


CLINICAL ARTICLE

Gynecology

The effect of BNT162b2 SARS-CoV-2 mRNA vaccine on menstrual cycle symptoms in healthy women

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Abstract

Objective: To investigate the impact of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA BNT162b2 vaccine on women's menstrual cycle.

Methods: In this questionnaire-based cross-sectional study, we assessed menstrual pattern and changes in women who completed the SARS-CoV-2 mRNA BNT162b2 vaccine 3 months before and after receiving the vaccine. Included were women aged 18–50 years without known gynecologic comorbidities who regularly monitor their menstruation through electronic calendars. All participants completed a detailed questionnaire on their menstrual symptoms including information on any irregular bleeding. To minimize bias, each woman served as a self-control before and after vaccination. Primary outcome was rate of irregular bleeding following vaccination and secondary outcome was presence of any menstrual change, including irregular bleeding, mood changes, or dysmenorrhea following the vaccine.

Results: A total of 219 women met the inclusion criteria. Of them, 51 (23.3%) experienced irregular bleeding following the vaccine. Almost 40% ($n = 83$) of study participants reported any menstrual change following vaccination. Parity was positively associated with irregular bleeding with 26 (50%) of those suffering from irregular bleeding being multiparous compared with only 53 (31.5%) of women with no irregular bleeding (nulliparous 46% vs 60%, multiparous 50% vs 31%, rest 4% vs 8%, $P = 0.049$). The presence of medical comorbidities was also significantly higher among patients who experienced irregular bleeding (20.0% vs 6.0%, $P = 0.003$).

Conclusion: Our study shows relatively high rates of irregular bleeding and menstrual changes after receiving the SARS-CoV-2 mRNA BNT162b2 vaccine. Further research is needed to confirm our findings and to better characterize the magnitude of change and any possible long-term implications.

KEYWORDS

any menstrual change, BNT162b2 SARS-CoV-2 mRNA vaccination, irregular bleeding

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1 | INTRODUCTION

Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, was declared a pandemic by the World Health Organization in 2020.¹ In an effort to minimize morbidity and mortality, vaccines based on different platforms were rapidly developed. Among them, were two novel mRNA-based vaccines: smRNA-1273 (Moderna) and BNT162b2 (Pfizer-BioNTech) who received Emergency Use Authorization from the US Food and Drug Administration in December 2020.

Great efforts are currently ongoing to characterize the safety and adverse effect profile of these recently approved COVID-19 vaccines.

Reported adverse effects of the BNT162b2 mRNA vaccine include fatigue, headache, muscle pain, joint pain, chills, tachycardia, fever, gastrointestinal discomfort, vomiting, and myocarditis.²⁻⁶

Shortly after mass vaccination began, public concerns were raised on possible menstrual cycle changes. Reported changes included changes in bleeding pattern, menstrual period length alteration, intermenstrual spotting, and menorrhagia.^{7,8} In response, health authorities called for more research on the effect of the COVID-19 vaccine on menstrual cycle changes.^{9,10}

Israel was among the first countries to initiate a mass vaccination campaign using the BNT162b2 mRNA vaccine, with the vast majority of the adult population receiving two doses of the vaccine.¹¹ Shortly after the initiation of the vaccination campaign, claims about possible changes in the menstrual cycle have arisen among Israeli women¹² leading to concerns and anxiety regarding vaccine safety and possible implications for fertility.¹³ Hence, we aimed to investigate the possible impact of the BNT162b2 mRNA SARS-CoV-2 vaccine on women's menstrual cycle.

2 | MATERIALS AND METHODS

We conducted a survey-based cross-sectional study. The study was carried out at a tertiary medical center between July 2021 and October 2021. Inclusion criteria were women aged 18–50 years who completed the two-dose series of the SARS-CoV-2 BNT162b2 mRNA vaccine. We excluded women who had previously contracted COVID-19, were pregnant or lactating during the study period, or had background hematologic or gynecologic diseases. Women were asked to retrospectively report their menstrual pattern and symptoms during the 3-month period before the first vaccine dose administration and during the 3-month period after the second vaccine dose administration. To minimize bias, each woman served as a self-control, and each woman's bleeding pattern and symptoms were compared between the three cycles she reported before being vaccinated and the three cycles reported after being vaccinated.

All women completed a questionnaire including: (1) demographic data; (2) medical and gynecologic background; and (3) menstrual symptoms including: duration of menses, frequency, regularity, and volume, as well as premenstrual symptoms. We included only

women who regularly follow their periods with an electronic diary, menstrual cycle tracking Apps, or any other written documentation.

