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Original Article

Is COVID-19 Vaccination Associated with Menstrual Irregularities? Myth vs. Reality

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Abstract

Background: COVID-19 vaccination has been associated with changes in menstrual patterns, including alterations in cycle length and blood flow in some women. The present study aimed to compare the prevalence of menstrual abnormalities among women receiving different COVID-19 vaccines, including Sinovac, Sinopharm, Pfizer, and Moderna, across Pakistan.
Methods: A cross-sectional web-based study was conducted from April 1, 2022 to June 30, 2022 in Pakistan. A convenience sampling was used to include women of reproductive age across Pakistan through an anonymous online survey checklist administered in English and Urdu. A checklist was used to gather data on sociodemographic characteristics, vaccination history, menstrual symptoms before and after vaccination, and other non-menstrual post-vaccination symptoms. Women with pre-existing gynecological conditions, pregnant women, and those with incomplete responses were excluded. Data were analyzed using SPSS version 26. Chi-square test was applied to assess the association between menstrual symptoms and COVID-19 vaccination status. A P value of <0.05 was considered statistically significant.
Results: Of the respondents, 693 (88.5%) received two vaccine doses, primarily Pfizer (36.8%), Sinopharm (30.9%), and Sinovac (24.4%). Our study found significant associations between vaccination status and both menstrual flow (P=0.001) and intermenstrual bleeding (P=0.037). Common general symptoms following vaccination included fatigue, muscle pain, and reactions at the injection site.
Conclusion: No significant changes in menstrual patterns were observed in relation to COVID-19 vaccination, aside from minor changes in flow and intermenstrual bleeding. Future research should encompass a larger, more diverse population across age groups to comprehensively assess any potential association between COVID-19 vaccination and menstrual irregularities.

Keywords: COVID-19 Vaccines, Menstrual Disorders, Women

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1. Introduction

The novel human Coronavirus Disease (COVID-19), caused by the SARS CoV-2 virus, became the fifth recorded pandemic after the 1918 flu pandemic. Initially reported in Wuhan, China, it rapidly adapted to, human to human transmission and spread worldwide (1). Globally as of now, 775,830,222 confirmed cases of COVID-19 have been reported, including 7,056,108 deaths (2, 3). Respiratory manifestations of this pandemic include, fever, cough, shortness of breath, sore throat. Other symptoms include, gastroenterological (nausea, vomiting, diarrhoea, abdominal pain), dermatologic (erythematous rashes, urticaria, chickenpox-like lesions), myocardial (myocardial injury, arrythmias, myocarditis, heart failure, cardiomyopathy), neurologic (viral encephalitis, peripheral nerve symptoms, cerebrovascular disease) and psychiatric (anxiety, depression, and loneliness) (4). COVID-19 infection has also been shown to cause menstrual irregularities with effect on the menstrual length and volume of blood loss in some women (5, 6).

Common types of COVID-19 vaccines include Pfizer/Moderna (mRNA vaccine), AstraZeneca/Johnson and Johnson (vector vaccine), Novavax (protein subunit vaccine) and Sinopharm/Sinovac (whole virus vaccine) (7, 8). Commonly reported side effects following the vaccines are pain, redness and swelling, fatigue, headache, fever, and nausea (8). These vaccines may cause thrombocytopenia leading to ineffective endometrial homeostasis and heavy menstrual bleeding. Immune cells lining the uterus may cause early shedding of the uterine wall,

