

Menstrual changes after COVID-19 vaccine administration: a systematic review

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Abstract. – OBJECTIVE: During the mass vaccination campaign for COVID-19, cases of menstrual cycle changes in women emerged, so it was thought that the COVID-19 vaccine could affect the menstrual cycle. Over time, these observations have become more frequent, which strengthens the idea. This systematic review aims to show changes in the menstrual cycle after COVID-19 vaccination.

MATERIALS AND METHODS: This study was carried out following the guidelines of the Cochrane Collaboration and the Meta-analysis of Observational Studies in Epidemiology and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

RESULTS: A suitable bibliography on PubMed/Medline and Scopus was searched by combining text, words, and titles of medical topics. After completing the search, a total of 42 articles were included in this systematic review.

CONCLUSIONS: The COVID-19 vaccines may have an impact on the quality of life of women. The changes in the menstrual cycle tend to resolve within 2-3 months of vaccination and the symptoms are mild to moderate and tend to self-limit over time.

Key Words:

COVID-19 vaccine, Menstrual disorders, Women, Menstrual changes, Systematic review.

Introduction

To date, more than 13.5 billion COVID-19 vaccines have been administered worldwide. Approximately 5 billion people have been vaccinated with 2 doses, and 70% of the world population has

received at least one dose of the vaccine¹. Some vaccines are made using the same technology (or “platform”) as vaccines currently in use, others are made using new approaches or approaches recently used in the development of SARS and Ebola vaccines². The goal of all these vaccines is to produce an immune response in order to neutralize the virus and prevent cell infection. The main platforms used are the following:

- Viral vector vaccines, typically based on an existing virus (generally an incompetent adenovirus for replication) carrying the sequence of the genetic code that encodes the spike protein.
- Recombinant protein vaccines, based on either the spike protein, the receptor binding domain (RBD), or on virus-like particles (VLP).
- Live attenuated vaccines, produced by generating a genetically weakened version of the virus that replicates to a limited extent, not causing disease but inducing immune responses similar to those induced by natural infection.
- Inactivated viral vaccines, produced by culturing the SARS-CoV-2 virus in cell cultures and chemically inactivating it.
- DNA vaccines, based on plasmids, are modified to carry genes that generally code for the spike protein, which is then produced in the vaccinated individual.
- RNA vaccines, based on messenger RNA (mRNA) or a self-replicating RNA that provides the genetic information for the spike protein^{3,4}.

It is possible to experience mild to moderate side effects with the COVID-19 vaccine, as with any vaccine⁵. Chills, diarrhea, redness at the injection site, headache, body aches, fatigue, pain, or fever are common side effects of COVID-19 vaccines. Not everyone experiences side effects from COVID-19 vaccines, and most side effects typically resolve within a few days. While more severe or long-lasting side effects are possible but rare⁵. Vaccines are continuously monitored to detect and respond to rare adverse events while they are in use. During the mass vaccination campaign for COVID-19, cases of menstrual cycle changes in women emerged, so it was thought that the COVID-19 vaccine could affect the menstrual cycle. Over time these observations have become more frequent and reinforced this idea⁶. An important indicator of women's health is a regular menstrual cycle; in fact, it has been found that irregular and prolonged cycles can increase the risk of premature mortality⁷. This systematic review aims to show changes in the menstrual cycle after COVID-19 vaccination.

Materials and Methods

The Cochrane Collaboration⁸ and the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) guidelines⁹ were followed to conduct the current systematic review. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses¹⁰ guidelines¹¹ were used to report process and results. A bibliographic search was conducted on February 24, 2023, on the Scopus and PubMed / MEDLINE databases, combining keywords using the Boolean operators "AND" and "OR". The search strategy is reported in [Supplementary Table I](#). No time filter was used.

Inclusion/Exclusion Criteria

Studies had to meet the following criteria to be considered eligible: (i) written in English; (ii) population: female ≥ 18 years; (iii) interventions: COVID-19 vaccines; (iv) comparators/control: post-vaccination menstrual cycle changes; (v) outcomes: menstrual changes; (vi) type of study: epidemiologic studies (case-control, cross-sectional, or cohort studies). Exclusion criteria were (i) articles not published in English; (ii) the inclusion of people under the age of 18; (iii) full text not available; (iv) interventions: not about COVID-19 vaccines; (v) comparators/control: not about post-vaccination menstrual cycle changes;

(vi) outcomes: not about menstrual changes; (vii) type of study: review article, meta-analysis, trial, expert opinion, commentary, editorial, case report or letter to the editor. The detailed description of the inclusion/exclusion criteria is reported in [Supplementary Table II](#).

