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Original Research Article

The effect of covid vaccination on menstruation and attitude to the vaccine among Indian women – Results of a prospective survey

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ABSTRACT

Aims: SARS COV-2 vaccination was a global effort to tackle the Covid-19 pandemic. During the vaccination drive, several concerns were raised about the potential adverse effects of the Covid-19 vaccines, which included the impact on menstruation and fertility in women. This study aimed to assess experiences of Indian Women with covid vaccination and its effects on their menstruation.

Materials and Methods: A prospective web-based survey was conducted targeting women aged 18years and above and who had taken atleast one dose of the covid vaccine.

Results: The total number of responses received were 363. After excluding those with missing details, 342 respondents were included in the analysis. The mean age of the participants was 38.02 ± 7.8 years. 68.1% of the respondents (233/342) reported no change in the periodicity of their cycles post vaccination and 79.5% (272/342) reported no change in the menstrual flow. Forty three women (12.6%) reported experiencing heavy flow post vaccination. In this group which experienced heavy menses, 81.5% (35/43) reported that the heavy menses was self-limiting and did not require any treatment. 9.3% (4/43) of these symptomatic women recorded that short term treatment was sought. Another 9.3% of women reported persisting menstrual changes, at the time of the survey, despite taking prescribed treatment. It was also noted that the changes in menstrual cycles were significantly more in vaccinated nulliparous women.

Conclusion: Covid vaccination appears to have no or little impact on menstrual cycles in two-thirds of the women taking the vaccine. 31.9% of the women in the survey reported some change in their menstrual timing or flow. Most changes were self -limiting. About 1% (4/342) may have longer standing menstrual impact, requiring treatment.

1. Introduction

Following the Covid-19 pandemic, the SARS COV-2 vaccination was initiated across the world as an essential step to reduce mortality and morbidity of the infection and as a crucial step in potentially bringing the pandemic to an end. When vaccination first began, there were many concerns about the overall safety and effectiveness, as the vaccines had been developed and tested over a relatively short period of time.[1,2] Gynaecologists faced a unique problem when patients questioned the effect of the vaccine on menstrual cycles as well as future fertility. These concerns turned into heated conversations on social media and may have contributed to vaccine hesitancy as well.

It is a known fact that questions regarding the effect of vaccines on womens reproductive or hormonal health are seldom answered by vaccine trials.[3–5] While effects on fertility may only be known over longer follow up

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post vaccination, it was imperative to study the effects of the vaccines on menstrual cycles so that gynecologists can adequately guide and counsel women regarding covid vaccines. The primary objective of this study was to assess the potential effects of the covid vaccines on menstruation.

2. Materials and Methods

This cross-sectional study was conducted from April 2021 to Dec 2021. Eligible women were those aged 18 years or older, those who were menstruating and who had taken at least one dose of the covid vaccine. Women were invited to take the online survey questionnaire through social media sites and through emails. Voluntary opt-in method of sampling was used. Post menopausal women (natural and surgical), pregnant and lactating women were not included in this survey. Consent regarding data collection was taken and confidentiality was assured. Ethical clearance was obtained.

The survey questionnaire consisting of 22 questions was created using google forms. The questions included a section on demographics and reproductive history which included age, place of living, current menstrual cycle and period length, past history of pregnancies, gynaecological or medical problems and current hormonal treatment if any. The section related to Covid, included the name of the vaccine taken. number of doses taken and history of Covid infection. The section on menstrual changes included questions on cycle length, menstrual flow pattern and the length of persistence of these changes. Details of treatment for the menstrual problem, if any, were also included as a descriptive response. The questionnaire ended with the subject's attitude towards the vaccine and if they were likely to recommend it to other women based on their current experience.

A pilot questionnaire was administered to group of ten women (medical and nonmedical) to assess the ease of understanding and clarity of questions and given responses. Subsequent corrections were made accordingly prior to the survey. Data collected was automatically updated into a dynamic Google Excel sheet which was integrated into the survey form. Statistical analysis was done using SPSS 27. Descritpive statistics were expressed using frequency/percentages and Mean ± SD. Association between those with symptoms versus those without symptoms was measured using Chi Square test. $P<0.05$ was considered as statistically significant.

