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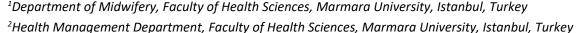


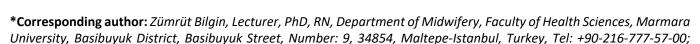
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ORIGINAL ARTICLE

Effect of COVID-19 Vaccines on Menstrual Cycle Changes and Quality of Life

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Abstract

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Objective: This study was aimed at determining the effect of the COVID-19 vaccines on menstrual change and quality of life.

Method: The study was conducted with the participation of female students studying in the health sciences at a university. A Google form was created in the digital environment by the authors. 593 students participated in the form shared with female students via WhatsApp on January 3, 2022.

Results: The mean age of the participants was 20.73 ± 2.83 years. In the study, a relationship was found between the type of COVID-19 vaccine and the rate of side effects (p < 0.05). The rate of side effects was higher in the Pfizer-BioNTech vaccine (36%) compared to the Sinovac vaccine (11.7%). While the rate of dysmenorrhea before vaccination was (76.4%) of the participants, it was determined to be after the first dose (77.8%) and after the second dose (74%). After the first dose of the vaccine (55.6%), there was a higher rate of increase in the number of days of menstrual bleeding compared to the second dose (10.1%). After the first dose (44.4%), there was a higher rate of increase in the amount of menstrual bleeding compared to the second dose (11.3%). A correlation was found between the effect of the pandemic on the quality of life, and the mean score of the scale.

Conclusions: The COVID-19 vaccine increased the number of menstrual bleeding days and the amount of bleeding. Further studies are recommended to determine the effect of the vaccine on menstrual changes.

Keywords

COVID-19 vaccine, Dysmenorrhea, Menstrual change, menorrhagia, Life quality

Introduction

The pandemic sickness, also known as severe acute respiratory syndrome-2 (SARS-CoV-2) or COVID-19, initially appeared in China in 2019 and quickly spread over the world, posing a global public health threat. On March 11, 2020, the World Health Organization (WHO) proclaimed the COVID-19 outbreak a pandemic [1-3]. The first COVID-19 case in Turkey was detected on March 11, 2020. In the ongoing process, there has been an increase in the number of cases in Turkey as well as around the world. Immediately after the detection of the first case, individual and social protective measures were started to reduce the spread rate and severity of the epidemic. Vaccination has been shown to be effective in increasing and providing individual and social immunity [4,5].

In addition to non-drug preventive measures, vaccination studies have been initiated to reduce the COVID-19 epidemic rate, cases, and death rates, which have a dramatic impact on human health. It has been explained by scientific authorities that vaccination is the most effective individual protective method. Various vaccines related to COVID-19 have been produced [6,7]. Pfizer-BioNTech's (BNT162b2) and Moderna's (mRNA-1273) mRNA vaccines are approved for emergency use in the US in 2020 [8]. One of the countries that started the COVID-19 vaccine campaign early was Turkey. In Turkey, starting on January 13, 2021, vaccination studies have been started gradually, starting with priority groups such as healthcare workers, those



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with chronic diseases, and the elderly [9]. In Turkey, vaccination started with the Sinovac vaccine, and then the Pfizer-BioNTech vaccine also started to be applied. Then, on June 25, 2021, everyone over the age of 18 was enrolled in the vaccination program, and everybody who wished to be vaccinated was vaccinated. Vaccination was recommended, especially for university students, and most students were vaccinated [9,10]. However, vaccines have created varying levels of side effects in individuals. Both the epidemic and the side effects of vaccines have affected the psychological and physical health and quality of life of individuals.

In the literature, local (arm pain, redness, etc.) and systematic side effects (fever, fatigue, muscle pain, etc.) have been reported frequently after the COVID-19 vaccine. In addition to the known side effects of the vaccine, it has been stated that it may cause complaints such as menstrual changes and unexpected vaginal bleeding in women in the fertile period [11]. An immunologist from Imperial College London, Dr. Victoria Male, has noted that some women who have gone through menopause or are taking hormones to stop menstruation experience bleeding after vaccination (https://haberglobal.com.tr/gundem/covid-19-asisisonrasi-jinekolojik-soru-yeniden-adet-gormeye-basladilar-110552).