The primary outcome was the rate of irregular bleeding following vaccination, defined as early or delayed menstruation of 7 days or more than the expected time of menstruation. Secondary outcome was the presence of any menstrual change, defined as one of the following: irregular bleeding (as aforementioned defined in the primary outcome), mood change during the bleeding following vaccination, or dysmenorrhea after vaccination.

2.1 | Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics (version 25, IBM Corporation). Patient demographics and characteristics, as well as menstrual characteristics were reported by means \pm standard deviation or percentage, as appropriate. We further compared rates of irregular bleeding and any menstrual change according to baseline characteristics, using unpaired Student *t* test and χ^2 test, as appropriate. A *P* value of less than 0.05 was considered statistically significant for all analyses.

2.2 | Ethics statement

Approval was obtained from the institutional review board of our medical center before recruitment (0490-21-HMO; July 7, 2021). Informed consent was given by all participants.

3 | RESULTS

We recruited 241 women to this study. Of them, 5 (2.2%) were excluded because of incomplete response and 17 (7.7%) were excluded because of background disease (polycystic ovarian syndrome, $n = 11$; uterine fibroids, $n = 4$; endometriosis, $n = 1$; and hematologic disease, $n = 1$). Two hundred and nineteen women met the inclusion criteria. Baseline characteristics of women are shown in [Table 1](#). Mean age was 29.6 ± 8.6 years and mean parity was 1.1 ± 1.5 . All participants completed the two-dose series of the BNT161b2 mRNA vaccine with a mean interval of 22.1 ± 5.1 days between doses.

Distribution of baseline menstrual characteristics is shown in [Table 2](#). The average menstrual cycle length before the vaccine was 29.4 ± 7.6 days with duration of menses of 5.0 ± 1.3 days.

Of the 219 women who participated in the study, 51 (23.3%) experienced irregular bleeding following the vaccine. Of them, 20 (39.2%) and 31 (60.8%) reported irregular bleeding after the first and second doses of the SARS-CoV-2 BNT162b2 mRNA vaccine, respectively. Of the 51 women who experienced irregular bleeding, 34 (66.7%) reported irregular bleeding that preceded their estimated menstrual date (mean 9.9 ± 3.0 days) and 17 (33.3%) reported a delay in their expected menstrual date (mean 12.3 ± 6.3 days). Irregular bleeding was reported as light in its severity in 24 (47%), moderate

TABLE 1 Baseline characteristics of study participants ($n = 219$)

Age (years)	29.62 ± 8.6
Parity	
0	130 (59.4)
1	15 (6.8)
≥2	74 (33.8)
Marital status	
Single	142 (64.8)
Married/permanent relationship	77 (35.2)
Background diseases	22 (10.1)
Endocrine disorders	7 (3.2)
GI diseases	3 (1.4)
Pulmonary diseases	2 (0.9)
Neurologic disorders	1 (0.4)
Cardio-metabolic diseases	4 (1.8)
Regular medications	
SNRI\SSRI	17 (7.8)
Levothyroxine sodium	4 (1.8)
Ventolin	3 (1.4)
Other	8 (3.6)
Hormonal treatment	
OCP	45 (20.5)
Levonorgestrel IUD	12 (5.5)
Non-hormonal IUD	11 (5.0)
Other	4 (1.4)

Note: Values are presented as mean ± standard deviation or as number (%). Abbreviations: GI, gastrointestinal disease; IUD, intrauterine device; OCP, oral contraceptive pill; SNRI, serotonin-norepinephrine reuptake inhibitors; SSRI, selective serotonin reuptake inhibitor.

TABLE 2 Baseline menstrual characteristics

Age at menarche (years)	12.8 ± 1.4
Cycle length (days)	29.4 ± 7.6
Days of bleeding	5.1 ± 1.3
Usual menstrual flow	
Light	62 (28.3)
Moderate	129 (58.9)
Heavy	38 (17.3)
Dysmenorrhea	
None	30 (13.7)
Mild	55 (25.1)
Moderate	101 (46.1)
Severe	33 (15.1)
Limitation in daily activities	41 (18.7)

Note: Values are presented as mean ± standard deviation or as n (%).

in 11 (21.6%), and heavy in 16 (31.4%). Among those who reported irregular bleeding, 16 (31.4%) reported persistent irregular bleeding during the 3-month period following vaccination, whereas 35

(68.6%) reported a transient change that did not continue throughout the study period.

In all, 83 (37%) study participants reported any menstrual change (including irregular bleeding, mood changes or dysmenorrhea) following vaccination.

