



Post-COVID-19 Vaccines and Menstrual Cyclicity, Mood, and Pregnancy in Albayda, Libya

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Abstract

Scanty studies are concerned with post-COVID-19 and menstrual cycle and pregnancy, and more global attention on the possible effect of COVID-19 vaccines on the menstrual cycle. Aim: This study aimed to evaluate the COVID-19 vaccine's impact on menstrual cycle features; changes in menstrual cycle length, mood, nervousness, and pregnancy chances. Method: This study was designed as a descriptive, cross-sectional study. A questionnaire was randomly distributed among 180 vaccinated menstruating women in Albayda City; east of Libya. from January 2022 to August 2022. Results: Eight vaccine types were reported in the questionnaire used by participants in this study; Sinopharm vaccine, Sputnik, AstraZeneca, and Pfizer-BioNTech, in addition to the combinations; Sputnik-Pfizer, Sinopharm-AstraZeneca, Sputnik-AstraZeneca, and AstraZeneca-Pfizer. Of the total sample numbers, 25.7% experienced change in menstrual cycles, about 15.1% of them had a prolonged period, and 5.6% had a shorter period. Post-vaccination menstrual change was higher in women who received a single vaccine compared with the combinations, where about 93.4% of the total received single-type vaccines. Depression and nervousness were reported in this study with single-type vaccines and not with mixed ones. This result also highlighted a low pregnancy incidence in non-contraceptive vaccinated women who were getting pregnant before being COVID-19 vaccinated. Conclusion: COVID-19 vaccination is associated with significant changes in menstrual cycle features; period days (+/-), depression, nervousness, and low pregnancy incidence were reported. Studying in larger prospectively-recruited cohorts is needed to determine how vaccination affects menstrual parameters and pregnancy chances accurately.

Keywords: COVID-19 vaccines, Menstrual cycle, Mood, Pregnancy

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Introduction

Corona disease is an infectious disease addressed as a pandemic disease by the World Health Organization which over time has reported 110749023 and 2455131 confirmed cases of infection and deaths, respectively. until February 2021/2022, these results change economic and social lifestyles all over the world (1). As a response to this widespread, in less than a year numerous vaccines were developed and approved.

By the middle of 2021 year; approximately, three billion vaccine doses were used worldwide. This large and rapid worldwide use of vaccines stimulated and directed the Center for Disease Control and Prevention (CDC) to use what is named the “V-Safe” system (a real-time vaccine adverse event reporting System) to follow up on the potential side effects of the vaccine.

There are many side effects that have been reported with other vaccines, ranging from mild ones such as injection site arm pain, headache, fever, chills, and fatigue to severe ones such as anaphylaxis and thrombosis. However, following a COVID-19 vaccine, several abnormalities in the menstrual cycle have been reported in a recent study including an increase in the pain, bleeding, and length of the cycle (2).

According to characterizing physiological and symptomatic variation in menstrual cycles using self-tracked mobile-health data (3), the risk of death before the age of 70 is higher in women with irregular and longer menstrual cycles, where these group of women is more likely to be prone to metabolic disorders as dyslipidaemia, and diabetes mellitus. Where these disorders in the menstrual cycles are accounting for their contact with women’s daily tasks, they create an important challenge for the healthcare system. (4).

Related to the COVID-19 vaccines, the Medicines and Healthcare Products Regulatory Agency (MHRA) (5) in the United Kingdom has reported 41,919 cases of menstrual problems, such as a feature heavier than usual periods, late arrival periods, and sudden vaginal bleeding. These problems disappeared within 6 months of the vaccine, signifying that any such vaccine side-effect was temporary. The changes were attributed to the use of human plasma to make the vaccine (antigens were derived from human plasma, containing hormonal impurities).

