exercise status was identified as a significant predictor of treatment adherence score (yes, $\beta = -0.158$, $p < 0.05$; sometimes: $\beta = -0.253$, $p < 0.01$) (Table 5). The Pearson correlation analysis showed a positive and significant correlation ($r = 0.152$; $p < 0.05$) between patients' age and their total treatment compliance score. However, no significant correlations were found among BMI, duration of diagnosis, and treatment compliance score ($p > 0.05$). Furthermore, no significant correlations were observed between the self-care score and age, BMI, and duration of diagnosis ($p > 0.05$) (Table 4). Conversely, the Pearson correlation analysis revealed a negative and significant correlation ($r = -0.315$, $p < 0.001$) between patients' self-care score and treatment compliance score.

DISCUSSION

This study explored the factors influencing self-care and treatment adherence in patients with type 2 diabetes. The relationship between these factors and the relevant literature was also examined. In this study, patients had a moderate level of diabetes self-care. A similar study conducted at a medical center in Southern Taiwan on patients with type 2 diabetes also found a moderate level of self-care in these patients.[9] Neşe *et al*. also found moderate self-care levels in their study of patients with type 2 diabetes.[19] Xie *et al*. reported that older patients with type 2 diabetes had high self-care levels, whereas another study conducted in East Delhi with patients with type 2 diabetes aged ≥20 reported weak self-care activities.[26,27] Self-care is a significant aspect of diabetes care.[5] Limited awareness about the importance of self-care practices and insufficient education on diabetes management could contribute to moderate self-care levels. Cultural beliefs and socioeconomic factors may influence self-care behaviors.

Therefore, healthcare providers can empower patients to engage in more effective self-care practices and improve outcomes in diabetes management through a multifaceted approach. This approach can include enhancing patient education, implementing culturally tailored interventions, providing better support from the healthcare system, and addressing psychosocial and socioeconomic barriers.

In this study, the treatment compliance of patients with type 2 diabetes was moderate. According to Yüksel and Bektaş 20.7%, 60.9%, and 66.2% of their patients had good, moderate, and poor compliance levels, respectively. Another study conducted in Nicosia found that 66.2% of their patients showed good compliance, 29.3% showed moderate compliance, and 4.5% did not comply with the treatment.[12] Similarly, in southwestern Ethiopia, 24.9%, 37.9%, and 37.2% of the patients had low, moderate, and high levels of treatment compliance, respectively.[13] Arı and Özdelikara also examined patients with type 2 diabetes and found that moderate treatment compliance, similar to our study.[21] Literature reports that patient follow-up has a positive effect on treatment compliance.[29] Therefore, treatment adherence is crucial in diabetes management. We believe that the moderate level of treatment compliance in this study may be attributed to the sociocultural characteristics of our sample. To improve treatment compliance, more frequent monitoring of the patients is necessary.

The findings of this study indicate that women with diabetes exhibit better diabetes self-care than men. This is consistent with other studies conducted in Iran and Poland, which also found that women with type 2 diabetes had higher self-care levels than men.[30,31]. However, a discrepancy was found between our study and the findings of Borba *et al*., who reported that men had higher self-care than women.[32] İlhan *et al*. and Neşe *et al*. also found no significant sex differences in self-care.[18,19] Given that women generally tend to prioritize self-care, the results of our study align with expectations.

In this study, unemployed patients demonstrated better self-care than employed ones. Specifically, self-care was better among civil servants and farmers than self-employed individuals. A study carried out in Poland also found that unemployed patients with type 2 diabetes exhibited higher self-care behaviors than employed ones.[31] However, a study reported opposite results, indicating that patients with type 2 diabetes had better self-care.[18] Neşe *et al*. mentioned that self-care did not vary based on profession.[19] It is speculated that unemployed individuals have better self-care, potentially due to having more time to dedicate to themselves and their illness. On the contrary, self-employed patients may struggle with self-care because they lack regular work schedules, making it difficult to allocate enough time to properly manage their diabetes.

In this study, patients who had been hospitalized for diabetes or its complications in the past year showed higher self-care levels than those who had not been hospitalized. This result aligns with the findings of Neşe *et al*., who concluded that hospitalization for diabetes did not affect self-care.[19] Furthermore, a meta-analysis revealed that patients, whether personal experiences or observing the complications of the disease in themselves and others, had a better understanding of the importance of self-care behaviors.[33] It is hypothesized that patients with hospitalization experience may improve their self-care because of fear of jeopardizing their health.

In this study, patients with diabetes who exercised regularly had higher self-care levels than those who did not exercise. This is supported by the results of Neşe *et al*., who also reported that patients with diabetes who exercised had better self-care.[19] Another study showed that exercise improved self-efficacy in patients with type 2 diabetes.[34] İlhan *et al*. analyzed data of patients with type 2 diabetes and revealed that those who exercised had higher self-care levels.[18] Exercise plays a crucial role in diabetes management because it improves blood glucose levels, reduces the risk of cardiovascular disease, and promotes overall well-being.[35] Given that exercise is a significant self-care activity, individuals with diabetes are encouraged to prioritize exercise.

In this study, patients who consistently exercised showed better treatment compliance than those who did not. This finding aligns with the results of Yüksel and Hicran who studied patients with type 2 diabetes and found that individuals who engaged in physical activity had higher treatment compliance.[28] Patients who exercise likely have a greater awareness of their diseases and choose to exercise because they believe it will positively affect their health. Therefore, healthcare professionals must inquire about patients' exercise habits when assessing their treatment compliance.

In this study, older patients with type 2 diabetes had lower treatment compliance. A study conducted in southwestern Nigeria on patients with type 2 diabetes also reported a decrease in treatment compliance with age.[15] Similarly, Shruthi *et al*. found that geriatric patients with chronic diseases had decreased treatment compliance with increasing age, which is consistent with our findings.[36] Another study on patients with chronic obstructive pulmonary disease found that advanced age was associated with lower medication compliance.[37] Factors such as forgetfulness and neglect negatively affect the treatment compliance of older individuals.[38] This may also contribute to the low treatment compliance rate among older patients. Therefore, healthcare providers must pay closer attention to treatment compliance in older patients with type 2 diabetes and offer more frequent follow-ups.

In this study, patients with high self-care levels exhibited better treatment compliance. This finding is supported by the results of Jannoo and Khan in their study of patients with type 2 diabetes, which also observed good self-care in individuals with good medication compliance.[39] Another study emphasized the significant effect of self-care behaviors on treatment compliance in patients with type 2 diabetes.[31] Walker *et al*. similarly noted that individuals with good medication compliance exhibited good self-care.[40] Neşe *et al*. further highlighted that individuals with type 2 diabetes who regularly took their medications had better self-care than others.[19] A meta-analysis further stated that difficulties in accessing drugs hindered treatment compliance, resulting in lower levels of diabetes self-care.[33] Overall, treatment compliance is a crucial aspect of self-care practices, and patients with high treatment compliance would also exhibit high self-care levels. When individuals with diabetes become more skilled at managing their health condition, they are more likely to adhere to their treatment plans and achieve better health outcomes. Consequently, increased self-care is directly linked to improved treatment compliance.

A strength of this study is that it is the first of its kind in Turkey to assess self-care and treatment compliance in patients with type 2 diabetes. However, this study is limited to a sample of 191 patients with type 2 diabetes who received treatment at the internal medicine outpatient clinic of Artvin State Hospital. Therefore, the

findings cannot be generalized to all individuals with type 2 diabetes, which is a significant limitation of our study.

CONCLUSIONS

This study revealed that patients displayed moderate self-care levels and treatment adherence. Furthermore, as self-care increased, so did treatment adherence. Further analysis indicated that several factors were associated with higher self-care levels. These factors were being female, unemployed, and a professional farmer or civil servant, having been hospitalized for diabetes or its complications within the past year, and engaging in regular exercise. Conversely, patients who did not exercise regularly showed lower treatment adherence. Thus, nurses are encouraged to prioritize patient education to enhance self-care behaviors among those with type 2 diabetes. In addition, nurses should actively encourage patients and conduct regular follow-ups while identifying patients who may be at higher risk for non-compliance with their treatment.

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CONFLICT OF INTEREST

The authors declare no potential conflicts of interests with respect to the authorship and/or publication of this article.

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Association of Self-Reported Disease Severity with Depression and Anxiety among COPD Patients

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Association of Self-Reported Disease Severity with Depression and Anxiety among COPD Patients

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Abstract

Background: This study was conducted to estimate the proportion of patients who experience a high impact from chronic obstructive pulmonary disease (COPD) on their health status and those who also experience symptoms of depression and anxiety. It also sought to determine whether the health impact of the disease is associated with anxiety and depression.

Methods: An analytical cross-sectional study was conducted among 177 randomly selected patients with COPD seeking treatment in various primary health centers in Al Ahsa, Saudi Arabia. The COPD Assessment Test (CAT) was used to determine the impact of COPD on health generally, and the Hospital Anxiety and Depression Scale was used to determine the presence of anxiety and depression symptoms. Multiple logistic regression was performed to determine the association between the health impact of COPD on the respondents and the presence of symptoms of anxiety and depression.

Results: Patients who had a CAT Score of >21 were 17.37 times more likely to experience anxiety. Patients with COPD who had a CAT Score of >21 were 5.62 times more likely to experience depression.

Conclusion: COPD had a severe impact on the health of nearly 30% of the patients affected. The high impact of COPD on health increases the likelihood of having anxiety and depression symptoms.