Nearly 68% ($n = 55$) of study participants reported dysmenorrhea following vaccination. Among them, 26 (47.3%) reported new-onset dysmenorrhea or an increase in the severity of pre-existing dysmenorrhea. Other menstrual symptoms were reported by 45 (55.5%) study participants after receiving the vaccine, including: abdominal pain ($n = 24$); pelvic pain ($n = 11$); appearance of new acne ($n = 11$); breast tenderness ($n = 4$); hot flushes ($n = 1$).

Mood changes associated with menstruation after the vaccine (that were not reported before the vaccine) were reported by 21 (9.6%) women.

There was no significant association between use of oral contraceptive pills and irregular bleeding or any menstrual change following the vaccine: 11 (18%) women who used oral contraceptive pills reported irregular bleeding following the vaccine, compared with 40 (25.5%) women who did not use oral contraceptives ($P = 0.28$). Eighteen (29%) of the women who used oral contraceptives pills reported Any menstrual change, compared with 65 (41.4%) of the women who did not use oral contraceptives pills ($P = 0.12$).

A comparison of rates of irregular bleeding and any menstrual change according to baseline characteristics of women is presented in Table 3.

The rate of parous women reporting irregular bleeding was significantly higher, as compared to nulliparous women with 26 (50%) of those suffering from irregular bleeding being multiparous compared with only 53 (31.5%) women with no irregular bleeding (nulliparous 46% vs 60%, multiparous 50% vs 31%, rest 4% vs 8%, $P = 0.049$). The presence of comorbidities was also significantly higher (20.0% vs 6.0%, $P = 0.003$) among patients who experienced irregular bleeding. The only variable that was found to be significantly associated with the composite outcome of any menstrual change was use of regular medications ($P < 0.001$). Among the participants who reported any menstrual change, women using medications regularly were less likely to report any menstrual change. Any menstrual change was reported in 11 (13.3%) of women using regular medications, compared with 72 (53%) women not using medication ($P < 0.001$).

4 | DISCUSSION

In the current study assessing the effect of the SARS-CoV-2 mRNA BNT162b2 vaccine on menstrual changes, almost 40% ($n = 83$) of women experienced menstrual changes and almost one-fifth reported irregular bleeding following the vaccination. Higher parity and the presence of medical comorbidities were associated with the occurrence of irregular bleeding following vaccination.

Few recent studies have examined the influence of COVID-19 vaccines on the menstrual cycle. In a large survey web-based

TABLE 3 Comparison of baseline characteristics between women with or without irregular bleeding and any menstrual change following the vaccine

	Irregular bleeding			Any menstrual change ^a		
	Yes (N = 51)	No (N = 168)	P value	Yes (N = 83)	No (N = 136)	P value
Age (years)	31.1 ± 8.1	30.2 ± 7.2	0.44	31.1 ± 8.3	30.0 ± 6.7	0.29
Parity						
0	46.0%	60.1%	0.0497	53.7%	58.8%	0.28
1	4.0%	8.3%		4.9%	8.8%	
≥2	50.0%	31.5%		41.5%	32.4%	
Presence of background disease	20.0%	6.0%	0.003	13.6%	6.6%	0.09
Regular medications	34.3%	32.3%	0.82	22.9%	59.0%	<0.001
Hormonal treatment	22.0%	29.8%	0.28	22.0%	31.6%	0.12
Menstrual cycle length (days)	28.8 ± 5.8	29.5 ± 8.1	0.59	29.2 ± 4.9	29.4 ± 8.8	0.85
Days of bleeding	5.0 ± 1.3	5.1 ± 1.3	0.74	4.9 ± 1.3	5.1 ± 1.25	0.59
Presence of dysmenorrhea	75.5%	83.3%	0.21	83.1%	79.0%	0.45

Note: Values are presented as mean ± standard deviation or as number (%).

^aIrregular bleeding, mood disturbance, or menstrual pain.

software platform-designed study of women without known gynecologic disorders Lee et al. reported high rates of heavier and longer menstrual bleeding after vaccination. Changes in the timing and amount of menses after receiving the SARS-CoV-2 mRNA BNT162b2 vaccine was reported also in another retrospective study.¹⁵ A study from the UK, specifically assessing women with regular periods before the vaccine, has reported a 20% rate of menstrual changes, up to 4 months after receiving the first dose of the vaccine.¹⁶ Of note, these studies suggest that menstrual changes are not specific to a particular COVID-19 vaccine.