More recently, mixed results reported from large-scale studies on the effects of vaccination on menstrual cycle symptoms. A study that investigated 24 menstrual cycle symptom types, ran in 2018 on a number of 29,846 female residents of Nagoya City, Japan, found that none of the investigated symptoms were associated with increased odds after administration of the HPV vaccine. Even though symptoms of irregular menstruation such as the chronic persisting abnormal amount of menstrual bleeding has documented regarding age. There is a study suggesting a possible link between the HPV vaccine and menstrual irregularities. Another study applying a signal detection analysis on the FDA Vaccine Adverse Event Reporting System (VAERS) shows a disproportionate number of reports of premature ovarian insufficiency, amenorrhea, irregular menstruation, increase in FSH, and premature menopause following administration of the HPV vaccine. However, the evidence is non-causal, and relationships might depend on the type of vaccine (6). This emphasizes the importance of investigating menstrual abnormalities post-COVID-19 vaccination. As mentioned above the change in the menstrual cycle signs is considered a vital sign of health and infertility problems that form a risk factor that leads to death (3). There is no study concerned with the correlation of the changes with each vaccine separately, which all previous studies talked about in general, therefore, this study attempted to investigate the menstrual cycle abnormalities and their relation to the different types of COVID-19 vaccines, separately. This will help in understanding the post-COVID-19 profile from the side of the menstrual cycle and the vaccine’s convenience in Libyan women.

Materials and Methods

Population sample:

A number of 180 participants women were included in this study. All the participants received both the first and second doses of vaccines. The participants were all from inside Albayda City, Libya. The participants were from different foundations; Universities, schools, and polyclinics.

Vaccines used:

Sinopharm, Sputnik, AstraZeneca, Pfizer, “Sputnik + Pfizer”, “Sinopharm+ AstraZeneca”, and “Sputnik+AstraZeneca”, are vaccines included in this study were available by the Libyan Ministry of Health and used by the Libyan population.

Study plan and duration:

This study was designed as a descriptive, cross-sectional study, where a survey was conducted from January to August (2022). The survey was done according to a questionnaire previously designed by this study's authors and answered by the participants. The participants were selected by a random sampling method from Albayda City, located in the east of Libya. The women included in this study were of ages (16-66 years).

The questionnaire comprised 22 questions divided into four parts, part (I): characteristics of participants; age, job, marital status, concomitant disease, number of children, and vaccine type, part (II): change in menstrual cycle; changes in period days number, bleeding, dropping, and blood color), part (III): change in mood; anger and depression, and part (IV): feeding type and pregnancy; breastfeeding, bottle feeding, mixed type, and pregnancy (Form 1). The participants were divided into 5 groups according to age; Group I (16-26 years), Group II (26 -36 years), Group III (36-46 years), Group IV (46-56 years), and Group V (56-66 years).

According to the number of children, the participants were divided into four groups; Group I (1-3 children), Group II (4-6 children), Group III (7-9 children), and Group IV (haven't children). For the statistical analysis, SPSS version 26 was used to analyze the data. Descriptive statistical parameters; mean, frequency, and percentage were calculated. Also, significance was evaluated by probability value (P-value) estimation.

Results and Discussion

In this study, a total of 180 COVID-19 vaccine recipients were enrolled to assess the predictive change in the menstrual cycle. The designed questionnaire was answered by the population participants. After answering the questionnaire, and analysis, table (1) clarifies that the participants' ages varied and ranged from 16 to 66 years old. The highest percentage (39.5%) belonged to group 3 (36-46). Also, the questionnaire data showed that the majority of participants received Sinopharm, Sputnik, AstraZeneca, and Pfizer-BioNTech Vaccine dosage forms with percentages of 44.7%,20.7%,16.8%,11.2%, respectively, and the lowest percentage was 6.7% who received mixed vaccines (table 1). In addition, table (1) in this study showed that the majority of participants were teachers (56.2%), students (15.7%), and lecturers (9.0%). However, this study data said that (91.6%) of volunteers were healthy with no concomitant diseases and (8.4%) were with the disease. Hypertension was presented in (3.4%) and diabetes was found in (2.2%) of the total diseased volunteers (Table 1). In the context of marital status, the highest percentage of the sample was married (62.6%) followed by (29.6%), (4.5%), and (2.8%) for single, divorced, and widow, respectively (Table 1). The volunteers enrolled in this study were categorized into 4 groups from the side on the number of children they have, This study stated that the highest percentage (38%) of volunteers who took the vaccine belonged to the women who don't have children (group 4), followed by group1 (1 – 3 children), group 2 (4 – 6), and group 3 (≥ 6 children) with percentages of 31.3%, 25.7%, and 5%, respectively. The statistical analysis done in this study revealed highly significant differences (P value=0.000) between these groups (Table 1).