Keywords: anxiety disorders, chronic obstructive, comorbidity, depression, pulmonary disease, tobacco smoking

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is now the third highest cause of death globally, accounting for 90% of all deaths in low- and middle-income countries (LMICs),[1–3] and its prevalence is expected to double by 2030 unless urgent steps are taken to reduce the underlying risk factors, primarily tobacco smoking and passive exposure to environmental pollutants.[4] COPD is a heterogeneous lung condition marked by chronic respiratory symptoms resulting in a persistent, often progressive, airflow obstruction.[5] A review of the Global Burden of Disease 2019 dataset shows that approximately half a million people in Saudi Arabia suffer from COPD, corresponding to a 329.82% increase over the number of people diagnosed in 1990.[6] In Saudi Arabia, the burden of COPD is anticipated to increase even further due to the relatively high smoking rate (19.8% overall, 30% for men, and 4.2% for women) among Saudis over 40 years old.[7] Moreover, the frequent exposure of the population to non-smoking factors (e.g., biomass fuel, dust, gases, and outdoor pollution) adds to the burden of the disease.[7] Substantial evidence has demonstrated the association of COPD with reduced physical activity,[8] low productivity,[9,10] rehospitalization,[11–17] and even death.[18] In addition, the negative effect of COPD can be further aggravated by the increasing prevalence of clinical comorbidities such as lung cancer, cardiovascular disease, and diabetes,[19] and psychological comorbidities such as depression and anxiety,[20–24] that have been shown to affect the disease prognosis, quality of life, and survival of patients with COPD.

As of 2020, over 300 million people worldwide suffer from depression, the leading cause of disability. Aside from depression, anxiety disorders are among the most common psychiatric disorders, affecting more than 260 million people worldwide. Depression and anxiety often occur as comorbidities, and prevalence rates continue to rise, especially in LMICs.[25] In Saudi Arabia, depression and anxiety are believed to affect between 22% and 71% of the population.[26] High comorbidity (>50%) exists between depression and anxiety disorders.[24] Furthermore, depression and anxiety are linked to worse health outcomes, particularly when they co-occur with long-term physical health conditions.[27,28] Patients with depression are more likely than those without depression to experience episodes of COPD exacerbation, and even moderate co-morbid depression is linked to twice as

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much use of hospital emergency services.[29] Both depression and anxiety are linked with less favorable outcomes, higher mortality, higher rates of hospitalization, and lower quality of life in patients with COPD.

Underdiagnosed and untreated depression in older patients with COPD may result in inadequate prognosis and health outcomes. However, if clinicians had a better grasp of how depression affects these two conditions, they might be able to offer patients and their caregivers the right kind of support and treatment plans.[28] Therefore, this study was conducted to estimate the proportion of Saudi patients with COPD who experience anxiety and depression and to determine whether the severity of the impact of COPD is associated with the development of anxiety and depression.

METHODS

The research proposal was approved by the Research and Ethics Committee at King Fahad Hospital Hofuf, Al Ahsa, Kingdom of Saudi Arabia (IRB KFHH NO. H-05-HS-065). The aim of the study was explained to the patients and their informed consent was obtained. Participation in this study was voluntary and the ability to withdraw from the study at any time and the confidentiality, privacy, and anonymity of the patients and their responses were assured. The study was conducted in accordance with the Declaration of Helsinki and followed ethical principles.

This study used an analytic cross-sectional approach involving COPD patients in Al Ahsa in the Eastern Region of Saudi Arabia. The participants in the study consisted of patients who attended respiratory and smoking cessation clinics at randomly selected primary healthcare centers in Al Ahsa. This study is a subgroup analysis of 177 patients with COPD from an original data set consisting of 390 patients with chronic respiratory diseases (COPD and bronchial asthma). The original sample size of 386 was calculated using Epi Info with the following parameters: a total population of 316,841 (based on the 2022 data from the Planning Department), 95% confidence level and 80% power.

Data collection took place from October 2021 to March 2022. COPD patients were deemed eligible to participate if they were over 18 years old, able to comprehend and verbalize, not previously diagnosed with mental disorders, and able to provide consent voluntarily to participate. A structured data collection instrument was used. The first section consisted of questions about demographic characteristics—age, gender, level of education, and marital status. Two standardized tools were used to assess disease severity and detect the presence of anxiety and depression.

The COPD Assessment Test (CAT) was utilized to determine the impact of current illness on patients' health. The CAT is a validated, short (8-item), and simple patient-completed questionnaire with good discriminant properties developed for use in routine clinical practice to gauge the health status of patients with COPD. Despite its small number of component items, it covers a broad range of effects of COPD on patients' health. In addition, studies have shown that it is responsive to change and treatment.[30] For this study, the impact of COPD on the patients was classified as severe when the CAT Score was >20, including those classified as high (>20) and very high (>30). For those patients with CAT scores of 10–20 (medium) and <10 (low), the impact of COPD on their health was classified as not severe.

The second tool was the Hospital Anxiety and Depression Scale (HADS), a self-report tool often used in non-psychiatric settings to detect the two most common expressions of distress: anxious and depressive states.[31] The HADS consists of seven questions for anxiety and seven for depression. Each item is measured on a four-point scale, with a score of 0 indicating "not present" and 3 indicating a "considerable event," giving a total score ranging from 0 to 21 on each of these two subscales. The cut-off score was eight or more. A score of more than eight was considered indicative of a severe case for both the depression and anxiety subscales. For anxiety, the HADS has a specificity of 0.78 and a sensitivity of 0.9, and for depression, it has a specificity of 0.79 and a sensitivity of 0.83.[32,33] The Arabic version of this test was used for this study. Cronbach's alpha was 0.83 (95% confidence interval: 0.79–0.88) for the HADS anxiety subscale and 0.77 (0.7–0.83) for the HADS depression subscale.[30]

Data were entered and analyzed using Epi Info 7. Descriptive statistics were performed for the categorical and continuous variables. Estimation of proportion using the default test provided in Epi Info (Exact Interval) was performed to determine the relative proportion of patients who experience a severe health impact of COPD and those who manifest symptoms of anxiety and depression. The proportion of respondents who perceive the impact of their illness as severe and not severe, and those with or without anxiety and depression, were tabulated with their corresponding frequencies and confidence intervals. Multiple logistic regression was applied to test the association between the perceived severity of the health impact of COPD and the presence of anxiety and depressive symptoms. A p-value of <0.05 was considered significant, with a confidence interval of 95%.

RESULTS

The study participants consisted of 177 patients with COPD currently being seen in the respiratory and smoking cessation clinics of health centers in Hofuf, Al Ahsa, Saudi Arabia. The demographic characteristics of the

respondents are presented in Table 1. The mean age of participants was 46.7 ± 10.49. Among the 177 patients, COPD had a low impact on the health of 64 (36.16%, 95% CI: 28.91–43.47%), a moderate impact on the health of 64 (36.16%, 95% CI: 29.44–44.05%), a high impact on the health of 34 (19.21%, 95% CI: 13.61–25.66%) and a very high impact on the health of 15 (8.47%, 95% CI: 4.79–13.52%).

Chronic obstructive pulmonary disease had a combined low and moderate impact on the health of 128 patients (72.32%, 95% CI: 65.29–78.89%), and a high and moderately high impact on the health of 49 patients (27.68%, 95% CI: 21.11–34.71%). The relative proportions of patients according to the health impact of COPD are presented in Table 2.

Symptoms of anxiety were present in 63 (35.59%, 95% CI: 28.38–42.90%) of the COPD cases, whereas 114 patients (64.41%, 95% CI: 57.10–71.62%) had a HADS score below eight and, therefore, did not experience anxiety. Of the 49 patients with high to very high CAT scores, 36 (73.47%, 95% CI: 58.92–85.05%) had anxiety symptoms, while only 13 (26.53%, 94% CI: 14.95–41.08%) did not. Among those with low to moderate CAT scores, 27 patients (21.09%, 95% CI: 14.27–28.97%) had anxiety symptoms, while in the same group, 101 (78.91%, 95% CI: 71.03–85.73%) did not have symptoms of anxiety. The relative proportions of patients according to the presence of symptoms of anxiety across sociodemographic groups are presented in Table 3.

Symptoms of depression were seen in 84 patients (47.46%, 95% CI: 39.68–54.80%), while the remaining 93 patients (52.54%, 95% CI: 45.20–60.32%) did not report symptoms of depression. Of the 49 patients with high to very high CAT scores, 36 patients (73.47%, 95% CI: 58.92–85.05%) had depression symptoms, while only 13 (26.53%, 94% CI: 14.95–41.08%) did not. Among those with low to moderate CAT scores, 48 patients (37.50%, 95% CI: 28.86–46.61%) had symptoms of depression. In the same group, 80 (62.6%, 95% CI: 53.84–71.14%) did not have symptoms of depression. The relative proportions of patients according to the presence of symptoms of depression across sociodemographic groups are presented in Table 4.

As seen in Table 5, patients with COPD with a CAT Score of >21 were 10.47 times more likely to experience anxiety than those patients whose CAT Score was less than 20 ($p < 0.0001$). In addition, older COPD patients were 57.97% less likely to experience anxiety than younger patients with COPD ($p = 0.0137$). Also, married patients with COPD were 1.93 times more likely to experience anxiety compared to unmarried patients ($p = 0.0438$). When the effects of gender, age, level of education, and marital status remained constant, patients who claimed that COPD had a high or very high impact on their health were 17.37 times more likely to have depressive symptoms than those who reported that their current illness had a medium or low impact on their health status ($p < 0.0001$).