Selection Process and Data Extraction

Titles and abstracts of manuscripts found using the search strategy and those retrieved from additional sources were independently assessed by two reviewers (C.F. and S.P.). Subsequently, the same authors assessed the eligibility of the articles and independently reviewed the full text. When there was an unresolved disagreement between the two evaluators, the discussion was resolved by discussing the case with a senior reviewer (O.E.S.). Full texts were downloaded only for potentially eligible studies.

Data extraction was conducted only for those articles that met all the inclusion criteria and was performed using a pre-defined and pre-piloted spreadsheet elaborated in Microsoft Excel[®] for Windows. Extracted data include author and year, study period, country where the study was conducted, study design, women population characteristics, vaccine administered, menstrual changes, funds, and conflict of interest.

Strategy for Data Synthesis

Given the PRISMA 2020 guidelines, a "flow chart" has been created showing the number of references at each stage of the review process¹². Summary tables were created showing the qualitative results of the literature. A comprehensive report has been generated, providing a general overview of the review's key findings.

Critical Appraisal

A critical evaluation of the articles using the Newcastle-Ottawa Scale (NOS) was carried out by two authors (O.E.S. and D.G.) independently¹³, this is a bias risk assessment tool for observational studies that assigns up to nine points for the lowest risk of bias in three domains: (i) study group selection, (ii) comparability, and (iii) assessment of exposure and outcomes for case-control and cohort studies, respectively. An adapted version of the NOS was used to assess cross-sectional studies¹⁴. Based on these criteria and on the standard cut-off used in previous literature^{15,16}, studies were classified as being of high, moderate, or low quality when their NOS score was ≥ 7 , 4-6, and ≤ 3 .

Results

Literature Search

126 and 85 records were found on Scopus and PubMed/MEDLINE respectively, for a total of 211. 74 records were eliminated because they were duplications, and 2 records retrieved by evaluating the bibliography of the downloaded studies were added. In the end, 137 records were evaluated for admissibility. By evaluating the title and abstract, 89 records were deleted because the topic was not related (n=71), the articles were not original (n=13), they were not written in English (n=4), one was preprint and have not been peer-reviewed (n=1), and one was case report (n=1). The full text of the 47 records was downloaded, and five records were excluded with reasons following an in-depth assessment. **Supplementary Table III** lists the detailed reasons for exclusion¹⁷⁻²¹. 42 records²²⁻⁶³ were included in our review at the end of the process. Figure 1 shows the selection flow chart. There was a 3.2% disagreement among the authors during the first screening. **Supplementary Table IV** lists the characteristics of the included studies in alphabetical order by author.

Characteristics of Included Studies

Supplementary Table IV shows the characteristics of the included studies. All studies were performed after 2020^{22-25,27-35,37,39-63}, no date is given in three studies^{26,36,38}. The studies were carried out in Saudi Arabia (n=6)^{24-28,53}, three studies were conducted in USA^{40,41,63}, three in Israel^{43,46,50}, three in Spain^{33,45,54}, two in China^{30,36}, two in the United Kingdom^{29,59} and two in Japan^{47,56} the remaining studies were conducted in Canada, Japan, Iran, Turkey, Indonesia, Lebanon, Italy, Netherlands, Jordan, Colombia and Pakistan^{22,23,32,34,36,37,39,48,51,57,58,60,61}. Finally, seven studies were multicentric^{30,31,38,42,52,55,62}. Only nine records were cohort studies^{24,29,40-42,49,59,62,63}. The vast majority were cross-sectional studies (n=33)^{22,23,25-28,30-39,43-48,50-58,60,61}. For most of the studies, the female population was represented by women over the age of 18 in general; for two studies^{27,35}, they were Healthcare Workers; for one study, Physicians and dentists aged 22-71 years³⁸; for another study⁵⁶, premenopausal female and for another premenopausal nurses⁶². Funds were reported by 9 studies^{29,33,35,36,40-42,62,63}, not reported for four studies^{46,50,51,56}. In all studies, the conflicts of interest were specified; in two studies^{40,41}, the authors declared they had conflicts of interest.