In general, among the participants, (74.3%) had regular menstrual cycles after taking the vaccine, and (25.7%) had changed menstrual cycles. About (15.1%), and (5.6%) out of 25.7% where have prolonged periods and shorter periods, respectively according to the volunteer's opinions. Of the 25.7% of volunteers whose Menstrual cycle style has changed, (11.2%) were vaccinated with the Sinopharm vaccine, (6.7%) received the Sputnik and (2.8%) were under the AstraZeneca vaccine (Table 2). Out of the total participants included in this study, (15.7%) of women who had irregular menstrual cycles after vaccination were teachers and the lowest percent of change was 0.6% with engineers.

The majority of the participants (94.9%) in this study were with normal color of blood, and (10.1%) of the sample had bleeding which was linked to increasing days of the period with high

significance ($P=0.000$). In the parallel line (15.6 %) had dropped blood and shortening in days (Figure 2). Also, this study revealed other symptoms linked with the vaccines including changes in mood, anger, and depression with percentages of (48.6%), (37.4%) and (19%) respectively.

On the side of depression, this study results presented that depression is reported with 5 out of 8 used vaccine types, where the highest percentage (10.1%) is found in women who were vaccinated with the Sinopharm vaccine, followed by (2.8%), (2.2%), (2.2%), and (1.7%) in women who vaccinated with Pfizer-BioNTech, AstraZeneca, Sputnik, and Sputnik-AstraZeneca, respectively. However, the anger symptom in this study has been reported with the use of 5 out of 8 vaccine types. The highest percentage (17.9%) appeared in women who were vaccinated with the Sinopharm vaccine, followed by (8.4%), (5.0%), (4.5%), and (1.7%) in women who were vaccinated with Sputnik, AstraZeneca, Pfizer-BioNTech, and Sputnik-AstraZeneca, respectively. Neither depression nor Anger appeared in this study related to Sputnik-Pfizer, Sinopharm-AstraZeneca, and AstraZeneca-Pfizer (Table 3).

With regard to breastfeeding and pregnancy parameters; this study's results proved that (8.4%) of the sample was on breastfeeding, (6.1%) was on artificial feeding, and (2.2%) was mixed. In addition, however, no pregnancy was shown after using almost all of the used vaccines. Out of a total of 113 married participants, only 24 took contraceptives and (2.2%.) out of the total were having pregnancies after the Sinopharm and Sputnik vaccines (Figure 3).

Table 1: Comparative Parameters of Participants in Percentages

Parameters	Percentage %
<u>AGE:</u>	
16-26	19.9%
26-36	18.6%
36-46	39.5%
46-56	21.5%
56-66	1.1%
<u>VACCINE:</u>	
Sputnik	20.7%
Sinopharm	44.7%
AstraZeneca	16.8%
Pfizer-BioNTech	11.2%
Sputnik -Pfizer	1.1%
Sinopharm-AstraZeneca	1.1%
Sputnik-AstraZeneca	3.9%
	6%
<u>OCCUPATION:</u>	
Teacher	56.2%
Administrative officer	7.7%
Students	15.7%
Engineer	1.1%
Housewife	2.2%
Pharmacist	3.4%
Nurse	2.8%
Doctor	1.7%
Lecture	9.0%
<u>CONCOMITANT DISEASES:</u>	
No disease	91.6%
With disease	8.4%
Hypertension	3.4%
Diabetes	2.2%
<u>MARITAL STATUS:</u>	
Married	62.6%
Single	29.6%
Divorced	2.8%
Widow	4.5%