TABLE 1. Demographic characteristics of patients with COPD, Al Ahsa, Saudi Arabia (N = 177)

Variables	N	%
Gender		
Male	112	63.28
Female	65	36.72
Age		
<46.7	114	64.41
>46.8	63	35.59
Marital status		
Single	77	43.50
Married	100	56.50
Level of education		
Pre-university	126	71.19
University	51	28.81

As seen in Table 6, patients with COPD with a CAT Score of >21 were 4.67 times more likely to experience depression ($p < 0.0001$). In addition, patients with COPD who have completed university education were 69.7% less likely to experience depression than those with a pre-university education level ($p = 0.0010$). When the effects of gender, age, level of education, and marital status remained constant, patients who claimed that COPD had a high or very high impact on their health status were 5.62 times more likely to have depressive symptoms than those who reported that their current illness had a medium or low impact on their health status ($p = 0.0002$).

DISCUSSION

This study sought to determine whether the health impact of disease is associated with anxiety and depression. Using a cross-sectional study design, the severity of the health impact of COPD and the prevalence of anxiety and depression symptoms among patients with COPD were estimated. In addition, the association between disease severity and the presence of anxiety and depression symptoms was calculated.

According to the World Health Organization (WHO), patient adherence to long-term treatment for COPD is influenced by how the illness is perceived.[34] Among COPD patients, the perception of illness has a substantial impact on their medical behavior and their levels of anxiety and depression. Consequently, the perception of illness requires regular evaluation in clinical practice.[35]

In the present study, 27.63% (95% CI: 21.11–34.71%) of patients reported that their illness impacted their health severely. However, a study in Greece found that the majority of patients with COPD perceived their respiratory condition as being of moderate to mild severity.[36]

TABLE 2. Health impact category of patients with COPD according to demographic characteristics (N = 177)

Variables	Non-Severe			Severe		
	N	%	95% CI	N	%	95% CI
Gender						
Male	92	82.14	73.78 – 88.74	20	17.86	11.26 – 26.22
Female	36	55.38	42.53 – 67.73	29	44.62	32.27 – 57.47
Age						
<46.7	74	64.91	55.41 – 73.62	40	35.09	26.38 – 44.59
>46.8	54	85.71	74.98 – 93.36	9	14.29	6.64 – 25.02
Marital status						
Single	63	81.82	71.38 – 89.69	14	18.18	10.31 – 28.62
Married	65	65.00	54.82 – 74.27	35	35.00	25.73 – 45.18
Level of education						
Pre-university	85	67.46	58.54 – 75.54	41	32.54	24.46 – 41.46
University	43	84.31	71.41 – 92.98	8	15.69	7.02 – 28.59

TABLE 3. Distribution of anxiety according to demographic characteristics of patients with COPD

Variables	Anxiety Positive			Anxiety Negative		
	N	%	95% CI	N	%	95% CI
Gender						
Male	42	37.50	28.53 – 47.15	70	62.50	52.85 – 71.47
Female	21	32.31	21.23 – 45.05	44	67.69	54.95 – 78.77
Age						
<46.7	48	42.11	32.92 – 51.71	66	57.89	48.29 – 67.08
>46.8	15	23.81	13.75 – 35.69	48	76.19	64.31 – 86.25
Marital status						
Single	63	81.82	71.38 – 89.69	56	72.73	61.38 – 82.26
Married	65	65.00	54.82 – 74.27	58	58.00	47.71 – 67.80
Level of education						
Pre-university	56	44.44	35.60 – 53.56	70	55.56	46.44 – 64.40
University	7	13.73	5.70 – 26.26	44	86.27	73.74 – 94.30

TABLE 4. Distribution of depression according to demographic characteristics of patients with COPD

Variables	Depression Positive			Depression Negative		
	N	%	95% CI	N	%	95% CI
Gender						
Male	56	50.00	40.40 – 59.60	56	50.00	40.40 – 59.60
Female	28	43.08	30.85 – 55.96	37	56.92	44.04 – 69.15
Age						
<46.7	60	52.63	43.06 – 62.06	54	47.37	37.94 – 56.94
>46.8	24	38.10	25.70 –50.49	39	61.90	49.51 – 74.30
Marital status						
Single	35	45.45	34.06 – 57.21	42	54.55	42.79 – 65.94
Married	49	49.00	38.86 – 59.20	51	51.00	40.80 – 61.14
Level of education						
Pre-university	70	55.56	46.44 – 64.40	56	44.44	35.60 – 53.56
University	14	27.45	15.89 – 41.74	37	72.55	58.26 – 84.11

The presence of a lower proportion of patients who reported that COPD has a high to very high impact on their health may be attributed to the fact that the respondents were ambulatory patients who attended primary healthcare centers. The WHO states that factors influencing patient adherence to long-term treatment for COPD include how they perceive the illness, the type of medication used, the effectiveness of the communication between the patient and the healthcare practitioner, and the social environment. When patients think their treatment will improve the management or control of their disease, or when they anticipate serious negative effects from non-adherence, they are more likely to maintain compliance with it.[34]

The review of pertinent literature shows that patients have an unclear perception of COPD, and this kind of perception is widespread among those in the terminal stage of their life.[20,23,24,26,28,29] Patients with COPD who had recently experienced exacerbated symptoms and severe

TABLE 5. Crude and adjusted association between disease severity and anxiety

Variables	Crude Association			Adjusted Association		
	Odds Ratio	95% CI	*p*	Odds Ratio	95% CI	*p*
COPD impact on health						
Severe	10.461	4.877 – 22.436	0.000	17.372	5.733 – 52.645	0.000
Not severe[Ref]						
Gender						
Male	0.795	0.417 – 1.516	0.487	0.255	0.088 – 0.741	0.012
Female[Ref]						
Age						
<46.7	0.421	0.211 – 0.837	0.013	0.826	0.337 – 2.023	0.675
>46.8[Ref]						
Marital status						
Single	1.930	1.018 – 3.660	0.043	1.410	0.640 – 3.109	0.393
Married[Ref]						
Level of education						
Pre-university	0.198	0.083 – 0.475	0.000	0.215	0.082 – 0.567	0.001
University[Ref]						

TABLE 6. Crude and adjusted association between disease severity and depression

Variables	Crude Association			Adjusted Association		
	Odds Ratio	95% CI	*p*	Odds Ratio	95% CI	*p*
COPD impact on health						
Severe	4.666	2.254 – 9.661	0.000	5.617	2.293 – 13.755	0.000
Not severe[Ref]						
Gender						
Male	0.756	0.409 – 1.399	0.374	0.427	0.191 – 0.957	0.038
Female[Ref]						
Age						
<46.7	0.540	0.288 – 1.009	0.053	0.797	0.372 – 1.707	0.560
>46.8[Ref]						
Marital status						
Single	1.152	0.635 – 2.091	0.640	0.879	0.448 – 1.724	0.707
Married[Ref]						
Level of education						
Pre-university	0.303	0.149 – 0.615	0.001	0.332	0.157 – 0.701	0.003
University						

breathlessness were more likely to describe their symptoms as severe or very severe.[36] Most COPD patients view their symptom burden as a substantial and continuous barrier to their activities of daily living.[37]

In the current study, symptoms of anxiety were present in 63 (35.59%, 95% CI: 28.38–42.90%) of the COPD cases, while symptoms of depression were seen in 84 patients (47.46%, 95% CI: 39.68–54.80%). In the current study, there was a lower proportion of anxiety among those who had completed university education, older patients, and those who were unmarried, while the relative proportion of anxiety was found to be fairly equal across gender groups. In addition, a lower proportion of patients with depression included those with a university education and those in the older age group. The differences found in the level of significance when multiple logistic regression was performed may have been due to effect modification of age, gender, level of education and marital status. However, the confounding effect of these variables were not tested as this was beyond the scope of study.

Age, gender, and poor quality of life, among other conditions, are associated with depression and anxiety symptoms.[38–40] For this reason, the Global Initiative for Chronic Obstructive Lung Disease has placed considerable emphasis on evaluating these conditions as part of a patient's evaluation of stable COPD.[41]

Patients with a CAT Score of >21 were 17.37 times more likely to experience anxiety. Among the sociodemographic variables considered in this study, significant associations with anxiety were found independently for age, level of education, and marital status. For example, older patients with COPD with university-level education were found to have a lower risk

of developing anxiety. However, married patients were nearly twice as likely to develop anxiety as unmarried patients with COPD.

It was seen in this study that patients with COPD who had a CAT Score of >21 were 5.62 times more likely to experience depression. Among the sociodemographic variables considered, only the level of education was independently associated with depression. Patients with COPD who had completed university education were found to be less likely to develop depression than those with lower levels of educational attainment.

A cross-sectional study carried out across China revealed that patients with mild COPD living in urban communities had higher rates of anxiety and depression than those in rural areas.[42] Anxiety or depression was associated significantly with female gender and poor health. More interventions should be developed to reduce the risks of anxiety and depression in the early stages of COPD.[42] Regardless of the clinical severity of COPD, patients under 60 were more likely to have clinically significant amounts of anxiety and depression.[34] Older patients with COPD had a considerably lower likelihood of experiencing anxiety or depression than younger ones.[38]

Although the exact mechanisms behind the association of depression and anxiety with COPD remain unclear, it has been suggested that mood disorders result from feelings of hopelessness, social isolation, reduced physical functioning, and lifestyle changes.[43] Some studies have hypothesized that the association may be partly mediated by chronic inflammation.[44]

This study had several limitations. First, the results apply only to patients who consulted the primary health centers of Al Ahsa at the time of the data collection. Selection bias could not be completely discounted as patients with COPD who consult the outpatient departments of the hospitals in the area were not considered in this study. Second, misclassification was probable in terms of segregating patients based on the severity of the impact of COPD on their health status. Third, the symptoms assessed by the CAT are time-varying variables and may thus be affected by recent exacerbations of respiratory symptoms. Similarly, anxiety and depression symptoms vary over time and may affect the result by the misclassification of patients into anxiety and depression categories.