3. Results

Menstruating women who took at least one dose of any of the approved COVID-19 vaccine were included in this study. The total number of responses received were 363. After excluding entries with missing details, 342 respondents were included in the final analysis.

The mean age of the participants was 38.02 ± 7.8 years (range 18 to 55 years). Majority 214(62.6%) were above 35 years of age. At baseline, all the patients were menstruating and 92.7% (n=317) of the respondents reported having regular periods. About 268(78.4%) were menstruating for 3-7 days on average (Table 1). 266 (77.8%) did not have COVID-19 infection. Forty six women (13.5%) had tested positive for the infection and 30 (8.8%) felt that they may have had the infection but did not get tested.

3.1. Types of COVID-19 vaccines taken

72.8% of the respondents(n=249) had taken two doses of one of the approved vaccine and 93 (27.2%) had taken one dose. Most had taken Covishield (256, 74.9%) followed by Covaxin (42, 12.3%) (Table 3).

3.2. Post vaccination survey of pattern change

3.3. Those without any menstrual abnormality

68.1% of the respondents (n=233/342) reported no change in the periodicity of their cycles following the vaccination and 79.5% (n=272/342) reported no change in the menstrual flow. Overall 211 (61.1%) did not have any change either in the menstrual cycle or in the flow.

3.4. Those with menstrual abnormality

Forty three women (12.6%) reported experiencing heavy flow following vaccination. Thirty five (out of 43) reported that the heavy menses was self-limiting and did not take any treatment for the same. Four women (out of 43) recorded that they needed short term treatment for their menstrual changes. Another 4 (out of 43) reported persisting menstrual changes at the time of the survey despite taking prescribed treatment. (Table 2) These four women with persiting flow changes accounted to 1.16% of the total number of respondents.

Twenty three women (6.7% of total respondents) believed that COVID-19 vaccine was the reason for their menstrual problem while 42 women (12.2%) who experienced menstrual problems after vaccination did not attribute it to the vaccine.

A higher proportion of women in younger age group (≤ 35 years) had changes in both menstrual cycle (35.9% vs 29.4%) and flow (21.9% vs 19.6%). However, none of these findings were statistically significant. (Table 4). Though not statistically significant, a slightly higher proportion of those who had tested positive for COVID-19 infection, had changes in menstrual cycle. Following analysis, we noted that the changes in menstrual cycles were significantly more in vaccinated, nulliparous women.

3.5. Other side effects

14.6% (n=50) did not observe any side effects following the vaccine. The most common side effect in those that did, was pain in the injected arm in 27.8% (n=95) followed by body ache or myalgia in 68 (19.9%), fever among 58 (17%), tiredness among 41 (12%), headache among 29 (8.5%) and sore throat in 1(0.3%).

Based on their experiences, majority 321(96.2%) said that they would recommend COVID-19 vaccines to others. Four women in this survey, said that they would not recommend the vaccine. These four were not in the cohort that had experienced any menstrual change.

Table 1: Baseline menstrual cycle details of women who received COVID-19 vaccine. (N=342)

Menstruation	Frequency (%)
Menstrual cycle	
Always regular	158 (46.2)
Mostly regular	159 (46.5)
Mostly irregular	25 (7.3)
Duration of menses	
Very light or scanty	3 (0.9)
< 3 days	65 (19)
3- 7 days	268 (78.4)
> 7 days	6 (1.8)

Table 2: Record of menstrual changes post vaccination

Menstruation after vaccine	Frequency (%)
Menstrual cycle	(N=342)
Was on time	233 (68.1)
Was delayed than usual	47 (13.7)
Was earlier than usual	62 (18.1)
Duration of menses	(N=342)
Same as before	272 (79.5)
Heavier	43 (12.6)
Lighter	27 (7.9)
When was the flow / cycle altered	(n=131)
After 1^{st} dose	72 (21.2)
After 2^{nd} dose / After both the doses	59 (17.3)
Duration of altered flow / cycle	(n=131)
Only 1 cycle	74 (21.6)
< 3 months	41 (12)
3- 6 months	11 (3.2)
> 6 months	5 (1.5)