NUMBER OF CHILDREN:	
1-3	31.3%
4-6	25.7%
7-9	5%
No children	38%
NUMBER OF MALE CHILDREN:	
1-3	51.4%
4-6	5.0%
7-9	0.6%
No male children	43.0%
NUMBER OF FEMALE CHILDREN:	
1-3	49.7%
4-6	5.0%
No female children	45.3%
Significance (P- value)	0.000

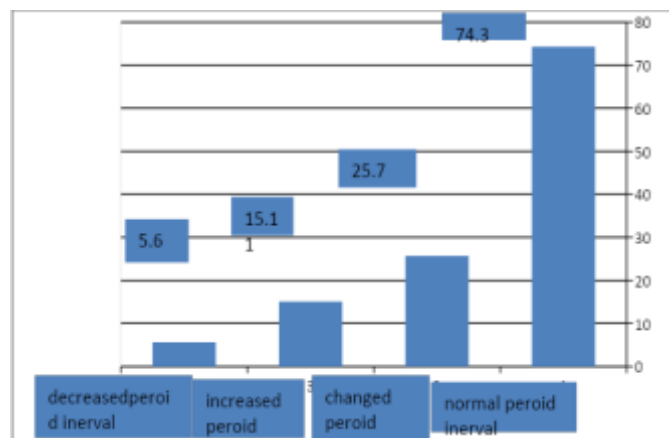


Figure (1): Menstrual Cycle Period Changes vs. Covid-19 Vaccination

(Table 2): Menstrual Cycle Changes vs Covid-19 Vaccine Types

Vaccine	Percentage of change
Sputnik	6.7%
Sinopharm	11.2%
AstraZeneca	2.8%
Pfizer-BioNTech	2.8%
Sputnik -Pfizer	0.0%
Sinopharm-AstraZeneca	0.0%
Sputnik -AstraZeneca	2.2%
AstraZeneca-Pfizer	0.0%

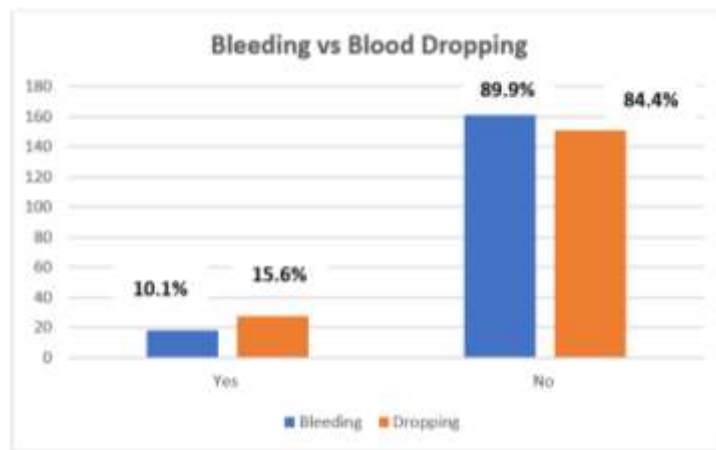


Figure (2): Percentages of Bleeding vs. Blood Dropping Among Participants

Table (3): Percentages of Anger and Depression related to the COVID-19 Vaccine.

