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## THE IMPACT OF THE COVID-19 VACCINATION ON HOSPITAL STAFF WOMEN'S REPRODUCTIVE HEALTH

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#### ABSTRACT

It is survey study of irregularities after the first and second doses of the COVID-19 vaccine. Hospital Staff women answered a customized online questionnaire aimed to assess the vaccine type, the occurrence of menstrual irregularities after the first and second doses, and how long this effect lasted. **Material & Methods**: In total 48 Hospital staff women completed the survey. All Medical & Paramedical women of reproductive age were invited to participate via digital link. Menstrual irregularities after both the first and second doses of the vaccine were found to self-resolve in approximately half the cases. Based on these results, it should be considering these elements during the counseling of women who receive the COVID-19 vaccine, letting them know about the potential occurrence of temporary and self-limiting menstrual cycle irregularities in the subsequent months.

KEYWORD: COVID-19, Vaccine, Menstrual irregularities, Abnormal uterine bleeding.

#### INTRODUCTION

According to the WHO COVID-19 Dashboard, the COVID-19 pandemic, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has caused over 55, 42, 90, 112 infections and 63, 51, 801 deaths worldwide, as of July 2022. [1] COVID-19 pandemic & COVID-19 Vaccination has significantly impacted the mental health of many people within the population, resulting in loneliness, social isolation, financial strain, as well as the anxiety and fear of contracting the virus, and uncertainty for the future. Initially there are misconceptions; lack of knowledge, regarding Vaccination significantly impacted the Menstrual Pattern of many Women.

In India 199 Cr COVID-19 Vaccination doses given. 66.8 % of population is fully vaccinated. The WHO region with the highest proportions of persons who have completed their primary series of vaccinations as of 2 May 2022 was the Western Pacific Region (82%), followed by the Region of the Americas (67%), the European Region (63%), the South-East Asia Region (62%), the Eastern Mediterranean Region (43%), and the African Region (14%). [2]

Our objective was to survey the general female population of reproductive age with regards to their

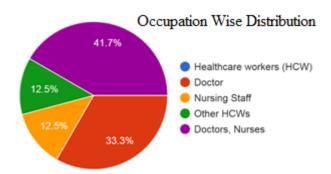
menstrual cycle, libido and changes in their lifestyle over the course of the COVID-19 Immunization. We performed an anonymous observational study by circulating a survey via social media.

#### MATERIALS AND METHODS

This was an anonymous observational study. A digital survey was created using the Google form all Hospital Staff women of reproductive age were invited to participate. The survey contained online questionnaire on demographic information, menstrual cycle and mental health symptoms, diet, exercise and working patterns from before and after the COVID 19 Vaccination. It took between 5 and 10 min to complete. The study was conducted and reported according to published best practice guidelines for reporting observational studies. [3]

In total 48 Hospital staff women completed the survey. All Medical & Paramedical women of reproductive age were invited to participate via digital link. Menstrual cycle data was also excluded from women who stated they were amenorrhoeic for due to an intrauterine system, intrauterine device. or implant, menopause, breastfeeding. Data was analyzed by Google Forms itself.

www.wjpls.org | Vol 9, Issue 5, 2023. | ISO 9001:2015 Certified Journal | 82

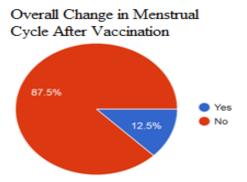


#### OBSERVATION

Total 48 women medical staff completed the survey from age group 22 to 45 out of which 50% are married & 50% are unmarried. In total participants 91.7% took COVISHIELD vaccine & 8.3% took COVAXINE. 12.5% women having preexisting factor of PCOD. 58.3% participants having past COVID 19 infection history. Only 8.3% participants having irregular periods with 41.7% moderate painful menses.

#### RESULTS

Some change in menstrual cycle After Vaccination & decreased in libido/sex drive After Vaccination found only 12.5%. Median cycle length (days) After Vaccination is also 12.5%. New painful periods after Vaccination found 16.7%. After the vaccine 33.3% of women reported alterations in the frequency of the subsequent menstrual cycle. Most of these women had menstruation 1–5 days earlier than expected, and this alteration occurred mainly when the dose of vaccine was administered during the first 14 days of the menstrual cycle.



#### **DISCUSSION**

However, we did not find significant differences in the occurrence of this menstrual irregularity based on when the vaccine dose was administered (follicular versus luteal phase). Moreover, we did not find significant differences between all vaccines. Additionally, after the first & second dose, it is reported alteration in the length of the subsequent menstrual cycle. Among these women, the most common alteration was menstruation that lasted more than usual, which occurred mainly when the vaccine was administered during the early midcycle phase, although we did not find significant differences based on when the vaccine dose was administered. Among these women, the most common alteration was heavier menstruation than usual, which occurred mainly when the vaccine was administered during the first 14 days of the menstrual cycle. We did not find significant differences based on when the first vaccine dose was administered. Overall, menstrual cycle irregularities after the first dose of the vaccine spontaneously resolved in approximately half the cases within two months.

