

Transient Alterations in Menstrual Pattern Following COVID-19 Vaccination: An Exploratory Survey in Indian Women

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Received on: 20 February 2023; Accepted on: 12 May 2023; Published on: 31 October 2023

ABSTRACT

Background: Menstrual cycle is an important indicator of a woman's health, and innocuous alterations in menstrual pattern can affect women profoundly. With the increase in the vaccination drive across the Indian subcontinent, women have reported irregularities in menstrual pattern after coronavirus disease-2019 (COVID-19) vaccination. Through this study, we aimed to assess the pattern and severity of menstrual irregularities observed in Indian women post COVID-19 vaccination and determine its association with vaccine type and dosage.

Materials and methods: It was a prospective cohort study conducted over a period of 1 year. Women visiting gynecology outpatient department who voluntarily consented to participate in the survey and who had received at least one dose of Government-of-India-approved COVID-19 vaccine at least 3 months prior were eligible for recruitment in the study. All symptomatic or asymptomatic COVID-19-infected individuals with confirmed reverse transcriptase polymerase chain reaction (RT-PCR) positive report within the past 14 days were excluded from the study. A structured survey questionnaire was used to obtain data pertaining to alterations in menstrual pattern, duration, and severity of menstrual dysfunction. During the first 6 months, eligible participants were recruited. All recruited patients were prospectively followed up for the next 6 months to assess the persistence and severity of their menstrual irregularity.

Results: A total of 355 women participated. Majority of the study population were less than 30 years of age. Among the recruited women, 82% had previously regular menstrual cycles and 6.5% had a polycystic ovarian morphology. Almost 91.8% women had received at least two doses of the COVID vaccine. Of them, 87.9% women had received Covishield (Astra Zeneca/Serum Institute of India) and 11.5% had received Covaxin (Bharat Biotech). Five women had a history of recent (within 3 months of vaccination) use of hormonal contraception. Of the 33 women afflicted with disordered menstrual pattern, 57.6% were less than 30 years of age. Early onset of menstrual flow (30.3%) followed by reduced flow in 24.2% and heavy flow in 21.2% was the most common complaint recorded. Around 72.7% experienced symptoms within the first month of vaccination. Only two cases required medical attention. Of the 33 women who reported experience symptoms of menstrual alteration after COVID-19 vaccine, all have recovered at 6-months follow-up.

Conclusion: Transient menstrual abnormalities have been reported to succeed vaccination with Covishield (Astra Zeneca/Serum Institute of India) and Covaxin (Bharat Biotech). Most alterations were mild and self-limiting. Further large-scale multicentric trials are needed to confirm the findings of this exploratory survey.

Keywords: Coronavirus disease-2019, Irregular menstruation, Vaccines.

Journal of South Asian Federation of Obstetrics and Gynaecology (2023); 10.5005/jp-journals-10006-2303

INTRODUCTION

The world has witnessed multiple resurgence of SARS-CoV-2 strains with alarming outbreaks consuming the attention of several national and international organizations. Social distancing and vaccination have been the most effective preventive measures in combating and curtailing the ferocity of the pandemic. The precipitate escalation and extreme virulence of the infection necessitated the subversion of the usual scrutiny that precedes the public dissemination of any vaccine and saw emergency use authorization being granted to many key candidates across the world. While coronavirus disease-2019 (COVID-19) vaccination has achieved global acceptance, Southeast Asian countries have demonstrated an exponential pace of immunization with countries like China and India having already achieved more than 90% coverage of the first dose.¹

Menstrual cycle is an important indicator of a woman's health, and even innocuous alterations in menstrual pattern can affect women profoundly.² With the increase in the vaccination

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How to cite this article: Sharma P, Jindal S, Kahlon N, et al. Transient Alterations in Menstrual Pattern Following COVID-19 Vaccination: An Exploratory Survey in Indian Women. *J South Asian Feder Obst Gynae* 2023;15(5):564–568.

Source of support: Nil

Conflict of interest: None

drive across the Indian subcontinent, women have reported irregularities in menstrual pattern after COVID-19 vaccination. Population-based data from Europe and the United States have

observed similar trends.^{3,4} There were twice more cases of menstrual irregularities with AstraZeneca vaccine compared with Pfizer (643 vs 315, respectively).⁵ However, menstrual pattern post COVID-19 vaccination is showing evolving trends. It is imperative to investigate all possible side effects of the COVID-19 vaccination – both major and minor, due to its wide coverage and possible public health implications.