and manifest as intermenstrual / postmenopausal bleeding, due to activation of the immune system following the vaccines (9, 10). Vaccination may either shorten or lengthen the menstrual cycle by affecting the secretion of oestrogen, follicle-stimulating hormone, progesterone, luteinizing hormone, and other hormones associated with female reproduction (11). The changes in menstrual cycle length, regularity, duration, and intensity of menstrual flow have created concern and hesitancy in women of reproductive age regarding COVID vaccination, due to the possible association leading to infertility (12). On the contrary, in a retrospective study carried out in the UK, 80% of the women did not report any alterations in their menstrual cycle up to four months following their first dose of COVID 19 vaccine, Moderna and Pfizer (13). A systematic review of 61 studies reported various menstrual disorders in the first cycle following different types and doses of COVID-19 vaccination, including alterations in cycle length (n=54), changes in the amount of bleeding (n=44), variations in the duration of menstruation (n=30), differences in premenstrual pain (n=21), and occurrences of breakthrough bleeding (n=18) (14). Another study with 2381 participants, 67% observed changes in their menstrual cycle, i.e., 22% of participants reported changes after the first dose, 55% after the second dose, and 1% after the booster. These findings suggest a noteworthy link between COVID-19 vaccination and menstrual cycle alterations (11).

The present study was conducted to determine the association of COVID-19 vaccine with menstrual abnormalities among vaccinated women in Pakistan. In addition, the study assessed the prevalence of COVID-19 vaccination and identified associated side effects among women residing in the country. Given that menstrual irregularities can impact fertility potential, quality of life, and psychological well-being, it is crucial to explore the potential effects of COVID-19 vaccines on women's health.

2. Methods

2.1. Design

A cross-sectional web-based study was conducted among women of reproductive age from April 1, 2022 to June 30, 2022 in Pakistan.

2.2. Selection and Description of Participants

Participants were recruited using a non-probability convenience sampling technique. An online survey link was disseminated across Pakistan through digital platforms, allowing voluntary participation by women of reproductive age. Women who provided informed consent were included in the study.

Exclusion criteria included residence outside Pakistan, current pregnancy, a history of chronic menstrual disorders (including polycystic ovary syndrome), pre-existing gynaecological conditions prior to COVID-19 vaccination, and incomplete questionnaire responses.

2.3. Sample Size Determination

The sample size was calculated based on the prevalence of menstrual irregularities among women receiving COVID-19 vaccination. Assuming the prevalence of 24.8% (15), a minimum sample of 745 was required with 3.1% of absolute precision and level of significance of 5% to estimate the menstrual irregularities among vaccinated women.

2.4. Data Collection and Measurements

A structured, self-administered web-based checklist was used to collect data on menstrual symptoms following COVID-19 vaccination among Pakistani women. The checklist was developed using simple, non-technical language, with gynaecological and scientific terminology replaced wherever possible to ensure clarity and comprehension for women from diverse educational and socioeconomic backgrounds. The checklist consisted of five parts. The first section consisted of demographics and medical history. The second was regarding vaccine information; it included questions regarding the type and dosages of vaccine and whether they were completely (two doses) or partially (one dose) vaccinated. The third and fourth sections were regarding menstrual symptoms before and after COVID-19 vaccination. To address the recall bias for symptoms, questions were standardized to symptoms that women could easily recall. In addition to this, recall period was shortened to six months before vaccination so that it was relatively easier for the participants to remember. The last section consisted of questions

about other non-menstrual symptoms after the COVID-19 vaccination. The checklist was first pilot tested among 15 women to check for any ambiguities, before the beginning of the study. The study instrument was made in both English and Urdu language to ensure that a significant proportion of the population was not left out.

2.5. Procedure

The checklist included necessary information about the study on the first page of the form before the consent form, thus, the participants were informed of what they were filling out the form for. It was administered in English and Urdu (local) language, and Urdu responses were translated into English after data collection. The link to the checklist was spread through social media platforms in the community and anyone with access to a mobile phone was able to fill out the form. A convenience sampling technique was employed to recruit participants who fulfilled the predefined inclusion and exclusion criteria. The confidentiality of the participants was maintained as no personal identification information was asked in the survey. Duplication of response was avoided by adding checks.