Quality Assessment of Included Studies

The quality of the 42 studies ranged from 6 to 9. The assessment revealed a medium-high quality level for cohort studies and cross-sectional. Flaws were discovered in the assessment of selection and comparability. A complete overview based on the NOS checklist is shown in **Supplementary Table V**.

Discussion

Many women have experienced menstrual cycle changes after COVID-19 vaccinations^{22,23,60}. After having COVID-19, women may experience more frequent changes in their menstrual cycle following vaccination⁵⁵. According to some authors^{26,27,32}, mRNA vaccines appear to cause changes in the menstrual cycle more frequently than other types of vaccines. According to Muhaidat et al⁵⁵ the vaccine type does not significantly modify the incidence of abnormality. In some studies^{28,31,45} they are reported as rare events, about 1-2%, in others as quite common events, even 40-50%²²⁻⁶³. Literature from the early stages of vaccine administration reported fewer events as compared to those carried out in 2022, where the percentage of events increased. This could be attributed to the greater attention given to the phenomenon, especially considering the exponential increase in vaccinations conducted. Some categories of women have a higher risk, for example, women being older or smokers³³ or having other disorders such as endometriosis⁴³. According to Cheng et al³⁵ and Rogers et al⁵⁹, changes in the menstrual cycle are more reported with the first dose and less with the subsequent ones, both in terms of delays and advances or menorrhagia. In contrast, the study of Namiki et al⁵⁶ shows that the frequencies of abnormal bleeding have an upward trend from the first to the subsequent doses. Furthermore, it is reported in the literature that cycle irregularities are often associated with worse premenstrual symptoms^{33,37}. According to Muhaidat et al⁵⁵ participants who had confirmed previous COVID-19 infection had a very similar percentage of menstrual abnormalities compared to people who did not have COVID-19 infection or symptoms suspected of COVID-19 infection and did not test (67.5%, 66.8%, respectively).

In addition, Wong et al⁶³ show that women no longer fertile also report symptoms such as menopausal bleeding (3,439 responses) and resumption of menses (2,378 responses). The stress on