Vaccine Type	Anger	Depression
Sputnik	8.4%	2.2%
Sinopharm	17.9%	10.1%
AstraZeneca	5.0%	2.2%
Pfizer-BioNTech	4.5%	2.8%
Spotunk -Pfizer	0.0%	0.0%
Sinopharm-AstraZeneca	0.0%	0.0%
Sputuink-AstraZeneca	1.7%	1.7%
AstraZeneca-Pfizer	0.0%	0.0%

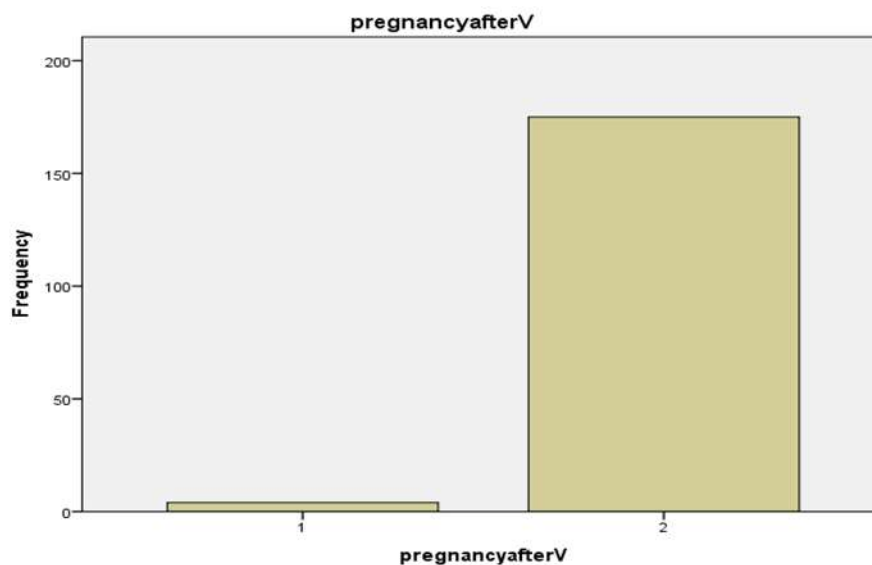


Figure (3): (1) Pregnancy vs. (2) No pregnancy post-vaccination

Discussion:

Despite vaccines being the optimal option to stop the spread of infections, including COVID-19, as with any medicine or vaccine, COVID-19 vaccines have been reported to have side effects.

Menstrual cyclicity is a vital sign of health and fertility. Moreover, women who have complained about menstrual changes are worried about the length of the side effects and if they have an effect on fertility, so these women are uncertain about receiving booster doses. This study was concerned with the worries of those women. The study was first designed to target at least 1000 samples, but the culture of our society is behind the low number of participants (180) included, where the fear of vaccination and the unwillingness of the participants were major hindrances. With the rational level of education of most of the participants, the women who work as teachers constitute the highest percentage of participants in this study, and showed a higher change percentage in the menstrual cycle studied parameters.

This study proved that the married participants were more likely to be vaccinated than non-married. Unmarried women may find moral support from the family, but this study attributes the increase in the number of married women receiving vaccinations to psychological support from husbands. There are different types of vaccines that are performed and used differently according to their differences in dose numbers and schedules, as well as safety and efficacy (7). Sinopharm, Sputnik, AstraZeneca, and Pfizer-BioNTech are the more common types of vaccine used by the participants included in this study, followed by the other four combinations of dosage forms.

Vaccines and medicines are reported to have some side effects. Differences in the methods of vaccine manufacturing between companies are behind the different types of COVID-19 vaccines, and this is affecting on type and severity of the expected side effects of vaccines. These side effects need to be continuously balanced in front of the expected benefits of preventing illness.

many previous studies concerned about COVID-19 vaccines in general reported that there is a change in the menstrual cycle observed (2, 8,9) A change in the menstrual cycle habits was observed in this study too, but among the used single vaccine types (not combined with another vaccine type) rather than the combined ones. Also, this study questionnaire highlighted a change in the mode and development of anger (nervousness) and depression among the participants.