CONCLUSIONS

Chronic obstructive pulmonary disease had a severe impact on the health of nearly 30% of patients seen in primary healthcare centers. Anxiety and depression symptoms are fairly common among patients with COPD and tend to vary across demographic variables. However, Saudi patients with COPD whose illness severely impacts their well-being are also highly likely to develop anxiety and depression. The patient-reported impact of illness and the presence of anxiety and depression should be clinically validated. In addition, health personnel in primary healthcare facilities must be trained to recognize early manifestations of the social and mental effects of COPD, as patients with COPD (with anxiety or depression) experience more acute exacerbations, instances of rehospitalization, and a greater risk of mortality than those with no comorbidities. Finally, a community-based support system must be developed among patients with COPD to reinforce appreciation for the holistic management of this chronic respiratory disease.

CONFLICT OF INTEREST

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Nursing Students' Epistemological Beliefs and Critical Thinking Skills

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Nursing Students' Epistemological Beliefs and Critical Thinking Skills

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Abstract

Background: Epistemological beliefs and critical thinking affect the approach to knowledge and decision-making processes in nursing practice. These characteristics positively contribute to the personal development and quality of patient care of nurses. This study investigated the relationship between nursing students' epistemological beliefs and critical thinking skills.

Methods: This descriptive and correlational study included 752 students studying nursing. The study was conducted with students enrolled in nursing programs at two state universities located in the northeast and west of Turkey. Data were collected using a Student Information Form, the Epistemological Beliefs Questionnaire (EBQ), and the Critical Thinking Disposition Scale (CTDS).

Results: The mean age of the students was 20.49 ± 1.73 years, and 78.2% were females. The students' mean scores were 82.73 ± 12.05 on the total EBQ and 43.00 ± 5.35 on the CTDS. A negative and moderate (r = −0.315, p = 0.000) relationship was noted between the nursing students' mean scores on the EBQ and CTDS.

Conclusions: The study results indicate that the nursing students' epistemological beliefs and critical thinking levels were above mean and that students with higher epistemological beliefs had higher critical thinking skills. According to these findings, utilizing instructional strategies incorporating practice and questioning in nursing education may enhance students' epistemological beliefs and critical thinking abilities.

Keywords: critical thinking, epistemology, nursing students, Türkiye

INTRODUCTION

Epistemological beliefs are judgments about what knowledge and knowing are, what the beliefs about learning are, and what the nature of acquiring knowledge is.[1,2] They are cognitive variables that enable students to actively participate in learning, understand and apply knowledge, and contribute to learning by facilitating decision-making.[3,4] Individuals who have undeveloped epistemological beliefs believe that knowledge is simple and unchanging, that it is conveyed by an authority, that learning is innate, and that learning cannot occur with effort or ability.[3] Individuals with advanced epistemological beliefs attempt to access information, question the information they obtain, have high motivation and academic success, and have a developed critical perspective.[5] Several studies have reported that personal beliefs about knowledge and learning are effective in the learning process and change an individual's perspective on learning and teaching.[6–8] Underdeveloped epistemological beliefs can affect nursing students' ability to acquire nursing knowledge and relate nursing concepts to practices and their capacity to understand. Nursing students with developed epistemological beliefs are more effective in clinical settings, develop good practice, and are more willing to access up-to-date information. A study showed that students with higher epistemological beliefs can cope more effectively with uncertainty in the clinical setting.[9] Thus, even throughout their school years, future nurses should possess the skills necessary to successfully obtain information and use it to provide evidence-based, safe nursing care for patients.[3]

Criticizing means evaluating something regarding its positive or negative sides. Critical thinking is defined as the constructive expression of an evidence-based perspective in explaining facts or events. Moreover, it means that students can evaluate their thinking skills and change their behavior by putting their knowledge into practice, evaluating the accuracy and precision of information, generating ideas and applying them, analyzing facts, upholding their opinions, making inferences and comparisons, solving problems, and evaluating discussions.[10] Students with high critical thinking skills can be more active and approach events more openly, comprehensively, interestedly, fairly, and logically.[10,11] Some studies revealed a relationship between students' critical thinking skills and epistemological beliefs,[2,6] and others indicated that this relationship has positive effects.[5,12,13] Currently, the aim of

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nursing education is to provide students with information and enable them to access information and raise them as nurses who think, produce, analyze, criticize, and learn to learn.[2] Some of the crucial qualifications sought among working nurses include knowing how to learn, access information, think critically, and reflect all of these in nursing care and practices.[6] From this perspective, nurses working in multiple fields should have high critical thinking skills and developed epistemological beliefs to continue their studies and development. For nurses to maintain quality continuous care treatment practices to effectively manage quality improvement studies, they should be versatile, use critical thinking skills, and have positive beliefs about knowledge and knowing.[14] Similar to this information, some studies showed that critical thinking skills have a positive effect on students' self-directed learning and problem-solving skills.[15,16]

Epistemological beliefs and critical thinking skills are critical in nursing students' education and the successful execution of the nursing profession. Studies reported that students with high epistemological beliefs are better at academic achievement and understanding science.[17,18] These findings indicate that utilizing instructional strategies that incorporate practice and questioning in nursing education may enhance students' epistemological beliefs and critical thinking abilities. When the relationship between students' critical thinking skills and epistemological beliefs is known, instructional designs that will improve epistemological beliefs and increase critical thinking skills can be developed, and thus, educational changes can be made. This study aimed to determine the relationship between the epistemological beliefs and critical thinking skills of nursing students.

METHODS

This descriptive and correlational research study was conducted to ascertain the connection between nursing students' epistemological beliefs and critical thinking abilities. The study was conducted from February 1, 2023, to March 1, 2023, with nursing students enrolled in two different state universities located in the northeast and west of Turkey. In these universities, nursing education is provided according to the National Core Education Program for Nursing.

This study included 1,212 students enrolled in the nursing programs in the academic year 2022–2023 at the state universities where the study was conducted. The sample size was determined using G*Power software (version 3.1.9.2, Heinrich-Heine University of Dusseldorf, Germany). A power analysis was done, and the sample size was calculated as 746 subjects, based on a confidence interval of 0.95%, statistical power of 0.80 (1-β), and a margin of error of 0.05.[3] The sample of the study consisted of 752 nursing students who voluntarily agreed to participate in the study and completed the data collection forms.

Data were collected using the questionnaire technique. The Epistemological Beliefs Questionnaire (EBQ), the Critical Thinking Disposition Scale (CTDS), and a Student Information Form were used. Student Information Form was created by the researchers. It consisted of eight questions about students' age, school year, high school that the student graduated from, economic status of the family, education level of the mother and father, and the voluntary choice of profession.

The EBQ scale was created by Schommer, and Deryakulu and Buyukozturk performed studies on its reliability and validity and its adaptation into Turkish. It is a 5-point Likert scale and consists of 34 items, including 17 positives and 17 negatives, and has three sub-factors, namely, "Belief in Learning Depends on Effort (Factor 1)," "Belief in Learning Depends on Capability (Factor 2)," and "Belief that Only One Truth Exists (Factor 3)." The scale scores vary between 34 and 170. A high score on one of the scale's factors indicates that the person has immature or underdeveloped beliefs about that factor, whereas a low score means the person has mature or developed beliefs. The Cronbach's alpha value of the scale was 0.83 for the first factor, 0.62 for the second factor, 0.59 for the third factor, and 0.71 for the total scale.[19] In this study, the first factor's alpha value was 0.86, the second factor's alpha value was 0.87, the third factor's alpha value was 0.75, and the total scale's alpha value was 0.83.

The Turkish validity and reliability of the CTDS scale developed by Sosu was performed by Akın *et al*.[20,21] It is a 5-point Likert scale with two dimensions, namely, critical openness and reflective skepticism, and a total of 11 items. The scale scores range between 11 and 55. An increase in the scale score indicates an increase in critical thinking tendency. Confirmatory factor analysis shows that the two-dimensional model fits well ($x^2 = 53.24$; df = 40; RMSEA = 0.040; NFI = 0.90; NNFI = 0.96; GFI = 0.96; AGFI = 0.93; CFI = 0.97; IFI = 0.97; and SRMR = 0.046). The Cronbach's alpha internal consistency reliability coefficients were 0.78 for the whole scale, 0.75 for the reflective skepticism subscale, and 0.68 for the Openness to Criticism subscale. The item-total score correlation coefficients of the scale vary between 0.25 and 0.57. These results show that the Turkish form of the CTDS can be used as a valid and reliable measurement tool. The scale's Cronbach's alpha value was 0.78.[20] In this study, the scale's alpha value was 0.85.

Research data were collected using an online questionnaire that was created on "Google Forms" after ethics committee and institutional approvals were obtained. The questionnaire includes the Student Information Form (8 questions), EBQ (34 items), and CTDS (11 items) which were used to collect the research data.