It has been stated that menstrual irregularities in women can be affected by structural formations, ovulation disorders, drug use, and various modifiable factors (sudden weight loss, excessive exercise, obesity, smoking, psychological problems). It has been reported that the prevalence of menstrual irregularity varies between 5% and 34%, and this is among the top reasons for women to apply to a gynecologist [12,13]. Although not yet proven, potential effects of the COVID-19 vaccine on the female reproductive system and menstrual pattern have been reported, but the effects have mostly remained as theoretical hypotheses. According to the literature, it has been stated that menstrual abnormalities that occur after vaccination may be temporary [14,15]. On the other hand, side effects from vaccination and unanticipated changes in menstrual cycles, had a detrimental impact on women's quality of life [16-18]. this study, it is aimed to determine the effect of COVID-19 vaccines on menstrual change and the quality of life of female students studying at the faculty of health sciences.

Materials and Methods

Type of research

This study was planned and conducted as a descriptive study.

Research Questions or Hypotheses:

The research questions created in line with the determined purpose are as follows:

Has the COVID-19 vaccine affected the menstrual cycle?

Has the COVID-19 vaccine caused dysmenorrhea?

Has the COVID-19 vaccine increased the number of menstrual bleeding days?

Has the COVID-19 vaccine increased menstrual bleeding?

Has the COVID-19 outbreak affected the quality of life?

Research variables: It consists of questions (30 questions) including socio-demographic characteristics (student's department, age, family type, etc.), menstrual cycle characteristics, the type of COVID-19 vaccine, the effect of the vaccine on changes related to menstruation, and quality of life.

Dependent variables: Quality of Life Scale.

Place and time of research: The research was carried out between 03.01.2022 and 24.01.2022 at the faculty of health sciences of a university in Istanbul.

The study's population and sample

The universe of the research consisted of female students studying in all departments of the health sciences faculty of a university in Istanbul. A sample calculation was not made in the study, and the study was conducted with female students studying at the faculty of health sciences who wanted to voluntarily participate in the study and who had at least one COVID-19 vaccine. The study was completed with the participation of 593 students.

Inclusion and exclusion criteria

Inclusion criteria:

- Individuals between the ages of 18 and 45
- · University education who continuing
- People who have received the COVID-19 vaccine
- Female students who voluntarily agreed to participate in the study

Exclusion criteria:

- Male students
- Female students who participated in the study and filled in the forms incompletely were not included in the study.

Data collection methods and tools

The research data were gathered by distributing online forms created in the Google form environment to students via WhatsApp (Student Diagnosis Form and COVID-19 Impact on Quality of Life Scale (COV19-QoLTR) and receiving feedback.

Introductory Information Form: The introductory

information form used in the study was developed by the researchers in line with the literature and includes questions (30 questions) about the socio-demographic characteristics of the students, menstrual cycle characteristics, the COVID-19 vaccine, and quality of life [12,13,18].

The Impact of COVID-19 on the Quality of Life Scale (COV19-QoLTR)

The scale was developed by Repiti, et al. (2020) and its validity and reliability in Turkish were performed by Sümen and Adibelli (2021) in individuals with and without a diagnosis of COVID-19. COV19-QoLTR consists of six items covering basic quality of life areas related to mental health. The first item covers people's feelings about the impact of the current pandemic on their overall quality of life. The second and third items include people's perceptions of mental and physical health deterioration. The fourth and fifth items measure the anxiety and depression levels of individuals due to the pandemic. The last item is aimed at determining the perceptions of individuals about the extent to which their personal safety is in danger. All items are in a fivepoint Likert type (1-strongly disagree–5-strongly agree) and evaluate the feelings and thoughts of the individuals in the last seven days. The scale score is calculated by dividing the total score by the number of items. A higher score indicates that the impact of the pandemic on a person's quality of life is greater. The Cronbach's alpha coefficient of the scale was found to be 0.910 for the data obtained from the general population, 0.905 for the undiagnosed sample, and 0.856 for the diagnosed sample [18]. In this study, the Cronbach's alpha coefficient was found to be 0.877.