The effect of the vaccine on the menstrual cycle may be explained by several mechanisms. Inflammatory and immunologic mediators, secreted by endometrial cells, play key roles in endometrial breakdown, regeneration, and repair.¹⁷ The vaccine's mechanism of action involves modulation of the immunologic milieu¹⁸ and this may provide a possible explanation for the association between vaccination and menstrual changes. Previous studies showing the effect of certain vaccines on the immunologic and hormonal environment, may lend support to this hypothesis.^{19–22} The effect of stress on menses is well established²³ with some studies showing that stress and/or emotional instability may have an effect on the estrogen–progesterone balance, thus leading to irregular bleeding and other menstrual symptoms.²⁴ Recent studies have described vaccine-associated stress,²⁵ which may also partially account for the association between vaccination and menstrual changes. In addition, a possible association between the SARS-CoV-2 mRNA BNT161b2 vaccine and menstrual cycle changes may also be explained by changes in sex hormone regulation. Ovulation is regularly controlled by follicle-stimulating hormone and luteinizing hormone levels. During severe illness, the levels of these hormones are altered, as described by Li et al.²⁶ in a study assessing 91 women who had been affected by SARS-CoV-2, suggesting their possible role in this regard.

Accordingly, we estimated that women who use hormonal therapy will be less affected by the vaccine because of suppression of the normal hormonal axis. However, in our study 22% of women who used hormonal therapy reported irregular bleeding or any menstrual change, though no significant correlation was found. Similarly, Male et al.¹⁷ reported no association between hormonal therapy and timing of the next period, but described that the period following vaccination was different from usual—mostly heavier in 42% of participating women. Albeit Li et al.²⁶ described longer and heavier menstrual bleeding for hormonal therapy users during the period following vaccination.

Our finding of higher rates of irregular bleeding in parous women warrants further confirmation and research. The association found between irregular bleeding following vaccination and the presence of comorbid conditions is not surprising, given the large body of literature reporting menstrual changes in those with non-gynecologic comorbidities.²⁷

Concerns were raised about the possible influence of the SARS-CoV-2 mRNA BNT162b2 vaccine on women's fertility. These concerns were refuted with the publication of a number of articles as well as an official statement from The American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine stating clearly that the vaccine has no negative effect on female fertility.^{28,29} Therefore, even if the vaccine is associated with temporary menstrual changes, it is extremely unlikely that this has any effect on current or future fertility. This is further supported by the current study finding that among those who experienced irregular bleeding following vaccination, the occurrence of any abnormal symptom was mostly transient and resolved during the study period.

Importantly, significant menstrual changes are reported also after SARS-CoV-2 infection.^{26,30} In a prospective study of 127 women, Khan et al.³⁰ reported irregular menstruation, increase

of premenstrual symptoms, and infrequent menstruation after severe illness with SARS-CoV-2. Among 177 women who recorded their menstrual pattern Li et al.²⁶ described that nearly 20% of patients exhibited menstrual volume decrease or cycle length alterations.

The main limitation of our study is its retrospective nature. This carries an inherent selection bias as a result of the voluntary recruitment of participants. To address this limitation, we mostly recruited patients who attended our clinic. Another limitation is a possible recall bias. In an attempt to minimize this possibility, when menstrual changes were reported, we asked the study participant to attach documentation via menstrual cycle tracking apps so we could validate the report. Another limitation is the possibility of personal interpretation of some of the questions that could not be validated by a physician. To address this, the questionnaire was validated on a group of women as well as on a group of gynecologists before recruiting commenced. Finally, the lack of a control group of women is an additional potential caveat. Our study was conducted on women who received two doses of the SARS-CoV-2 mRNA BNT162b2 vaccine. As such, our findings may not be applicable for other COVID-19 vaccines. However, similar findings were reported in two recently published studies^{16,26} examining the SARS-CoV-2 mRNA BNT162b2 vaccine, which further reinforces our finding of a possible effect of the vaccine on women's menses.

In conclusion, the effectiveness and importance of the vaccine against SARS-CoV-2 to prevent severe morbidity and mortality is now unquestionable.³¹ In this study, assessing the association between the SARS-CoV-2 mRNA BNT162b2 vaccine and menstrual changes, we found significant rates of menstrual changes following the vaccine. Further research is needed to confirm our findings and to better characterize the magnitude of change, its underlying mechanisms, possible long-term implications and ways to attenuate any possible negative effect of the most important tool we have to fight the ongoing pandemic—the vaccine.

AUTHOR CONTRIBUTIONS

NL, AR, and UPD conceived and designed the study, analyzed and interpreted the data, and drafted the manuscript; data were acquired by NL, SS AG, and TDS. The manuscript was revised critically for important intellectual content by AR, SS, SP, UPD and the version of the manuscript to be published was approved by NL, AR, SS, AG, P, TDS, and UPD.

CONFLICT OF INTEREST

There is no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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