Table 3: Type of COVID-19 vaccine. (N= 342)

Type of COVID-19 vaccine	Frequency (%)
Viral vector based vaccine	287 (83.9)
Covishield	256 (74.9)
Pfizer	31 (9.1)
Inactivated (Covaxin)	42 (12.3)
Any other not specified	7 (2)
mRNA (Moderna)	6 (1.8)

Table 4: Factors affecting changes in menstrual cycle/flow (N=342)

	Present (%)	Absent (%)	p value*
Age group	**Changes in menstrual cycle**		
≤ 35 years	46 (35.9)	82 (64.1)	0.13
> 35 years	63 (29.4)	151 (70.6)	
	Changes in menstrual flow		
≤ 35 years	28 (21.9)	100 (78.1)	0.35
> 35 years	42 (19.6)	172 (80.4)	
	Overall Changes in menstrual cycle / flow		
≤ 35 years	54 (42.2)	74 (57.8)	0.15
> 35 years	77 (36)	137 (64)	
COVID-19 infection	**Changes in menstrual cycle**		
Tested positive	20 (43.5)	26 (56.5)	0.05
Tested negative	89 (30.1)	207 (69.9)	
	Changes in menstrual flow		
Tested positive	9 (19.6)	37 (80.4)	0.5
Tested negative	61 (20.6)	235 (79.4)	
	Overall Changes in menstrual cycle / flow		
Tested positive	22 (47.8)	24 (52.2)	0.1
Tested negative	109 (36.8)	187 (63.2)	
Pregnancy	**Overall Changes in menstrual cycle / flow**		
Previous Pregnant	76 (34.1)	147 (65.9)	**0.01**
Nulliparous	55 (46.2)	64 (53.8)	

*Chi square test

4. Discussion

The Covid pandemic has dominated conversations within the medical community as well as in the general public, since 2020. Many aspects of the disease and its effects have been new learning and are still evolving. The development and testing of the covid vaccines have been done over a relatively short period of time compared to other vaccines in current use. This had led to a lot of vaccine hesitancy and questions still circulate regarding the potential long term effects of the vaccines.

All stakeholders involved in the vaccine delivery program have been facing questions regarding the benefits and risks. In May 2021, several women shared their personal experience of heavy menstrual changes following covid vaccination on the social media platform “Twitter”. These anecdotal experiences brought attention to the fact that scientific data on whether covid vaccines affect menstrual cycles or fertility was lacking at the start of the vaccination drives.

This survey gave a starting point to address women’s questions on the effect of covid vaccines and their effect on menstrual health in Indian women, majority of whom

have taken the viral vector based vaccine or the inactivated vaccine. Similar studies have emerged from many countries. Zhang et al, reported that menstrual irregularity was the most common reported event and that a higher percentage of women in the 30-49 years age group seemed to be affected. This data was based on their analysis from the US Vaccine Adverse Event Reporting System (VAERS) database.[6] Our study found that a higher proportion of women in younger age group ≤ 35 years had changes in both menstrual cycle (35.9% vs 29.4%) and flow (21.9% vs 19.6%) compared to women over 35 years of age, although this was not statistically significant.

A large analysis from UK, looked into potential risk factors for menstrual irregularities following covid vaccination with or without covid infection. This online survey reported that in their premenopausal vaccinated cohort, 18% reported menstrual changes after their first dose of vaccination. The relative risk for reporting changes was higher in women who smoked or had a history of COVID-19 infection, but not in those using estradiol containing contraceptives. In a cohort of both vaccinated and unvaccinated particpants, the study found that COVID-19 vaccination alone was not associated with abnormal menstrual cycle parameters but a history of COVID-19 infection was associated with menstrual complaints inlcuding heavier bleeding, missed periods and inter-menstrual bleeding.[7] In our analysis, we found a slightly higher proportion of those who had COVID-19 infection reported changes in menstrual cycles, though not statistically significant. This, however, was in contrast to the findings reported by Wang et al, who prospectively examined pre-menopausal women from the Nurses Healthy Study-3, living in the US and Canada. Their observation was that COVID- 19 infection per se, was not associated with menstrual changes.[8]