Statistical analysis of data

The research data were analyzed using the demo statistics package program in a computer environment. Whether the continuous variables were normally distributed or not was analyzed with the Shapiro-Wilks test of normality. The Chi-square test was used to test relationships between categorical variables, the t test for independent groups in normal distribution data, and the Oneway ANOVA parametric tests; nonnormal distribution data was tested using the Kruskal-Wallis and Mann Whitney U nonparametric tests. Bonferroni post hoc tests were conducted to identify groups that made a difference. As for descriptive statistics, numerical variables (mean SD (standard deviation) and (minimum-maximum) and numbers and percentages were calculated for categorical variables. The statistical significance level was accepted as p < 0.05.

Results

In this study, the data of 593 female students who continue their university education and who have been vaccinated against COVID-19 have been analyzed and

reported. The mean age of the 593 students participating in the study was 20.73 \pm 2.83 (Min-Max: 18.0-42.0). 97.4% of the students are 18-24 years-old, and 67.3% of them have a body mass index of 18.5-24.9 kg. The family income of 79.6% of the students is equal to the expenses. It was determined that 83.8% of them did not have a problem requiring psychological support. Of the students, 9.1% had menarche at the age of fifteen or over, 76.4% had dysmenorrhea before vaccination, and 35.2% had dysmenorrhea a few days before bleeding. In the study, 20.9% of them went to the doctor for a complaint of dysmenorrhea, and 62.1% of them were found to use painkillers for this complaint.

In the study, 89.9% of the students stated that they had the Pfizer-BioNTech vaccine, 98.5% had two doses of the vaccine, and 33.6% stated that the vaccine caused side effects. 60.2% of the students experienced dysmenorrhea in their menstruation after the first vaccination, and 52.8% of them used painkillers for their dysmenorrhea. 24.8% of the participants stated that the vaccine affected their menstrual pattern, 10.8% stated that the number of menstruation days increased after vaccination, 11.8% stated that the amount of menstrual bleeding increased after vaccination (Table 1).

When some variables of the participants were compared with the type of COVID-19 vaccine, a relationship was found between the type of vaccine and side effects (p < 0.05). There was no relationship between vaccine type and post-vaccine dysmenorrhea complaints, time of dysmenorrhea, the effect of the vaccine on the menstrual cycle, the increase in the number of menstrual days after vaccination, or the increase in the amount of menstrual bleeding after vaccination (p > 0.05; Table 2).

When the participants' menstrual and psychological changes were compared with the average of the COV19-QoLTR score, a correlation was found between the side effects of the vaccine, the effect of the vaccine on the menstrual cycle, and the mean score of the scale (p < 0.05). A relationship was found between the effect of the pandemic on the quality of life, a problem requiring psychological support, feeling more depressed than before, and the mean score of the scale (p < 0.05). However, no correlation was found between the number of COVID-19 vaccine doses, post-vaccine dysmenorrhea, an increase in the number of menstrual days after vaccination, an increase in the amount of menstrual bleeding, and the mean score of the scale (p > 0.05) (Table 3).

Discussion

In this study, the effect of COVID-19 vaccines on menstrual change and quality of life was discussed in line with the literature. The most common side effects of the COVID-19 vaccine are arm pain, fever, fatigue, and myalgia. The side effect rates of the COVID-19

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Table 1: Comparison of participants' menstrual changes with the COVID-19 vaccine type.