MATERIALS AND METHODS

This was a prospective cohort study conducted over a period of 1 year. Institutional Ethics Committee approval was obtained prior to the commencement of the study. Written informed consent was obtained from all participants. Our aim was to study the pattern and severity of menstrual irregularities observed in Indian women post COVID-19 vaccination and determine its association with vaccine type and dosage. Women visiting gynecology outpatient department who voluntarily consented to participate in the survey and who had received at least one dose of Government-of-India-approved COVID-19 vaccine at least 3 months prior were eligible for recruitment in the study. All symptomatic or asymptomatic COVID-19-infected individuals with confirmed reverse transcriptase-polymerase chain reaction (RT-PCR)-positive report within the past 14 days were excluded from the study.

A structured survey questionnaire was used to obtain data pertaining to alterations in menstrual pattern, duration, and severity of menstrual dysfunction. The questionnaire consisted of 12 questions. The questions enquired about whether previous cycles were regular, whether any anticoagulant or antiplatelet drugs were taken, whether there was any change in menstrual pattern following administration of the COVID-19 vaccine, how many doses were taken, and how long after vaccination did the symptoms arise. They were also asked about the pattern of menstrual irregularity and whether any medical advice was sought for the same. Information was also collected about the relevant medical comorbidities and treatment history. During the first 6 months, eligible participants were recruited. All recruited patients were prospectively followed up for the next 6 months to assess the persistence and severity of their menstrual irregularity. The obtained data were tabulated in a Microsoft Excel worksheet. Statistical analysis was performed on SPSS Version 16. Descriptive data were expressed as percentages.

RESULTS

During the study timeframe, a total of 355 women participated in the survey. Baseline characteristics of the study population are summarized in Table 1. Majority of the study population were less than 30 years of age. Almost 41.1% of the participants were doctors or medical interns. Among the recruited women, 82% had previously regular menstrual cycles and 6.5% had a polycystic ovarian morphology. No other medical comorbidity likely to influence menstrual flow patterns was observed in the study population. Till the date of completion of the primary survey, 91.8% women had received at least two doses of the COVID vaccine. Of them, 87.9% women had received Covishield (AstraZeneca/Serum Institute of India), and 11.5% had received Covaxin (Bharat Biotech). One patient was on antiplatelet therapy for coronary heart disease. Five women had a history of recent (within 3 months of vaccination) use of hormonal contraception.

Table 2 lists the pattern and associations of menstrual pattern observed post COVID vaccination. Of the 33 women afflicted with

Table 1: Baseline characteristics of study population

Parameters	Frequency (n = 355)	Percentage
Age group		
≤30 years	213	60%
31–50 years	136	38.3%
≥50 years	6	1.7%
Designation		
Doctor/Intern	146	41.1%
Nursing staff	68	19.2%
Paramedical workers	76	21.4%
Administrative staff	8	2.3%
Ancillary staff	43	12.1%
Others	14	3.9%
Previous menstrual pattern		
Regular cycles	291	82%
Irregular cycles	61	17.2%
Menopausal	3	0.8%
Previous significant comorbidities		
Bleeding diathesis	0	0%
Coagulation defects	0	0%
Poly cystic ovarian syndrome	23	6.5%
Premalignant cervical lesions/cervical malignancy	0	0%
None	332	93.5%
Participants on antiplatelet agents/anticoagulants		
Yes	1	0.3%
No	354	99.7%
Participants on current/recent hormonal therapy		
Yes	5	1.4%
No	350	98.6%
Vaccine doses		
1 dose	29	8.2%
≥2 doses	326	91.8%
Vaccine type		
Covishield	312	87.9%
Covaxin	41	11.5%
Sputnik	2	0.6%

a disordered menstrual pattern, 57.6% were <30 years of age. About 90.0% had received Covishield. Early onset of menstrual flow (30.3%) followed by reduced flow in 24.2% and heavy flow in 21.2% was the most common complaint recorded. About 72.7% experienced symptoms within the first month of vaccination and only one participant experienced after 3 months of vaccination. About 63.6% abnormalities resolved within 1 month of onset. Only two cases required medical attention. Of the 33 women who reported experience symptoms of menstrual alteration after COVID-19 vaccine, all have recovered at 6-months follow-up. Figure 1 describes the prevalence of menstrual disturbance by vaccine type.

Table 2: Pattern of menstrual disturbance observed post COVID vaccination

Parameters	Number (n = 33)	Percentage
Age group		
≤30 years	19	57.6%
31–50 years	14	42.4%
≥50 years	0	0%
Previous menstrual pattern		
Regular	27	81.8%
Irregular	6	18.2%
Menopausal	0	0%
Type of vaccine		
Covishield	30	90.9%
Covaxin	3	9.1%
Sputnik	0	0%
Type of menstrual disturbance		
Heavy flow	7	21.1%
Reduced flow	8	24.2%
Inter-menstrual bleeding	2	6.1%
Earlier than usual onset of next menses	10	30.3%
Later than usual onset of next menses	6	18.2%
Onset of symptoms in relation to vaccination		
<1 month	24	72.7%
1–3 months	8	24.2%
>3 months	1	3.0%
Persistence of menstrual disturbance beyond 1 cycle/month		
Yes	12	36.4%
No	21	63.6%
Symptoms needed medical attention		
Yes	2	6.1%
No	31	93.9%
Persistence of symptoms at 6 months following onset		
Yes	2	6.1%
No	31	93.9%

Transient alteration in menstrual pattern was observed in 9.2% women receiving Covishield and 7.3% women receiving Covaxin.