The link to the questionnaire was sent to the students' WhatsApp groups, and they were requested to fill it out. On the first page, participants approved an informed consent form which included information about the purpose of the study, that the participation was voluntary, and that their data would be kept confidential. After approving the consent form, they were allowed to access the questionnaire. No identifying personal information was collected, which ensured the confidentiality of the participants' information in the study. After the questionnaire was completed by the participants, the data were downloaded from the "Google Form" to the researcher's password-protected computer and saved.

Data were analyzed using the SPSS 25.00 software (IBM Corp., Armonk, NY, USA). The Kolmogorov–Smirnov test showed no evidence of a normal distribution of the data ($p < 0.05$). Descriptive and comparative methods were used to analyze the data. The relationship between the scales was evaluated using the Spearman Correlation analysis. A 95% confidence interval and a significance level of $p = 0.05$ were used to assess the outcomes.

Ethics committee approval was obtained from the Trakya University Faculty of Medicine Scientific Research Ethics Committee (date: 28.11.2022, decision number: TUTF-BAEK/ 23/08), and institutional permission was obtained from the institutions where the research would be conducted. Scale usage permission was obtained from the authors of the scales used in the study. Data were collected using a questionnaire created on Google Forms. Furthermore, students' consent was obtained online via an "Informed Volunteer Consent Form" at the start of the questionnaire. All items on the form were made available to students who agreed to participate in the study.

RESULTS

The students included in the study had a mean age of 20.49 ± 1.73 years; 78.2% were females, 32.0% were first-year students, and 79.1 were Anatolian/Science High School graduates. Additionally, 80.0% of the nursing students were found to have a medium income, 56.4% of their mothers and 49.2% of their fathers were primary school graduates, and 84.5% of them had voluntarily chosen the nursing profession (Table 1). A significant difference was noted between students' sex and their mean scores on the total EBQ ($p < 0.05$). However, no significant difference was observed between sex and mean scores on the total CTDS ($p > 0.05$). The male students scored higher on the EBQ on mean than the female students (Table 1).

A significant difference was found between the students' school year and their mean scores on both total EBQ and CTDS ($p < 0.05$). Although the second-year students had higher mean EBQ scores than other students, they had lower mean scores than first- and fourth-year students on the total CTDS (Table 1). A significant difference was determined between students' family income status and their mean scores on the total EBQ ($p < 0.05$). However, no difference was noted between income level and mean scores on the total CTDS ($p > 0.05$). Furthermore, students who had a low family income had higher mean scores than those who had a medium family income (Table 1).

While no difference was observed between students' desire to become a nurse and their mean scores on the total EBQ ($p > 0.05$), a significant difference was determined between this variable and their mean scores on the total CTDS ($p < 0.05$). Students who wanted to study nursing had a higher overall CTDS score than other students (Table 1). No significant difference was found between the types of high schools that students graduated from, the education level of their parents, and their mean scores on the total EBQ and CTDS ($p > 0.05$) (Table 1).

The students' mean scores on the EBQ were as follows: total scale, 82.73 ± 12.05; Factor 1 subdimension, 35.38 ± 7.78; Factor 2 subdimension, 20.17 ± 5.15; and Factor 3 subdimension, 27.17 ± 5.15. Regarding CTDS, the mean scores were 43.00 ± 5.35 for the total scale, 27.11 ± 3.45 for the Openness to Criticism subdimension, and 15.88 ± 2.31 for the Reflective Skepticism subdimension (Table 2).

Regarding the relationship between students' mean scores on EBQ and CTDS, a negative significant relationship was noted between the mean scores on the total EBQ, the Factor 1 subdimension, and the Factor 3 subdimension and their mean scores on the total CTDS and its subdimensions. Moreover, a positive relationship was determined between mean scores on the Factor 2 subdimension of the EBQ and the scores on the total CTDS and reflective skepticism subdimension (Table 3).

DISCUSSION

In this study, which examines the epistemological beliefs and critical thinking skills of student nurses, it was found that the demographic variable of sex affects epistemological belief levels. Specifically, female students received lower scores than male students, indicating that they possess more advanced epistemological beliefs. In a study by Kutluca *et al*. examining epistemological beliefs, it was determined that female students possess more advanced epistemological beliefs than male students.[22] In a meta-analysis, which included 36 studies, it was concluded that women's epistemological beliefs were more developed than those of men.[23] Similar results were found in another study.[3] Additionally, in a mixed-methods study, it was identified that sex is a significant factor influencing university students' epistemological beliefs.[24] In the current study, female students are found to possess higher epistemological beliefs, consistent with the findings in the literature.

TABLE 1. Nursing students' demographic characteristics and their distribution by EBQ score and CTDS score (N = 752)

	N (%)	EBQ Mean ± SD	*p*	CTDS Mean ± SD	*p*
Characteristics					
Sex					
Female	588 (78.2)	82.11 ± 11.38	0.016*	43.21 ± 4.69	0.644
Male	164 (21.8)	84.94 ± 14.00		42.24 ± 7.20	
Grade					
1	241 (32.0)	81.67 ± 11.33	0.005*	43.36 ± 5.70	0.026*
2	181 (24.1)	85.41 ± 10.65		42.36 ± 4.90	
3	182 (24.2)	82.02 ± 12.57		42.89 ± 5.53	
4	148 (19.7)	81.97 ± 13.68		43.33 ± 5.02	
Graduate of high schools					
General high schools	49 (6.5)	86.87 ± 11.32	0.052	42.18 ± 6.86	0.979
Health occupational high school	108 (14.4)	83.34 ± 13.92		42.88 ± 5.80	
Science and Anatolian high schools	595 (79.1)	82.28 ± 11.69		43.09 ± 5.12	
Perceived economic level					
High	44 (5.9)	84.70 ± 11.59	0.038*	42.37 ± 6.51	0.662
Moderate	602 (80.0)	82.16 ± 11.91		43.11 ± 5.12	
Low	106 (14.1)	85.15 ± 12.76		43.00 ± 5.29	
Mother education status					
Illiterate	66 (8.8)	81.18 ± 12.98	0.245	42.95 ± 5.19	0.830
Literacy	34 (4.5)	80.97 ± 14.37		43.00 ± 7.45	
Primary school graduates	424 (56.4)	82.41 ± 12.33		43.01 ± 5.40	
High school and above	228 (30.3)	84.03 ± 10.76		43.00 ± 4.94	
Father education status					
Illiterate	11 (1.5)	84.54 ± 13.47	0.276	36.63 ± 8.45	0.246
Literacy	29 (3.9)	78.55 ± 14.93		41.24 ± 7.52	
Primary school graduates	371 (49.2)	82.56 ± 12.43		43.19 ± 5.30	
High school and above	341 (45.4)	83.21 ± 11.27		43.04 ± 5.01	
Willingness to come to nursing education					
Yes	136 (84.5)	82.46±12.05	0.165	43.24±5.45	0.028*
No	25 (15.5)	83.48±12.06		42.33±5.01	

EBQ: Epistemological Beliefs Questionnaire; CTDS: Critical Thinking Disposition Scale; SD: standard deviation; Mann–Whitney U test, and Kruskal–Wallis Test were used appropriately; * $p < 0.05$.

TABLE 2. Mean scores for EBQ and CTDS subscales (N = 752)

EBQ and CTDS subscales	Mean ± SD	Min–Max
Total EBQ	82.73 ± 12.05	41–136
Belief in Learning Depends on Effort (Factor 1)	35.38 ± 7.78	17–85
Belief in Learning Depends on Capability (Factor 2)	20.17 ± 5.15	8–40
Belief in Only One Truth is Exist Factor 3)	27.17 ± 5.15	9–45
Total CTDS	43.00 ± 5.35	11–55
Openness to Criticism	27.11 ± 3.45	7–35
Reflective Skepticism	15.88 ± 2.31	4–20

EBQ: Epistemological Beliefs Questionnaire; CTDS: Critical Thinking Disposition Scale; SD: standard deviation.

TABLE 3. Correlation (r) between the EBQ and CTDS scores of nursing students (N = 752)

EBQ	CTDS		Total CTDS
	Openness to Criticism	Reflective Skepticism	
Belief in Learning Depends on Effort (Factor 1)	−0.500*	−0.457*	−0.530*
Belief in Learning Depends on Capability (Factor 2)	−0.061*	−0.097*	−0.090*
Belief in Only One Truth is Exist (Factor 3)	0.109*	0.093*	0.105*
Total EBQ	−0.279*	−0.288*	−0.315*

EBQ: Epistemological Beliefs Questionnaire; CTDS: Critical Thinking Disposition Scale; Spearman Correlation statistical Analysis was used.

Moreover, the present study shows that the school year variable affected students' epistemological belief levels and critical thinking skills. The epistemological beliefs of second-year students were less developed than those of other students, and they had a lower level of critical thinking skills than first- and fourth-year students. Orhan revealed that students studying in the upper classes had more mature epistemological beliefs and that their epistemological beliefs matured in parallel with the education they received.[25] Additionally, Kaya *et al*. found that the level of critical thinking increases as nursing students advance through their academic years.[26] Furthermore, Jimenez *et al*. noted significant differences in the mean critical thinking scores of students across their academic years.[27] In a study by Hunter *et al*., it was indicated that academic year is a significant predictor of critical thinking skills, with first-year students achieving the lowest scores.[28] As the level of education increases, students' self-confidence and professional development also increases as they will have different problems, solutions, and experiences. Similarly, students' multidimensional thinking, analysis, and synthesis skills, that is, their epistemological beliefs and critical thinking levels, will increase to find solutions to the problems they encounter. However, in the present study, second-year students had the highest epistemological beliefs and lowest level of critical thinking, demonstrating that variables other than the school year may have affected this situation.