	Pfizer-Bi	ioNTech	Sinov	ac	Toplai	m	Test va	lue
Menstruation change	(n:533)		(n:60)		(n:593)			
	n	%	n	%	n	%	X2/t	p
Side effect of the vaccine	<u>'</u>		'		<u>'</u>	'	'	
Yes	192	36.0	7	11.7	199	33.6	14.348	0.000
No	341	64.0	53	88.3	394	66.4		
Post-vaccine dysmenorrhea								
Yes	395	74.1	45	75.0	440	74.2	0.022	0.004
No	138	25.9	15	25.0	153	25.8	0.022	0.881
Post-vaccine dysmenorrhea time	<u>'</u>		'		<u>'</u>	'	'	
During menstruation after the first vaccination	318	59.7	39	65.0	357	60.2	1.034	0.500
During menstruation after the second vaccination	77	14.4	6	10.0	83	14.0		
No post-vaccine dysmenorrhea	138	25.9	15	25.0	153	25.8		0.596
Effect of the vaccine on the menstrual cycle								
Yes	137	25.7	10	16.7	147	24.8	2.362	
No	396	74.3	50	83.3	446	75.2		0.432
Increase in menstrual days after vaccination		-		'	'			
Yes	59	11.1	5	8.3	64	10.8	0.419	0.543
No	474	88.9	55	91.7	529	89.2		0.517
ncrease in menstrual bleeding after vaccinatio	n		,	'				
Yes	66	12.4	4	6.7	70	11.8	4.000	0.400
No	467	87.6	56	93.3	523	88.2	1.693	0.193

^{*}X2: Chi-square analysis, t: Independent Samples Test, p < 0.05

Table 2: Comparison of participants' menstrual changes with the number of doses of COVID-19 vaccine.

Menstrual change	First	First dose (n:9)		ond dose 34)	Total (n:593)		Test value	
	n	%	n	%	n	%	X ²	p
Effect of the vaccine on the	menstrual cy	cle	'					
Yes	3	33.3	144	24.7	147	24.8	0.057	0.550
No	6	66.7	440	75.3	446	75.2	0.357	
Post-vaccine dysmenorrhea	a					`		
Yes	7	77.8	433	74.1	440	74.2	0.000	0.802
No	2	22.2	151	25.9	153	25.8	0.063	
Increase in menstrual days	after vaccinat	ion						
Yes	5	55.6	59	10.1	64	10.8	11.106	0.001
No	4	44.4	525	89.9	529	89.2	11.106	
Increase in menstrual bleed	ding after vacc	ination						-
Yes	4	44.4	66	11.3	70	11.8	6 100	0.013
No	5	55.6	518	88.7	523	88.2	6.128	

^{*}X²: Chi-square analysis, p < 0.05

vaccine vary, and it is stated that side effects last for one or two days. Some vaccines cause more side effects after the first dose, while others cause more side effects after additional doses [11]. In the study, a relationship was found between the rate of side effects and the type of COVID-19 vaccine (p < 0.05). It was observed that the

rate of side effects was higher in the Pfizer-BioNTech vaccine (36%) compared to the Sinovac vaccine (11.7%). It has been reported that the side effects of COVID-19 vaccines vary depending on the age, health status, and dose of the vaccine [11]. Studies have reported a higher frequency of vaccine-related side effects in

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Table 3: Comparison of participants' menstrual changes with the mean of the COV19-QoLTR score.

Opinions	COV19-Q	oL _{TR} (n:533)	Test value		
	n	Mean ± SD	t/F	р	
Side effect of the vaccine		<u>'</u>	'		
Yes	199	3.52 ± 0.90	4.013	0.000	
No	394	3.19 ± 0.95	4.013	0.000	
Number of COVID-19 vaccine	doses		,		
Yes	9	3.51 ± 1.07	0.670	0.502	
No	584	3.30 ± 0 .94	0.672	0.502	
Post-vaccine dysmenorrhea		·	·		
Yes	440	3.34 ± 0.95	1.423	0.155	
No	153	3.21 ± 0.91	1.423	0.155	
Effect of the vaccine on the m	enstrual cycle				
Yes	147	3.46 ± 0 .98	2.310	0.021	
No	446	3.25 ± 0 .93	2.310		
Increase in menstrual days aft	er vaccination	·	·		
Yes	64	3.48 ± 0.98	1.604	0.400	
No	529	3.28 ± 0.94	1.004	0.109	
Increase in menstrual bleedin	g after vaccination				
Yes	70	3.41 ± 0.91	1.025	0.306	
No	523	3.29 ± 0.95	1.025	0.300	
Effect of the epidemic on qual	ity of life				
Yes	521	3.42 ± 0.89	0.070	0.000	
No	72	2.42 ± 0.83	8.978	0.000	
A problem requiring psycholog	gical support				
Yes	96	3.66 ± 0.89	4.104	0.000	
No	497	3.23 ± 0.94	4.104	0.000	
Feeling more depressed than	before		'	'	
Yes	167	2.25 ± 0.62		0.000	
Partially	323	3.91 ± 0.63	411.157		
No	103	3.11 ± 0.51			