Significantly, more change found was with the Sinopharm vaccine ($P=0.000$), and this might be referred to as that nearly half of the sample population was vaccinated with the Sinopharm vaccine. For the Sinopharm vaccine, previous studies reported that the observable side effects were pain at the injection site and fever, but both were mild, self-limiting, and did not require hospitalization. Moreover, no treatment was required for any side effects, while other studies reported general lethargy, and myalgia (10; 11;12;13). This study was not concerned with primary side effects following the vaccination injection but it focused on the post side effect that appeared on the female menstrual cycle habits and related symptoms and pregnancy chances, where it proved that there was a change in menstrual cycle habits in 11.4% of the total participants who take Sinopharm vaccine. Of this total 52% experienced 2 days more than their normal period, while only 16% of participants experienced 2 days less than their normal period.

In addition, this study found that 10.1% Sinopharm vaccinated population developed depression, and 17.9% developed anger (nervousness). Also, this study documented that only one of the Sinopharm-vaccinated married participants who had not received any contraceptives got pregnant, and this low incidence of pregnancy might be related to the depression developed post the Sinopharm vaccination, especially with the knowledge that the non-pregnant participants were got pregnant before being vaccinated.

For Sputnik, also the previous study talked about the general primary side effects that were transient, and in the forms of muscle pain, fatigue, fever, and chills (12). Out of 20.7% who vaccinated with the Sputnik vaccine in this study 6.7% were suffered from a change in their menstrual cycle habit, where 53.8% were experienced 2 days more, 7.6% participants experienced 3 days more than their normal period, while only 15.4% experienced a lower period time (2 days). Same as what developed with the Sinopharm vaccine, depression, and anger were also reported in this study with the Sputnik but with lower percentages of 2.2% and 8.4%, respectively. This change in cycle upon the usage of Sputnik is less than that appeared with the

Sinopharm vaccine except for the pregnancy where both showed an equally low incidence of getting pregnancy post-COVID-19 vaccination.

General side effects were reported with AstraZeneca and Pfizer vaccines too rather than concerned with the menstrual cycle (14 & 15). The percentage of change in general in this study was equal between both AstraZeneca and Pfizer; although it differs in between among the features. The increase in the days of the period appeared in this study more with AstraZeneca than with Pfizer. Both nervousness and depression features were equally developed in this study between AstraZeneca and Pfizer. The flash point observed in this study is although the vaccinated participants were not under contraceptives, no pregnancy happened with AstraZeneca and Pfizer.

When the data was analyzed in this study the output showed that the percentages of anger and depression that appeared with the usage of the Sputnik + AstraZeneca (MIX) were equal and lower than that showed with other provided single vaccines. Also, the ratio of the number of increases and decreases in period days was closely equal, and no pregnancy was reported with this vaccine. However, only one pregnancy case was registered in this study with each of the Sinopharm and Sputnik vaccines, and no pregnancy was registered with other all vaccines. This finding is opposite to the previous study which said that there is no impact of COVID-19 vaccination on fertility (16, 17).

This study found that all participants who were vaccinated with a single vaccine (either Sinopharm, Sputnik, AstraZeneca, or Pfizer) experienced changes in the menstrual cycle period days, and mood (nervousness, depression). No anger and depression were observed in this study with the vaccine combinations; Sputnik/Pfizer, Sinopharm/ AstraZeneca, and AstraZeneca/Pfizer. Furthermore.

In the time that pregnancy chance in this study appeared low with both Sinopharm and Sputnik single vaccines, no pregnancy case was reported with AstraZeneca, Pfizer, and the Sputnik + AstraZeneca mixed vaccine, and this needs more in-depth to stand about the real effect of on pregnancy and fertility.

The incidence of blood bleeding (heaviness) in this study was lower than that of blood dropping, with a significant positive relationship ($P=0.000$) that has been clarified between the increase in the length of the cycle and the blood heaviness. This finding is inconsistent with (18), who reported that there is a probability of blood heaviness caused by COVID-19 vaccination.

Conclusion

This demonstrates that females subjected to COVID-19 vaccines have experienced changes in their menstrual cyclicity, including increases/decreases in days of period, amount of blood, change in mood, and pregnancy chances. This is worrying, and this study advised doing a longitudinal deep study on a large sample number to accurately determine how vaccination affects menstrual parameters.

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