In the study, it was determined that another factor affecting nursing students' epistemological belief levels was their family's income level. Notably, the epistemological beliefs of individuals with medium family income were more developed than those of individuals with low family income. This shows that the income level of the family can affect the way and perception of individuals in accessing education and information. Thus, having a moderate-income level can be a balance point for students to access sources and information and enable them to develop a positive perspective on their knowledge and thoughts. In a study by Abedalaziz *et al*., students with a higher socioeconomic status had more advanced epistemological beliefs.[29] Ata and Alpaslan found that university students with a middle/high economic level possess more advanced epistemological beliefs compared to other students.[30] A study conducted by Ozturk *et al*. with science teachers showed that income level did not affect epistemological beliefs.[31] Studies have shown contrasting results. While this may have been due to differences between samples, the association between income level and epistemological beliefs can be revealed by conducting comprehensive studies that show the effect of economic level on epistemological beliefs more clearly.

Students who voluntarily chose the nursing program scored higher on critical thinking tests. Critical thinking is a basic skill in the nursing profession. High critical thinking increases the quality and adequacy of nursing services and contributes to the professionalism and autonomy of the profession.[32] In addition, being successful in the profession is closely related to wanting the profession.[33] It is reported that nurses who choose their profession voluntarily have a greater love for their job, higher professional relationships and job satisfaction, reduced intention to quit, and a higher quality of patient care and professional development.[34] No study has examined the relationship between liking the profession and critical thinking. However, in this study, the critical thinking level of students who had willingly chosen their profession was higher than that of other students, which is a crucial finding regarding the future of the profession, the quality of patient care, and increasing commitment to the profession.

In the present study, it was determined that students' mean scores on the total Epistemological Beliefs Scale were below the mean. Considering that individuals had more highly developed beliefs as the score obtained from the Epistemological Beliefs scale decreased, this result is critical in that it showed that the students had an advanced level of beliefs. In the literature, it is noted that epistemological beliefs are significant cognitive variables affecting learning and teaching processes. Additionally, students with more developed epistemological beliefs have been reported to have higher academic success and more effective learning habits and acquire new information more easily.[35] Research in the literature into student nurses' epistemological beliefs is limited. Karadağ *et al*. showed that students possessed high levels of epistemological beliefs.[2] They demonstrated that advanced epistemological beliefs facilitate a more critical, creative, and objective approach to events, thus enhancing students' scientific thinking skills.[2] Similarly, Yılmaz and Kaya reported that among nursing students, the subdimension of the scale indicating the belief that learning depends on effort was the most developed. They underscored the importance of providing diverse learning experiences and involving students in the teaching-learning process.[6] Furthermore, Özen *et al*. identified that the belief in learning as a function of ability was the most developed, recommending an increased emphasis on the philosophy of knowledge within the nursing curriculum. They argued that this could improve students' perspectives on knowledge and their ability to critically question it.[3] Having well-developed epistemological beliefs is crucial because of the significance of fostering creative and critical thinking in modern nursing education.[2]

Another concept examined that is as important as epistemological belief is critical thinking, which is an art of thinking that involves analyzing and evaluating information and drawing conclusions. Nurses and nursing students should be able to think creatively, self-directedly, and critically to make appropriate decisions and solve the

clinical problems they encounter.[36] Critical thinking enables nurses to perform self-assessment and reflect these insights into healthcare services, identify and address individuals' needs, make rapid and accurate decisions, communicate by striving to understand individuals' emotions and thoughts, and develop awareness in this regard.[37] Critical thinking is a critical process for safe, efficient, and skilled nursing practice. Therefore, nursing education programs should adopt attitudes that encourage critical thinking and stimulate critical reasoning skills.[38] In this study, students' mean scores on the Critical Thinking Skills Scale were above the mean, which is a desired result for nursing students. In other studies, on the examination of the critical thinking levels of nursing students, it was seen that students' critical thinking levels were mostly at low[39,40] or medium levels.[41] The high level of critical thinking obtained in this study is a positive finding in that it is a relevant indicator for improving the quality of nursing care for future nurse candidates.

This study started with the premise that highly developed epistemological beliefs and strong critical thinking abilities were significantly correlated. Critical thinking is a higher-order cognitive skill that is crucial for nursing students.[42] Epistemological beliefs are closely related to critical thinking.[13] Similarly, a weak and negative correlation between the total scores on the critical thinking scale and the Epistemological beliefs scale was found in the analysis between the study's scales. That is, it was found that people with developed epistemological beliefs displayed higher critical thinking abilities. Studies have reported a close relationship between having high-level thinking skills and developed epistemological beliefs. Additionally, it has been stated that since critical thinking is one of the high-level thinking skills that an individual should possess, the development of critical thinking skills will positively affect the development of epistemological beliefs.[1] A study by Orhan demonstrated that epistemological beliefs significantly influence critical thinking.[25] In a study by Kandemir and Eğmir, a relationship between critical thinking and beliefs was identified.[5] Additionally, in studies by Çarkıt and Kurnaz, positive relationships were found between subdimensions of teacher candidates' epistemological belief perceptions and subdimensions of their critical thinking tendencies.[43] The findings of the present study were consistent with those in the literature. These findings support the notion that students' epistemological beliefs have a positive impact on their critical thinking abilities. In a profession such as nursing, where critical thinking and epistemological beliefs are crucial, determining and developing the characteristics of students while they are still in the education period is important for individual and professional development.

The study was limited to nursing students enrolled in two public universities, and the data used to draw conclusions came from the students themselves. Additionally, this study examined a limited number of factors that influenced epistemological beliefs.

CONCLUSIONS

The results of this study reveal that female nursing students had higher epistemological beliefs than their male counterparts. It was found that epistemological beliefs were influenced by students' sex and academic level and their family's income status. In contrast, the level of critical thinking among students was affected by their academic level and their voluntary choice to pursue nursing. Additionally, the study demonstrates that the nursing students' levels of critical thinking and epistemological beliefs were above mean, and those with stronger epistemological beliefs possessed stronger critical thinking abilities. Future studies should include larger samples to better determine the epistemological beliefs of nursing students. This study examined a limited number of factors affecting epistemological beliefs. It is recommended that future research address a broader range of factors and that intervention-based initiatives be implemented to enhance students' epistemological beliefs. Further, it is recommended that students be mentored and guided, continuous feedback is provided, and interactive learning methods with different clinical experiences are offered.

CONFLICT OF INTEREST

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Nursing Students' Attitudes to the Recording and Protection of Patients' Health Data: A Cross-Sectional Study

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Abstract

Background: Understanding nursing students' attitudes toward patient data protection is crucial, as it can affect their future practice and adherence to legal and ethical standards. The primary aim of this study was to assess nursing students' attitudes toward the recording and protection of patients' health data.

Methods: In this descriptive and cross-sectional study, 460 students were selected using the convenience sampling method. The intention was to contact the whole research population; however, data were collected from those who agreed to participate in the study and who completed the data collection form, which accounted for 70% of the population. For data collection, a five-question student description form and the personal health data recording and protection attitude form for nursing students, consisting of 31 questions checked for language validity, were used. The independent samples t-test and one-way variance analysis were used in independent groups.

Results: The students' mean score on the personal health data recording and protection attitude form for nursing students total was 3.96 ± 0.56. The attitudes to the recording and protection of patients' health data of female students, in their second-year of study, who had knowledge concerning personal data and health data, who desired to work in fields of practice related to their studies, and whose levels of communication with patients in their fields of practice were significantly better than those of other students (p = 0.001, p = 0.001, p = 0.000, p = 0.000, p = 0.001, respectively).

Conclusions: Nursing students demonstrated positive attitudes to the recording and protection of patients' data, and certain independent variables affect this. The results of the study may provide nursing educators with an opportunity to carry out interventions relating to factors that affect the attitudes of nursing students to the recording and protection of patients' health data. Qualitative and interventional studies on the research topic with larger samples are warranted.

Keywords: medical records, nursing students, records, Turkey

INTRODUCTION

Personal data include sensitive topics such as ethnical issues, genetic or mental health, substance dependence, sexually transmitted diseases, data relating to children and young people, disabilities, reproductive health, palliative care, sex life, behavior profiles, violence within the family, geographic location, and finance.[1,2] At present, the increasing digitalization of health records has raised concerns about the security of patients' health data.[3-5] Between 2005 and 2019, 249.09 million people were affected by breaches in health service data security.[6]

The rapid global development in information technologies and the electronic recording of health data raise questions about its protection and privacy.[7] In health service, data sharing violations may cause concerns about patient privacy and problems of trust in health workers. This concern may prevent the establishment of effective communication between patients and health professionals and thereby negatively affect care.[8] Shen *et al*.[9] reported that 42% of patients were worried about sharing their medical information outside their control. In another study, the possibility of access to health data and its misuse by unauthorized third parties using health systems worried 48.8% of the patients.[10]

In health services, patients seeking health care will share information, including their most private data, with the health care team. Accordingly, nurses who are with the patients 24 hours a day and are responsible for their care have access to patients' physical, social, cultural, economic, and psychological data. Respect for the privacy of patients is a professional responsibility of all healthcare professionals, particularly nurses.[11] Therefore, nurses must protect the confidentiality of patients' health data.[12]

Conversely, nursing students play an important role in patient care. For their professional development, students immerse in various fields of clinical practice. In this process, students attend to people who come for health services, so they have access to their health data.[13] In clinical practice, nursing students participate in various

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care procedures that may involve privacy issues, such as the exposure of a patient's body during a physical examination. For this reason, they have important responsibilities in processing patients' data.[4]

In nursing education, courses aimed to create awareness among students about the use of patient data within acceptable boundaries and the protection of its confidentiality.[14] Nursing students must have competencies such as acting in accordance with professional ethical principles and values and taking into account relevant laws and regulations when making use of information and care technologies in their work.[2] When the nursing curriculum incorporates awareness of such topics, students may have a lower chance of encountering problems relating to professional and legal responsibilities in their professional lives.