2.6. Data Analysis

Data from the web-based google forms was exported to SPSS version 26. The relevant questions were converted into scores. Given the symmetrical distribution, the scores were summarized as mean values with standard deviation and other independent variables in terms of frequencies and percentages. A Chi-square test was applied to examine the association between menstrual symptoms and other factors with partial and complete COVID-19 vaccination status. A McNemar test was used to assess menstrual symptoms before and after the vaccination. A P value of <0.05 was considered as significant.

3. Results

A total of 927 women responded to the online checklist. Of these, 22 checklists were excluded due to incomplete / irrelevant information and 42 were excluded based on the eligibility criteria. The responses from the remaining 783 participants were included in the analysis. Around 36.8% of the participants received Pfizer, followed by Sinopharm (30.9%) and Sinovac (24.4%). Most responses were recorded from the province of Punjab (45%), followed by province Sindh, Pakistan (28.2%).

The socio-demographic characteristics of the study participants are shown in Table 1. Approximately 592 (75.6%) participants were aged between 18-25 years with mean Body Mass Index (BMI) of 21.21±4.27 kg/m^2. Among the total participants, 693 (88.5%) received two doses of vaccine while 90 (11.5%) received single dose of vaccine. Most of the participants (87.2%) did not receive the booster shot. Around 215 (27.5%) individuals were previously infected with COVID-19 before receiving the vaccination.

Table 2 shows menstrual symptoms before and after receiving the vaccination. Before vaccination, the mean cycle length and bleeding

Table 1: Socio-demographic characteristics of the participants (n=783)

Variable	Frequency (Percentage)
Age	
13-17	156 (19.9%)
18-25	592 (75.6%)
25-30	28 (3.6%)
30-40	5 (0.6%)
40-50	2 (0.3%)
No History of Comorbidities	697 (89.0%)
History of Smoking	21 (2.7%)
History of Alcohol	9 (1.1%)
Use of Anti-estrogenic Drugs	4 (0.5%)
Pap Smear	19 (2.4%)
Complete Vaccination Status	693 (88.5%)
Booster Dosage	100 (12.8%)
COVID Infection Before Vaccination	215 (27.5%)
COVID Infection after Vaccination	133 (17.0%)

days were reported as 28.16±11.54 and 5.94±2.59, respectively. Around 643 (82.1%) participants mentioned using more than five pads per day during bleeding, with complete soakage stated in 452 (57.7%) individuals, indicating heavy bleeding. Dysmenorrhea was reported by 690 (88.1%) of the respondents. Among them, 4(0.5%) had pain before menses, 538 (68.7%) had pain during menses and 149 (19.0%) had pain both before and during menses. After receiving the vaccination, the mean cycle length and bleeding days were 27.87±10.06 and 5.84±2.25, respectively. The number of respondents reporting the use of more than five pads declined to 628 (80.2%) and full soakage of pads to 426 (54.4%) individuals. 92.9% of female individuals reported an associated menstrual pain after the vaccination, of which 77 (9.8%) had pain before menses, 408 (52.1%) had pain during, and 298 (38.1%) had pain both before and during menses. 72 (9.2%) of respondents reported the persistence of abnormal menstrual symptoms in the third month of vaccination, and 51 (6.5%) of them received treatment.

Table 3 illustrates the association between two biologically plausible menstrual symptoms and participants' vaccination status. Among the fully vaccinated respondents, the majority i.e., 569 (82.1%), reported using more than five pads during their menstrual cycle. Although the association between the number of pads used and vaccination status did not reach statistical significance, a higher proportion of fully vaccinated women reported heavier menstrual flow. Likewise, intermenstrual bleeding was absent in 659 (95%) of fully vaccinated women, although demonstrating a non-significant association, with the effect appearing more pronounced in this group.

The results of the other general symptoms after vaccination have been summarized in Table 4. Around 61% of the respondents indicated pain, redness and swelling at the site of injection after receiving their first dose of vaccination and 70.2% of individuals reported fatigue. Whereas 39.2% reported headache and 61.6% of participants recorded symptoms of muscle and joint pain after the first dose of vaccination. Swelling, fatigue, muscles and joints pain were the most common symptoms after the second dose of vaccine.