^{*}t: Independent Samples Test, F: One-Way ANOVA test, p < 0.05

younger individuals compared to older individuals [19,20]. Alhazmi, et al. (2021) reported vaccine-related side effects at a rate of 60% in their study. About 84% of the participants reported side effects on the day of vaccination, 15% on the second and 1% on the third day after vaccination [21]. Also, in a study of people receiving the Pfizer-BioNTech vaccine in Saudi Arabia, 70% to 80% of participants reported pain at the injection site [22]. Similar data was reported in a study conducted by Menni, et al. [23].

At the time of the study, Pfizer-BioNTech and Sinovac vaccines are used in our country. In the study, it was observed that the rate of side effects of the Pfizer-BioNTech vaccine was higher than the Sinovac vaccine. This difference was caused by the different production technologies of the vaccines [22,23].

The menstrual cycle is a natural process for most females that occurs in the reproductive years between puberty and menopause. A 'normal' menstrual cycle lasts 22-35 days [24]. The menstrual cycle is accepted as an indicator of both reproductive health and the quality of life of women [25]. This cycle includes changes in menstrual duration, frequency, rhythm, and volume (heavy bleeding), increased complaints of dysmenorrhea, and changes in premenstrual syndrome (PMS) [25]. COVID-19 infection may cause deterioration in the immune system, causing changes in the hypothalamic-pituitary-gonadal axis and menstrual cycle [26]. At the same time, immune responses to the COVID-19 vaccine may lead to temporary changes in the menstrual cycle [27]. In the study, the rate of women experiencing dysmenorrhea before vaccination was 76.4%. Although no relationship was found between the vaccine dose and the rate of experiencing dysmenorrhea after the vaccine, it was determined that the participants experienced a higher rate of dysmenorrhea after the first dose (77.8%) than

^{*}COV19-QoLTR: The Impact of COVID-19 on Quality of Life Scale

the second dose (74%) (p > 0.05). Balbi, et al. (2009) determined the frequency of dysmenorrhea to be 85% in their study [28]. Şahin, et al. found the frequency of dysmenorrhea in university students to be 66.2%. [29]. Phelan, et al. (2021) reported that almost half of women had heavy and painful menstrual periods compared to pre-pandemic [30,31].

The International Federation of Gynecology and Obstetrics (FIGO) defined the deviation from the standard parameters in menstrual frequency, duration, regularity, and amount of bleeding as abnormal uterine bleeding [32]. Changes in menstrual duration, frequency, pattern, and bleeding volume (heavy bleeding) have been reported in women during the pandemic process [25]. Ozimek colleagues (2022) found some variation in the menstrual cycle in more than half of the women during the COVID-19 pandemic. It has also been stated that COVID-19 vaccines cause menstrual changes [25]. Alvergne, et al. (2021) reported menstrual discomfort following the COVID-19 vaccine in one-fifth of the participants in their study [33]. Most people in the literature reporting a change in the post-vaccination period reported a return to normal after the next cycle [34].

A correlation was found between the number of COVID-19 vaccine doses received by the participants and an increase in the number of menstrual bleeding days after vaccination and an increase in the amount of menstrual bleeding after vaccination (p < 0.05). After the first dose (55.6%), there was a higher rate of increase in the number of days of menstrual bleeding compared to the second dose (10.1%). Likewise, after the first dose (44.4%) compared to the second dose (11.3%), a higher rate of increase in the amount of menstrual bleeding was observed after vaccination.