DISCUSSION

The endometrium is a site of constant tissue remodeling and vigorous immunological activity. The upper genital tract is sporadically exposed to foreign stimuli such as sperm and fetoplacental tissue, whereas the vagina harbors a distinct resident microbiome, and is also exposed to the antigenic stimulus of various microbiological and non-microbiological pathogens. The response to antigens is partly gender-based and the innate as well as adaptive immune responses in women are more robust than in males.⁶ This is

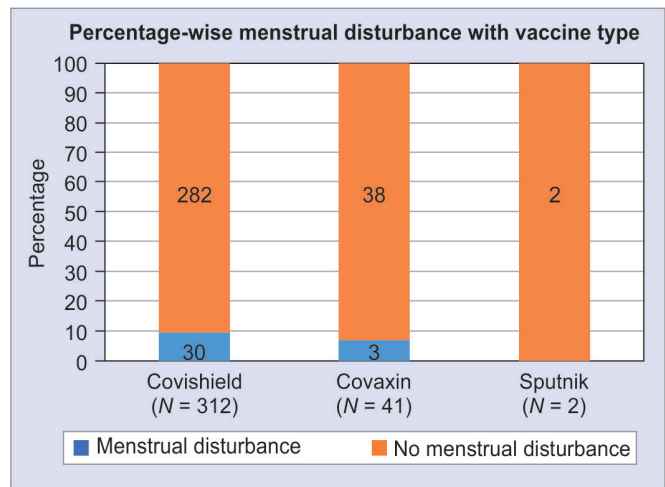


Fig. 1: Prevalence of post vaccination menstrual disturb

also reflected in the higher CD4+ T-cell levels, IgG levels, and greater propensity of autoimmune disorders in females.⁷ Sex hormone fluctuations also impact the immunological responses of the female genital tract. Estrogen affects T-cell homing during infection and autoimmunity.⁸ The steroid hormone cortisol may act as a link between reproductive function and immune response. A meta-analysis showed that cortisol levels were higher in the follicular phase of the menstrual cycle.⁹ The timing of vaccination may also impact their immune response and adverse reaction profile. Higher cortisol levels can interfere with the HPA axis resulting in menstrual abnormalities, by increasing pro-inflammatory cytokines.¹⁰

Women mount more robust immune reactions to antigenic stimuli than males. For instance, the immune reactions noted in women at half-dose of the influenza vaccine were equivalent to the full dose received by males.¹¹ Sex- and gender-based differences have been reported in immune responses to the dengue, rubella, measles, mumps, and typhoid vaccines. Since they produce a greater antibody response to the vaccine, women are also likely to manifest more serious adverse effects. For instance, in a Chinese vaccine adverse effects reporting (VAER) signal detection analysis from 2006 to 2018 detected a link between amenorrhea, abnormal menstrual pattern, and premature ovarian insufficiency in recipients of the quadrivalent HPV vaccine.¹² There are other large scale studies that refute such findings.¹³

As early as in April 2021, data started accumulating from post marketing surveillance and observational studies regarding the possible increase in menstrual abnormalities post COVID vaccination.⁵ And the evidence is still evolving!

A recent systematic review of 78,138 vaccinated females over 14 cross-sectional studies noted at least some menstrual irregularities in 52.05% of women after vaccination. No causal links have been identified. The authors have noted that most data were contributed by studies from the United States, United Kingdom and Norway – all industrialized nations with higher standards of healthcare access and services. At the same time, data from South Asian countries, such as India and Pakistan, were unavailable.¹⁴ In contrast, Male V did not find any significant abnormalities in 1273 vaccinated women in a UK-based study.¹⁵ Another vaccine adverse surveillance study failed to find significant menstrual abnormalities in African women.¹⁶

Some authors have proposed predictors of menstrual distress, although no causal links have been established. Alvergne et al.

noted that smoking and previous history of COVID infection were predictors, while use of estradiol-containing contraception was protective.¹⁷ The authors of the MECOVAC survey in Italy also observed increased menstrual irregularities post COVID vaccination, and they concluded that women receiving the first dose of vaccine during the first 14 days of menstrual cycle experienced greater alteration in the frequency of the subsequent menstrual cycle.¹⁸ Morsi et al. studied the effect of the Pfizer vaccine on menstrual abnormalities in Saudi women and concluded that these could be linked with age and number of doses received.¹⁹