Few descriptive studies have examined nursing students' attitudes to recording and protecting patients' health data.[2,4,5] Therefore, this study aimed to determine nursing students' attitudes to recording and protecting the health data of patients and examine influencing variables. The study findings may contribute to the literature and help determine nursing students' attitudes to recording and protecting patients' health data, increasing the chance for interventions. Moreover, the results will provide valuable information and guide the development of interventions relating to nursing students' recording and protection of patients' health data. In addition, such interventions may help nursing educators develop students' practice strategies before they begin clinical practice. The findings will also contribute to the limited literature available.

The study aimed to determine the attitude levels of nursing students towards the recording and protection of patients' health data as well as whether nursing students' independent variables affect their attitudes to the recording and protection of patients' health data.

METHODS

Ethics committee permission (No. 2023-07 dated 27 September 2023) was obtained from Bursa Uludağ University Health Sciences Research and Publication Ethics Committee. Before commencing the questionnaire survey, in accordance with the Declaration of Helsinki, necessary approvals were obtained online from the participants indicating that their participation was voluntary.

This descriptive and cross-sectional study aimed to determine nursing students' attitudes to the recording and protection of patients' health data and the influencing variables. The study, which was conducted between September and December 2023, enrolled students in the Nursing Department of the Health Sciences Faculty of a government university in the Marmara region of Turkey. The cross-sectional and descriptive design was chosen to address its aim of determining the attitudes to the recording and protection of patients' health data of nursing students studying at a particular period in a single university. In addition, with its descriptive design, a scale was used as a data collection tool, which had been tested for language validity and reliability.

Second-, third-, or fourth-year nursing students who can speak and understand Turkish and participated voluntarily in the study were included. First-year nursing students and those who declined participation in the study were excluded. The study population consisted of second-, third-, and fourth-year students of the nursing department of a state university in the Marmara region of Turkey. First-year students were not included in the study because they lacked clinical experience. During the study period, 460 second-, third-, and fourth-year nursing students were recruited using the convenience sampling method. The intention was to contact the whole study population; however, data were collected from 322 students who agreed to participate in the study and who completed the data collection forms, which accounted for 70% of the study population. A sociodemographic information form and the Personal Health Data Recording and Protection Attitude Form (PHDRPAF) for nursing students were used to collect research data.

The sociodemographic information form was created by the researchers according to the literature[2,5,15] and included questions on students' age, sex, year of study, knowledge concerning personal data and health data, liking to work in fields of practice related to their classes, and the description of their levels of communication with patients in their fields of practice.

The PHDRPAF scale was developed, and its validity and reliability were tested by Gözmener *et al*.[16] It consists of 31 items in five subscales: health data knowledge, legal information, legal data sharing, health data sharing, and health data recording. A five-point Likert-type scale was used: 1 = I definitely disagree, 2 = I disagree, 3 = I have no opinion, 4 = I agree, and 5 = I definitely agree, and no items are scored in reverse. The mid-point of this five-point Likert-type scale was reported to be 3.[16] The calculation and evaluation of the total scale score were performed in the same way for all subscales. The scale was evaluated according to the item-order average.[16] Students who scored <3 points on the scale were evaluated as having negative attitudes to data recording and protection, and those scoring ≥3 as having positive attitudes to it. A negative attitude indicated students' low awareness concerning personal data recording and protection, whereas a positive attitude indicated high awareness. The Cronbach alpha reliability coefficient of the scale was 0.94.[16] In this study, the Cronbach alpha value of the scale was 0.95.

The consent form, student description form, and PHDRPAF were put online using Google Forms. The link to these data collection instruments was sent to the students' email addresses. After all necessary legal permissions were obtained, the students' e-mail addresses were obtained through the coordinator instructors of each class. All research information was sent to the students by email. Before filling out the data collection forms, they were assured that all their data would be used for scientific study and that their responses would in no way affect their grades. Information about the study and an informed consent form were added to the head of the online data collection form. After providing approval through the consent form, they responded to the questions on the data collection form. Research data were collected from students who agreed to participate in the research online and who completed all forms.

Because the PHDRPAF used in previous studies on topics similar to those in the present study [2,4,5,16] had been tested for Turkish validity and reliability, it was thought to be appropriate for use in this study. In studies that had previously used this scale, the Cronbach alpha reliability coefficient was >0.85. [2,4,5,16] Before the PHDRPAF was used in the study, written permission was obtained by email from the authors who conducted the Turkish validity and reliability testing of the scale.

Data obtained were evaluated using IBM SPSS Statistics for Windows version 28.0 (IBM Corp., Armonk, NY, USA). The conformity of data to normal distribution was examined with the Kolmogorov–Smirnov test, which revealed the normal distribution of data ($p > 0.05$). Descriptive statistics for quantitative data were expressed as means and standard deviations and qualitative data as frequencies and percentages. When comparing variables such as sexuality, knowledge about personal data and health data, and liking to work in fields of practice related to their classes, an independent samples t-test was used. When comparing the variables of the year of study and description of the level of communication with patients in practice fields, the one-way analysis of variance was used. Within-group difference was examined by the one-way analysis of variance, and the Tukey test was used as the post hoc test. The 95% confidence interval of the results was calculated, and $p < 0.05$ were accepted as significant.

RESULTS

Table 1 shows the descriptive characteristics of the study participants. The mean age of the students was 21.18 ± 2.00 years; 75.8% (N = 244) were female, and 36.6% (N = 118) were in their second year. In addition, 65.2% (N = 210) of the students stated that they knew about personal data and health data of the patients, 86% (N = 277) liked to work in fields of practice related to their classes, and 51.2% (N = 165) described having a good level of communication with the patients in their fields of practice (Table 1).

The total score mean on the PHDRPAF was 3.96 ± 0.56. On the PHDRPAF subscales, the mean scores were 3.95 ± 0.60 on health data knowledge, 4.16 ± 0.63 on legal information, 4.16 ± 0.59 on legal data sharing, 3.84 ± 0.72 on health data sharing, and 3.71 ± 0.72 on health data recording (Table 2).

Table 3 shows the distribution of students' total PHDRPAF score means according to their descriptive characteristics. A significant difference was found between the PHDRPAF total score and variables of sex, year of study, knowledge about personal data and health data, liking to work in fields of practice related to their classes, and description of level of communication with patients in their fields of practice ($p < 0.05$, Table 3). The Tukey test was applied to determine the group showing a difference between the scale score and the variables of the year of study and description of their level of communication with the patients in their fields of practice. The results showed that

TABLE 1. Descriptive information of nursing students

Variables	N	%
Sex		
Female	244	75.8
Male	78	24.2
Year of study		
Second	118	36.6
Third	103	32.0
Fourth	101	31.4
Knowledge about personal data and health data		
Yes	210	65.2
No	112	34.8
Liking to work in fields of practice related to their classes		
Yes	277	86.0
No	45	14.0
Description of the level of communication with patients in practice fields		
Poor	6	1.9
Medium	104	32.3
Good	165	51.2
Very good	47	14.6

TABLE 2. Total and mean subdimension scores in the personal health data recording and protection attitude form for nursing students

Scales and subdimensions	Mean ± SD	Min–Max score
Health data knowledge	3.95 ± 0.60	1–5
Legal information	4.16 ± 0.63	1–5
Legal data sharing	4.16 ± 0.59	1–5
Health data sharing	3.84 ± 0.72	1–5
Health data recording	3.71 ± 0.72	1–5
Total	3.96 ± 0.56	1–5

TABLE 3. Distribution of PHDRPAF mean scores according to students' descriptive information