Menstrual changes have been reported in the literature after COVID-19 vaccines with both mRNA and adenovirus vectors [11]. After vaccination, some women have reported menstrual irregularities such as heavy menstrual bleeding (menorrhagia), frequent bleeding (metrorrhagia/polymenorrhea), or postmenopausal bleeding (Kurdoğlu 2021). Studies have shown that women experience a change in their menstrual cycle, worsening of premenstrual symptoms, and menorrhagia [3,35]. Some women in the UK have reported temporary changes in their menstrual cycles, heavier-than-normal bleeding, missed periods or unexpected vaginal bleeding after the coronavirus vaccine [36]. In a retrospective case-control study of 21,380 pre-menopausal participants living in the United States (USA), 45.8% of 9,579 people with regular menstrual cycles were reported to experience heavier bleeding after the COVID-19 vaccination [13]. Edelman, et al. (2022) reported an approximately 1-day increase in cycle length in women who received 1 dose of the COVID-19 vaccine compared to unvaccinated women. They found that the increase in cycle length was not related to any change in the number of bleeding days [37].

In the Turkish population, the prevalence of irregular menstrual cycles in women in the fertile period is approximately 16%, while the rate of irregular menstrual cycles in pandemic conditions has been reported as 28.7% [38]. In another study conducted in Turkey during the COVID-19 pandemic, it was stated that 27.6% of women experienced menstrual irregularities [39]. It has been stated that this result may be an immune response to the vaccine rather than a specific vaccine component [11]. This finding of the study is that vaccination causes menstrual changes, and there is a possibility of recurrence of these changes with repeated vaccine doses.

Menstrual changes or irregularities in the fertile period affect the individual's mood and quality of life [25,40]. A correlation was found between the side effects of the COVID-19 vaccine, the effect of the vaccine on the menstrual cycle, and the mean score of the scale (p < 0.05). It has been reported that high stress levels and emotional instability in women cause menstrual irregularities [31]. Women's menstruation-related symptoms affect their quality of life and daily lives [40]. It is also known that the COVID-19 pandemic, which causes lifestyle changes, adversely affects the quality of life [27]. This finding of the study is important for women to be aware of the relationship between menstruation changes and quality of life after vaccination.

The rapid spread of the COVID-19 virus has affected human life in different dimensions. A correlation was found between the effect of the pandemic on the quality of life, feeling more depressed than before, and the mean score of the scale (p < 0.05). Studies conducted during the pandemic period have shown that women perceive significantly higher levels of stress, anxiety, and depression than men [41-43]. Preventive measures and restrictions in the pandemic have adversely affected the quality of life and mood of individuals [30,31].

Ethical Statement

The study was conducted after obtaining ethical permission from the ethics committee, institutional permission from the institution, and the necessary permissions and consent from the volunteers to participate in the research. Permission for the scale to be used in the research has been obtained and is shown in the appendix. In addition, research by T.C. Written approval was obtained from the Ministry of Health.

Strengths

The data for this study were gathered through selfreports of health professional candidates who have understanding of the importance of preventive measures and vaccines in the COVID-19 pandemic. Strength of the study is the fact that all of the participants knew the importance of the menstrual cycle pattern.

Limitations

Since all participants in the study were required to be vaccinated in order to participate in clinical practical training, the control group for the study was not formed.

Research Budget

Research expenses were covered by the researchers.

Conclusion

The results of this study, in which the effects of COVID-19 vaccines on menstrual change and quality of life were evaluated:

It was observed that the rate of side effects was higher in the Pfizer-BioNTech m-RNA vaccine compared to the Sinovac vaccine.

Although no relationship was found between the vaccine doses and the frequency of post-vaccine dysmenorrhea, it was determined that the participants experienced a higher rate of dysmenorrhea after the first dose compared to the second dose.

After the first dose of the COVID-19 vaccine, the participants had a higher rate of increase in the number of days of menstrual bleeding compared to the second dose.

Similarly, an increase in the amount of menstrual bleeding after the first dose was observed at a higher rate after vaccination.

A correlation was found between the effect of the pandemic on the quality of life, feeling more depressed than before, and the mean score of the scale.

In addition to the known factors affecting the menstrual cycle, it is thought that the COVID-19 vaccine may cause changes in the number and amount of bleeding days during menstruation. Clinicians and non-physician health professionals (nurses and midwives) should inform women about menstrual changes or unexpected vaginal bleeding changes and should encourage them to consult a specialist. As a result, it is recommended to conduct quantitative and qualitative studies with larger samples to determine the effect of the COVID-19 vaccine on menstrual changes.

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