It is true that women are traditionally underrepresented in vaccine trials. Most of the vaccine trials fail to consider and account for the inherent sex bias. The COVID trials have followed the same trend. A systematic review investigating the sex and gender bias in COVID vaccine research noted that while women were equally represented in seven randomized controlled trials included, only two trials had provided sex/gender-disaggregated efficacy data and none had provided safety data. Overall, only 30% of studies presented sex/gender-disaggregated efficacy data, and 34% of studies with safety data presented data by gender/sex.¹⁴ Only one of the included studies examined adverse events of the reproductive system, but did not provide gender-disintegrated data.²⁰

Covaxin (inactivated whole-virion vaccine) and the Covishield (adenovector vaccine) have been used for mass coverage in India till the completion of this study.

This led to phase I safety and immunogenicity trial for the Covaxin (SARS COV2 vaccine BBV152). In each of the four subgroups (3 test and 1 control), the representation of women ranged from 19 to 24%. Reproductive symptomatology receives no mention in the trial data, for either males or females.²¹ In the phase III trial testing efficacy, safety, and lot-to-lot immunogenicity of Covaxin SARS CoV-2 (BBV152), women constituted 32.7% of the vaccine recipients.²²

The participant composition of the Phase III Safety and Efficacy trial for the Covishield vaccine was partly less gender-skewed than the Covaxin trial results (55.6% males vs 44.4% females). However, there are no data on reproductive tract-related severe adverse events.^{23,24}

The COVID pandemic and post-vaccination side effect trends point to need to view vaccine research with a gender-sensitive lens. Regulatory bodies as well as medical journals can play a distinct role in ensuring that there is equity in sex-specific data in trial reporting. Also, supplementary data on sex-specific outcomes should be made available for pooled analysis. The availability of sex-specific efficacy and safety data will definitely promote confidence and ensure higher vaccine acceptance.

Due to the unique emergent situation created by the COVID pandemic, most vaccines received emergency use authorization, with only a short-term postvaccination follow-up mandated for licensing. In the absence of long-term trial data, the main sources of public information on vaccine side effects are post-marketing surveillance and vaccine adverse effect reporting systems. Despite their failings such as inaccurate, incomplete, and underrepresented reporting, vaccine adverse effect surveillance and self-reporting systems help raise red flags for vaccine safety, which can be further proven or refuted by traditional research.

In a Chinese VAERS analysis that included 13,118 reports of COVID vaccine-associated menstrual disorders, the reporting odds ratio was 7.83. The most common reported event was abnormal

menstruation with women aged 30–49 years reporting 42.55% of all events.²⁵

UK MHRA data on Yellow Card self-reporting of vaccine-related adverse events revealed 51,548 suspected reactions related to menstrual function. Most were transient in nature. The most common disturbances with the Astra Zeneca vaccine were heavy menstrual bleeding (4870), delayed menses (3355), and irregular menstruation (2459). Postmenopausal hemorrhage was seen in 313 women.²⁶

In India, the Indian Pharmacopoeia Commission allows self-reporting of vaccine adverse effects. But due to a lack of public awareness, the numbers are extremely underwhelming. Only 225 of the 49,819 adverse effects were reported to the Commission as of December 2021.²⁷

We have first noted an increase in our outpatient attendance for postvaccination menstrual abnormalities, as early as in June 2021. Since our survey data were collected retrospectively, it was desirable that women with sufficient menstrual pattern awareness be included. Also, since in India, first responders such as healthcare and allied workers were given priority in immunization, earliest data were available for this subset. Therefore, hospital employees were specifically recruited to augment the meaningfulness of data collected. We noted transient alterations in 9.2% and 7.3% of Covishield and Covaxin recipients. The alterations were largely self-limiting and rarely required medical attention. No long-term change in menstrual pattern has been observed.²⁸ However, large-scale population-based studies should further explore vaccine-related gynecological side effects. A more robust and effective vaccine adverse event reporting program must operate at the national level with clear pathways for self-reporting to identify vaccine-associated adverse effects timely and with greater precision. More gender sensitivity should be emphasized in designing and data collection in clinical trials. Gender-disaggregated data should be made available, and the outcomes should be analyzed by gender and sex.

CONCLUSION

Transient menstrual abnormalities have been reported to succeed vaccination with Covishield (Astra Zeneca/Serum Institute of India) and Covaxin (Bharact Biotech). Most alterations were mild and self-limiting. Further, large-scale multicentric trials are needed to confirm the findings of this exploratory survey.

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