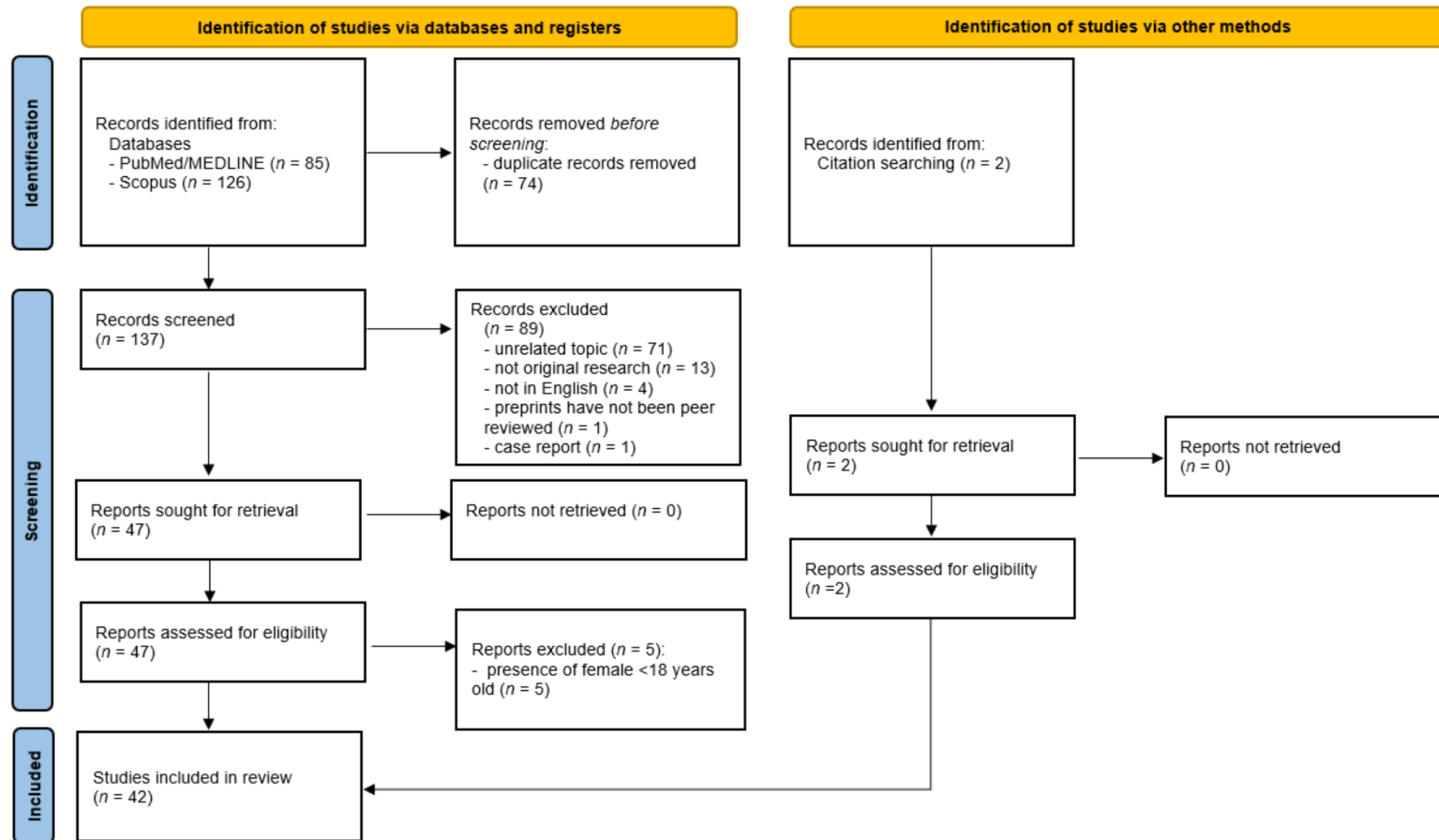


Figure 1. Flowchart of the study selection process.

the hypothalamic-pituitary-ovarian axis – which regulates the length, quality, and quantity of menstruation, the stress induced by vaccination – and the mental stress induced by the pandemic could be the two main biological factors involved in the change of the menstrual cycle, however the debate is still open today^{58,64}.

Limitations

Our systematic review has limitations and strengths that are important to emphasize before generalizing the results of our study. The strengths include that our systematic review adhered to the latest internationally approved guidelines for conducting and reporting reviews. This is the most recent review conducted to evaluate the association between COVID-19 vaccine and menstrual changes. It is worth mentioning that the studies' quality is medium-high. It is important to note that our study has certain limitations. The results we have obtained may be influenced by the inherent limitations of the original studies we have recovered. Additionally, the number of duplicate articles we were able to recover (n=74) was lower than what we had expected. This could possibly be due to the fact that the articles were published in journals that are not indexed in more than one medical archive. Studies in which female subjects under 18 were present were excluded, thus not providing an overview extended to the entire population of childbearing age. Preprint studies were also excluded, but in the meantime, they could have been published. In addition, some other limitations could be attributed to the review itself, as we only included articles published in English, and this may have affected the total number of eligible studies. However, English is the commonly accepted language within the scientific community, and high-quality results are generally published in international journals that only accept articles in English.

Conclusions

This systematic review shows that there are many studies in the literature that report changes in the menstrual cycle in women after COVID-19 vaccination. The vaccines against COVID-19 can alter the quality of life of women. The changes in the menstrual cycle tend to resolve within 2-3 months of vaccination, and the symptoms are mild to moderate and tend to self-limit over time. This review aims to inform female vaccine recipients about possible adverse reactions. The phenomenon seems to be underestimated, and it would be

advisable to conduct further prospective studies to investigate the subject.

Conflict of Interest

The authors declare that they have no conflict of interests.

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Authors' Contributions

Conceptualization, O.E.S.; methodology, O.E.S.; data curation, O.E.S., S.P., D.G. and A.F.; writing-original draft preparation, O.E.S., S.P., D.G., C.F., F.C., and A.F.; writing-review draft and editing O.E.S. and S.P.; Supervision, O.E.S. and S.P.; Funding acquisition A.F. All authors have read and agreed to the published version of the manuscript.

Ethics Approval

Not applicable.

Informed Consent

Not applicable.

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