Variable	Personal health data knowledge	Legal information	Legal data sharing	Personal health data sharing	Personal health data recording	Total PHDRPAF
Sex						
Female	4.00 ± 0.57	4.25 ± 0.59	4.20 ± 0.55	3.89 ± 0.70	3.78 ± 0.68	4.02 ± 0.52
Male	3.80 ± 0.67	3.87 ± 0.68	4.03 ± 0.70	3.71 ± 0.74	3.51 ± 0.78	3.79 ± 0.62
p	0.010*	0.001**	0.031*	0.055	0.005*	0.001
Year of study						
Second[a]	4.14 ± 0.53	4.40 ± 0.49	4.35 ± 0.44	4.02 ± 0.68	3.88 ± 0.65	4.16 ± 0.61
Third[b]	3.80 ± 0.63	3.97 ± 0.68	4.01 ± 0.67	3.71 ± 0.78	3.55 ± 0.77	3.81 ± 0.56
Fourth[c]	3.90 ± 0.59	4.06 ± 0.64	4.09 ± 0.60	3.77 ± 0.65	3.67 ± 0.69	3.90 ± 0.56
p	0.001** (a > b, c)	0.001** (a > b, c)	0.001** (a > b, c)	0.002** (a > b, c)	0.002** (a > b, c)	0.001** (a > b, c)
Knowledge about personal data and health data						
Yes	4.05 ± 0.59	4.26 ± 0.60	4.26 ± 0.56	3.87 ± 0.75	3.80 ± 0.73	4.05 ± 0.54
No	3.78 ± 0.58	3.96 ± 0.64	3.96 ± 0.60	3.79 ± 0.65	3.55 ± 0.67	3.81 ± 0.55
p	0.000**	0.000**	0.000**	0.314	0.004*	0.000**
Liking to work in fields of practice related to their classes						
Yes	4.01 ± 0.55	4.23 ± 0.57	4.21 ± 0.54	3.87 ± 0.70	3.77 ± 0.68	4.02 ± 0.50
No	3.61 ± 0.76	3.72 ± 0.81	3.82 ± 0.77	3.65 ± 0.78	3.37 ± 0.83	3.63 ± 0.74
p	0.000**	0.000**	0.000**	0.053	0.000**	0.000**
Description of the level of communication with patients in practice fields						
Poor[d]	3.11 ± 1.45	3.28 ± 1.56	3.16 ± 1.55	2.82 ± 1.31	2.33 ± 0.91	2.94 ± 1.33
Medium[e]	3.84 ± 0.60	4.08 ± 0.64	4.08 ± 0.54	3.83 ± 0.69	3.66 ± 0.76	3.91 ± 0.55
Good[f]	4.01 ± 0.52	4.19 ± 0.56	4.18 ± 0.52	3.88 ± 0.64	3.73 ± 0.64	3.99 ± 0.48
Very good[g]	4.12 ± 0.60	4.31 ± 0.59	4.39 ± 0.61	3.96 ± 0.84	3.94 ± 0.66	4.14 ± 0.55
p	0.000** (f, g > d, e)	0.000** (f, g > d, e)	0.001** (f, g > d, e)	0.003* (f, g > d, e)	0.001** (f, g > d, e)	0.001** (f, g > d, e)

independent t-test and ANOVA test were used accordingly (*p< 0.05, **p< 0.001)
PHDRPAF: Personal Health Data Recording and Protection Attitude Form for nursing students

the levels of attitudes concerning the recording and protection of patients' health data were significantly higher in female students who were in their second year, had knowledge about personal data and health data, liked to work in fields of practice related with their classes, and had good or very good communication level with patients in fields of practice (p < 0.05, Table 3).

DISCUSSION

Awareness of personal data protection is an important topic both for the health team and nursing students, who are at the stage of learning the profession and its responsibilities.[4,17] In this study, an answer was first sought regarding nursing students' attitudes to the recording and protection of patients' health data and its level. In this regard, the students' total score mean was 3.96 ± 0.56, which indicates that the nursing students' demonstrated positive attitudes to the recording and protection of patients' health data. Among similar studies conducted in Turkey, Eskimez and Tosunöz[4] determined that the attitudes of nursing students to the recording and protection of health data were indicated by the total score mean of 4.20. Other studies with nursing students reported that the students demonstrated positive attitudes to the topic.[2,5,14] In studies conducted in other countries, Park and Woo found a positive correlation between the practices of nursing students relating to the protection of medical data and their perceptions of the importance of medical data protection in South Korea.[17] The results of the present study support those of other studies. Altogether, the study findings revealed that nursing students demonstrated positive attitudes to the recording and protection of patients' health data. Ethics lessons to students and emphasis on the topics of patient privacy and respect for personal values may have positively affected the students' attitudes to the protection of personal data. In a study in Iran with medical faculty students, students' knowledge and attitudes concerning confidentiality and sharing of patient data were low.[18] The difference between the findings of this study and the present study arises from the variables analyzed such as the faculty where the study was conducted, country, culture, measurement instruments, or way of education. The study participants had a high awareness of protecting and not sharing patients' health data, which is accepted to be sensitive. Nursing students demonstrating a positive attitude on this topic is a pleasing finding.

Easy access by nursing students during their education to patients' health data and the inappropriate use of these data put the students at risk of breaking the law.[15] Moreover, the misuse of data of patients receiving health services gives rise to ethical problems.[6] Thus, nurses and potential nurses should handle patients' health data more

carefully than other health professionals.[19] According to the International Council of Nurses' (ICN) Code of Ethics for Nurses, nurses should hold all personal information obtained in a professional capacity in confidence.[20] In addition, this study sought to answer the question of whether nursing students' independent variables affected their attitudes to the recording and protection of patients' health data. The results revealed that students who stated that they had knowledge about patients' health data demonstrated good attitudes to the topic. In a study by Bani Issa *et al*., nurses reported worries about the security of electronic health records because of the inadequacy of education on administrative security measures and access by unauthorized users.[21] Thus, high awareness and good attitudes on this topic by nursing students who stated that they have knowledge of patients' health data is an expected finding. Bae and Lee found that as students' knowledge levels increased, their perceptions concerning the protection and confidentiality of personal data also improved.[22] Maraş and Ceyhan found that students who knew about the protection of personal data had good attitudes on the topic.[5] Çetin and Çevik reported that students who stated that they had previously heard of the concepts of personal data and health data had significantly high scores on the subscale on health data sharing.[15] The results of the present study are similar to those in the literature. Only students with clinical practice experience were included in this study. A study conducted with nursing students found a positive correlation between having clinical practice experience and the development of students' professional values.[23] Thus, the education given to students by teachers and nurses in clinical practice areas and students' experiences in this regard may have affected students' professional values and their attitudes to the recording and protection of patients' health data. This concept implies that students with knowledge and experience of the topic would have high levels of attitude.

The knowledge level score means on the subdimension of legal data sharing or patient rights of students in the literature differed by sex, with female students having higher score means than male students.[24] In the present study, female students demonstrated higher attitudes regarding the recording and protection of patients' health data than male students. In some studies, female students had better attitudes to the recording and protection of patients' health data,[2,19] whereas others reported that sex did not affect this level.[2,5,14,15] Moreover, differences were between the studies, which may arise from the differences in the numbers of female students participating in the study and city, faculty, or field of clinical practice of the students. In some studies,[2,4,24] female students expressed higher levels of attitudes to the recording and protection of patients' health data than male students, similar to the findings of the present study. These findings indicate that female students may be more sensitive on this topic than male students. It may be difficult to explain the reasons in detail. The findings may have been affected by factors such as culture, personal values, or sensitivity to health data. To clarify this, qualitative studies that take into account sex as a factor affecting nursing students' attitudes to the recording and preservation of patients' health data are needed.

In this study, second-year nursing students had significantly better attitudes to the recording and protection of patients' health data than third- and fourth-year students. Eskimez and Tosunöz, Maraş and Ceyhan, and Olğun and Adıbelli reported that fourth-year students had better attitudes to the topic than lower-year students.[4,5,14] Hosseini-Ghavam-Abad *et al*. and Al Anazi *et al*. reported that fourth-year students had the highest level of knowledge about patients' rights.[18,25] These results may show that a higher-year of study and an increase in theoretical knowledge and clinical experience are reasons why higher-year students have better attitudes than students in lower years. Conversely, Çetin and Çevik found that third-year students had better attitudes than those in other years to the recording and protection of patients' health data.[15] Our results do not agree on those of similar studies. As mentioned, previous studies found that higher-year students demonstrated better attitudes, whereas in the present study, second-year students demonstrated higher attitude levels. This difference indicates that second-year students developed a greater awareness of the topic in their clinical fields.

The results revealed that the study participants who liked to work in fields of clinical practice related to their classes and those who described their level of communication as very good had significantly better attitudes to the topic than other students. Çetin and Çevik reported similar results, although their results were not significant.[15] Expectedly, students who liked to work in their clinical practice fields and those who described their communication as very good would have high awareness of the recording and protection of patients' health data. In addition to developing their psychomotor skills, they also harness their affective skills such as comprehending the philosophy of the profession and respecting and defending patients' rights in the clinical environment.[15] This awareness of student nurses is seen as something positive for the nursing profession. In solving students' ethical dilemma that patients' data in the clinical field must both be protected and kept hidden from the patient, ethics lessons given using scenarios may be effective in increasing awareness. The results of the study may provide nursing educators with an opportunity to perform interventions relate to factors that affect the attitudes of nursing students to the recording and protection of patients' health data.

The study has some limitations. First, this study was conducted in the nursing department of a single government hospital; thus, the conclusions can only be

applied to the study population. To increase the generalizability of the results, replication studies with a larger sample and wider-ranging research of students with different sociodemographic characteristics are needed. Second, because many factors can affect the concept of the recording and preservation of health data, qualitative studies are needed to facilitate an in-depth investigation of the topic. Third, even though the students were given information on the topic and the importance of the research before the study, their responses to the questionnaires depended on self-reporting. Because students' responses depended only on quantitative data, understanding the depth to which the students' attitudes and the reasons behind them may be limited. This may result in prejudice regarding objective attitudes to the recording and protection of patients' health data. Thus, in-depth interviews with nursing students and qualitative research methods are warranted, and the effectiveness of education programs aimed at encouraging awareness of the topic in students must be evaluated.

CONCLUSIONS

In this study, nursing students demonstrated positive attitudes to the recording and protection of patients' health data, and certain independent variables affected these attitudes. Thus, preclinical practice orientation programs must allocate time to informing nursing students on the recording and preservation of patients' health data. In addition, the nursing curriculum should be reviewed with regard to classes supporting positive attitudes and awareness concerning the protection of health data. In this regard, practical lessons on the importance of the preservation of health data and patients' privacy should be presented as simulations and scenarios. Finally, quantitative and qualitative studies on the topic with a broader sample are warranted.

CONFLICT OF INTEREST

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