A study from Japan found that vaccination could prolong menstrual cycles and they also made an interesting observation that changes were likely to be more if vaccination was taken during the menstrual time and was likely to be minimal if taken during ovulation.[9]

The EVA project, which was a retrospective, survey-based, cross-sectional study reported that 78% of the respondents reported some menstrual change, with increased menstrual flow and pain being the most frequently noticed adverse effect.[10]

A large multicentric observational study from India, noticed very similar patterns in menstrual changes. Kumar et al,[11] who surveyed 5709 women, reported that 5.8% of the women had menstrual changes. This study quoted that 50.2% of the respondents had excessive bleeding and 48.8% had scanty periods. The women in this survey had received either the Covaxin or the Covishield vaccine, which were also the vaccines that were taken by the women in our survey. The study reported that irregularities of the menstrual cycle and length were significantly higher in the COVAXIN group (7.2%) as compared to the COVISHIELD (5.3%) group.[11] Similar to this Indian study, a retrospective cohort study from Columbia, reported heavy menstrual changes in 41.8% of the respondents and irregular cycles in 42%.[12]

In our study, it appears that the risk of heavier menses following covid vaccination is likely to be is 1 in 10. The UK Nurses study noted that there is 1.7 fold increased risk of short-term menstrual changes.[7] Our study found that the change in menstrual changes tended to be short-term and most women do not need long term treatment and this finding was echoed in the UK Nurses study as well.

A systematic review of menstrual abnormalities following COVID-19 vaccination, published in 2022, noted that menorrhagia, metrorhagia and polymenorrhea were the commonly observed menstrual problems from analysing 78,138 vaccinated women. The overall rate of menstrual abnormality ranged widely from 0.83% to 90.9%.[13] The wide variation in the rates of events related to menstruation quoted in this systematic review and the lack of evidence from randomised controlled trials, emphasizes the need for incorporating research questions regarding womens health while designing vaccine trials. This would be an important step to get reliable evidence to questions on whether vaccines can impact menstrual health or not. Widely varying rates of menstrual changes reported thus far, may be attributed to several factors, which may be dependent on population characteristics or vaccine type.

New and rare side effects from drugs or vaccine may be missed even in randomised controlled trials. Spontaneous Reporting Systems (SRS) help identify emerging adverse effects and form the basis of newer research or changing guidance or issuing regulatory warnings. Noh et al., investigated the reporting rates of adverse effects following covid vaccination, by a cross-sectional web based survey. The authors concluded that spontaneous reporting of AEFI (adverse effects following immunisation) after COVID-19 vaccination was associated with younger age, female sex, moderate to severe AEFIs, comorbidities, history of allergic reactions, and vaccine type. They warned that AEFIs under-reporting should be considered when delivering information to the community and in public health decision-making[14] Lee et al, in their opinion piece published in the JAMA, advised that a harmonized list of prioritized Adverse effects of Special Interest (AESI) will enhance comparability across different surveillance systems and enable timely evaluation of potential safety signals. Short-term AESIs (eg, within 6 weeks of vaccination) may be considered for near real-time safety surveillance, whereas AESIs with longer latency periods may require different methodologic approaches and systems to evaluate potential safety issues.[15] This is applicable to adverse effects related to womens menstruation and fertility as well.

The strength of our study is that it is one of the few studies from India to explore women's menstrual experiences in relation to covid vaccination. It gives us a rough estimate of risks regarding menstrual cycle irregularities in Indian women. The weakness of this survey is that it is subject to potential recall bias which is inherent to most surveys. Moreover, the results cannot be generalised to all since most of the respondents were from India with majority having taken either a viral vector based vaccine or an inactivated vaccine.

While the COVID-19 pandemic has officially ended, studies like these help to nudge vaccine manufacturers to include research questions on menstruation while testing future vaccines.

5. Conclusion

This study concluded that the commonly used vaccines in India did not appear to cause any major menstrual change in the majority of vaccinated women. About 30% of those taking the vaccine are likely to have short term menstrual changes which are likely to be self limiting in almost all cases.

6. Source of Funding

None.

7. Conflict of Interest

None.

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