Table 2: Menstrual symptoms of patients before and after vaccination (n=783)

Variables	Before Vaccination	After Vaccination	P value
	Frequency (%)	Frequency (%)	
More than Five Pads	643(82.1)	628(80.2)	0.33
Complete Soakage of Pads	452(57.7)	426(54.4)	0.19
Pain Associated with Periods	690(88.1)	727(92.9)	0.003
Pain during Menses	538(68.7)	408(52.1)	<0.001
Analgesic Use for Pain	308(39.3)	312(39.8)	0.84
Intermenstrual Bleeding	35(4.5)	38(4.9)	0.70
Post Coital Bleeding	8(1.0)	10(1.3)	0.64
History of Family Planning	15(1.9)	24(3.1)	0.15
Method of Family Planning			
Hormonal Pills	8(29.6)	16(35.6)	0.66
Intrauterine Device	2(7.4)	3(6.7)	0.92
Surgery	1(3.7)	2(4.4)	0.88
Condom	16(59.3)	24(53.3)	0.67

Results are presented as n (%). McNemar test was applied.

Table 3: Association of menstrual symptoms with the vaccination status of the participants (n=783)

	Partial Vaccination (n=90) Frequency (%)	Complete Vaccination (n=693) Frequency (%)	P value
Number of Pads			0.98
Less than Five	16 (17.8%)	124 (17.9%)	
More than Fve	74 (82.2%)	569 (82.1%)	
Intermenstrual Bleeding			0.85
No	86 (95.6%)	659 (95%)	
Yes	4 (4.4%)	34 (5%)	

Results are presented as n (%). Chi-square test was applied.

Table 4: General symptoms reported by participants following vaccination (n=783)

Signs and Symptoms	Partial Vaccination (n=693) Frequency (%)	Complete Vaccination (n=693) Frequency (%)
Pain, Redness, Swelling at the Site of Injection	478(61.0%)	357(45.6%)
Fatigue	550(70.2%)	392(50.1%)
Headache	307(39.2%)	218(27.8%)
Chills	219(28.0%)	144(18.4%)
Muscle and Joint Pain	482(61.6%)	353(45.1%)
Nausea	162(20.7%)	103(13.2%)
Swollen and Tender Lymph Nodes	108(13.8%)	72(9.2%)
Severe Anaphylactic Reaction	23(2.9%)	-

4. Discussion

The present study was a web-based survey aimed to observe the impact of COVID-19 vaccine on menstrual cycles, addressing an important gap in the existing local literature. Our findings revealed an association between vaccination status and the number of pads used, suggesting heavier menstrual flow among partially vaccinated women. Additionally, a link was observed between intermenstrual bleeding and vaccination status, with a more pronounced effect among those partially vaccinated. These results align with a study conducted in Italy in March 2022, where over 60% of women reported menstrual variabilities following their first COVID-19 vaccine dose, regardless of the vaccine type (16). Similarly, a descriptive study from Pakistan, focusing on healthcare providers, reported menstrual disturbances following COVID-19 vaccination, most commonly after receiving the first dose, with heavy menstrual bleeding as the most frequently observed pattern, followed by prolonged / irregular bleeding (17).

The incidence of intermenstrual bleeding was 91(18.8%) in a study highlighting the menstrual changes following COVID infection (13). Our findings showed that a post-vaccination altered the cycle length of less than a day. A similar change was highlighted in another study where the cycle length changed by less than a day although there was no change in the number of bleeding days (18). In a review, Payne and colleagues examined the link between COVID-19 vaccination and menstrual health and indicated a temporary association between the COVID-19 vaccine and menstrual changes, such as cycle length, flow, and menstrual pain. Notably, vaccination during the follicular phase appears to be linked to a greater increase in cycle length. Recognizing the importance of menstrual health, this review recommended including menstruation as an outcome measure in all future vaccine trials (19). Our study indicated slight menstrual changes after receiving different brands of vaccine suggesting that no particular brand or strategy is clearly associated with menstrual abnormalities, which is consistent with another retrospectively recruited study (14). In another relevant studies, statistically significant differences occurred between vaccination status groups, but the change in cycle length was less than one day, which is below the reportable difference in the menstrual cycle tracking application and is not clinically significant. One plausible explanation can be that mRNA vaccines create a strong immune response, which could temporarily influence the hypothalamic-pituitary-ovarian axis if scheduled correctly (11, 20). The results of a similar study showed an onset of menstruation of about a day later than usual following the vaccination. However, no significant change was observed on the overall number of menstruation days following the vaccine (21). The COVID-19 vaccine was linked to a change in cycle duration of less than 1 day for both vaccine-dose cycles compared with pre-vaccine cycles, as per current data comparing women who underwent vaccination and unvaccinated controls. Furthermore, 20-42% of women who received the vaccine reported having irregular menstrual cycles. The menstrual irregularities appeared to be a little higher after the second dose (60-70%) suggesting a potential additive effect. Our study findings are in line with the previously research (15).

In addition, our study highlighted other general symptoms linked to the COVID-19 vaccine, the major ones being fatigue, pain, redness and swelling at the site of injection and muscle and joint pain. These findings are consistent with the findings of another study evaluating side effects

associated with COVID-19 vaccine (22). The alterations in menstrual cycle are similarly reported all over the world, but they are not found to be statistically significant (23, 24). This might be due to small sample sizes. Nonetheless, many women are reporting fluctuations in their menstrual symptoms following vaccination, as suggested by other studies and in this study, and they have to seek medical treatment. Accordingly, we suggest that the assessment of menstrual symptoms should be included in clinical trials for vaccinations as women are unlikely to report menstrual symptoms unless asked for. In fact, some women may consider the menstrual changes to be a normal routine since the cycle can vary from month to month.

4.1. Limitations

There were some limitations in the study. Due to the cross-sectional design of the study, drawing a causal association is a limitation. Additionally, the survey is sensitive to reporting bias, and some participants may not have fully reported all applicable data resulting in a reporting bias. Due to time-lag between the respondents' last received vaccination dosages and filling in the checklist, it is possible that they may not have recalled some of the post vaccination menstrual symptoms vital in the process of data collection.

5. Conclusions

Our study did not detect significant changes in most of the menstrual symptoms pre- and post-vaccination except for two. Overall, no significant changes in menstrual symptoms were determined following vaccination. Nonetheless, to declare an association remarkably, it is suggested to do a study on a larger scale having an adequate sample size which include women from all age groups including young, middle-aged and post-menopausal so that any possible association between menstrual irregularities and COVID-19 vaccine can be assessed.

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Authors' Contribution

Azra Amerjee: Substantial contributions to the conception of the work; drafting the work and reviewing it critically for important intellectual content. Noor Ul Huda Ibrahim: Substantial contributions to the conception of the work; interpretation of data for the work; drafting the work; Zahid Hyder Wadani: Substantial contributions to the analysis and interpretation of data for the work; drafting the work and reviewing it critically for important intellectual content. Sumaira Naz: Substantial contributions to the conception of the work; drafting the work and reviewing it critically for important intellectual content. Khujasta Gul: Substantial contributions to the collection, analysis, and interpretation of data for the work; drafting the work. Muhammad Talha Nawaz: Substantial contributions to the collection, analysis, and interpretation of data for the work; drafting the work. All authors have read and approved the final manuscript and agree to be accountable for all aspects of the work, such as the questions related to the accuracy or integrity of any part of the work.

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Ethical Approval

The Ethics Review Committee of The Aga Khan University, Pakistan approved the present research with the code of 2022-7312-21078. Also, written informed consent was obtained from the participants.

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