Overall, our preliminary report highlights approximately 50-60% of reproductive age women who received the first dose of COVID-19 vaccine had menstrual cycle irregularities, regardless of the type of vaccine administered. The occurrence of menstrual irregularities seems to be slightly higher (60-70%) after the second dose, suggesting a potential additive effect. After both the first and second doses of vaccine, the most common alterations seem to be anticipated, longer, and heavier menstrual cycle than expected and usual. More than 30,000 reports of irregularities in the menstrual cycle have been reported by 2 September 2021, across all COVID-19 vaccines in the world. [4] Concern regarding this specific issue has been raised by an editorial recently published in the British Journal of Medicine, although the regulatory agencies did not find convincing evidence of a link between changes to menstrual periods and COVID-19 vaccines. [5] According to latest data comparing women who received vaccination and unvaccinated controls, COVID-19 vaccine associated with a less than one day change in the cycle

www.wjpls.org | Vol 9, Issue 5, 2023. | ISO 9001:2015 Certified Journal | 83

length for both vaccine-dose cycles compared with prevaccine cycles (first dose 0.71 day-increase, 98.75% confidence interval (CI) 0.47-0.94; second dose 0.91, 98.75% CI 0.63–1.19). [6] We cannot discard that the COVID-19-related spike protein could exert a causative pathogenic role, as similar changes in menstrual cycles have been recorded during COVID-19 infection.[7] Diffusion of the spike protein in women tissues either linked to COVID-19 infection or released after mRNAbased vaccination can also interfere with the endocrine homeostasis of the menstrual cycle, given that the use of combined oral contraceptive pills was associated with lower odds of reporting any menstrual changes. [8] Although, we may hypothesise that what we observed could be due, at least in part, to phase-specific hormonal variation caused by potential pro-inflammatory and procoagulative changes. Several pieces of evidence suggest crosstalk between inflammatory homeostasis and menstrual cycle regulation, [9] which may be slightly disturbed by temporary hormonal variation and secondary to the inflammatory reaction induced by the vaccine. Somehow eproductive toxicity performed in the mouse models with Comirnaty (Pfizer-BioNTech),<sup>[10]</sup> Spikevax (Moderna),<sup>[11]</sup> Vaxzevria (AstraZeneca),<sup>[12]</sup> and Janssen (Johnson & Johnson)<sup>[13]</sup> says no special hazard for humans regarding fertility. It is reported changes to the menstrual cycle after vaccination are temporary and self-limiting and no cases resulted in clinically significant consequences, the link between COVID-19 vaccination and irregularities in the menstrual cycle deserves to be investigated in further specific studies.

This is one of the few preliminary reports aimed to investigate menstrual cycle irregularities among Hospital staff women who received the first and second doses of the COVID-19 vaccine. We investigated the alteration of frequency, length, and quantity of the subsequent menstrual cycles, stratifying data for the type of vaccine and the phase of the menstrual cycle during which the first and second doses were administered. There are some limitations should be taken into account for a proper and cautious data interpretation such as of all, we used a customized questionnaire, without a previous validation and also this questionnaire was selfadministered and diffused among the general population through social media, so we cannot rule out that women who had menstrual cycle irregularities after COVID-19 vaccination were more motivated to answer than women who did not experience this event; for the same reason, we could not exactly measure the quantity & pattern of the menstrual cycle, and we left this parameter as a subjective evaluation from the patient's perspective, apart this we used exact ranges for the frequency and length of the menstrual cycle. In general the recall bias may be significant for this preliminary report. The number of Hospital staff women who answered the questionnaire is limited, impeding the observation of statistically significant associations between menstrual

irregularities and the vaccine type or the menstrual phase at the time of administration.

#### CONCLUSION

According to our preliminary report, more than half of reproductive-age women who received the first and second doses of COVID-19 vaccine had menstrual cycle irregularities at least in the following menstrual cycle, regardless of the vaccine type and the phase of the menstrual cycle during which the vaccine was administered. However, the occurrence of menstrual irregularities after both the first and second doses of the vaccine was found to self-resolve in approximately half the cases within two months, without clinically relevant consequences. Definitely there is need of further studies to confirm or disregard this observational evidence on large data. Based on these results, it should be considering these elements during the counseling of women who receive the COVID-19 vaccine, letting them know about the potential occurrence of temporary and self-limiting menstrual cycle irregularities in the subsequent months.

#### REFERENCES

- 1. https://www.who.int/data/
- 2. WHO Coronavirus (COVID-19) dashboard, 20 April 2022 [online database] (https://covid19.who.int, accessed 12 May 2022).
- 3. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol, 2008; 61(4): 344–9. doi: 10.1016/j.jclinepi.2007.11.008
- 4. Medicines and Healthcare Products Regulatory Agency. Coronavirus vaccine weekly summary of yellow card reporting. [Internet], 2021. [cited 2021 Dec 27]. https://www.gov.uk/government/publications/corona virus-covid-19-vaccine-adverse reactions/ coronavirus-vaccine-summary-ofyellow-reporting.
- 5. Male V. Menstrual changes after covid-19 vaccination. BMJ, 2021; 374: n2211. doi:10.1136/bmj.n2211.
- Edelman A, Boniface ER, Benhar E, Han L, Matteson KA, Favaro C, et al. Association between menstrual cycle length and coronavirus disease 2019 (COVID-19) vaccination: a U.S. Cohort. Obstet Gynecol, 2022. doi: 10.1097/ AOG.00000000000004695.
- Costeira R, Lee KA, Murray B, Christiansen C, Castillo-Fernandez J, Ni Lochlainn M, et al. Estrogen and COVID-19 symptoms: associations in women from the COVID Symptom Study. PLoS One, 2021; 16(9): e0257051. doi: 10.1371/journal.pone.0257051.
- 8. Lee KMN, Junkins EJ, Fatima UA, Cox ML, Clancy KBH. Characterizing menstrual bleeding changes

- occurring after SARS-CoV-2 vaccination. [Preprint], 2021. [cited 2021 Dec 27]. doi:10.1101/2021. 10.11.21264863.
- Li K, Chen G, Hou H, Liao Q, Chen J, Bai H, et al. Analysis of sex hormones and menstruation in COVID-19 women of childbearing age. Reprod Biomed Online, 2021; 42(1): 260–7.doi: 10.1016/j.rbmo. 2020.09.020.
- 10. EMA/707383/2020 Corr.1\*1 (19 February 2021)
  Committee for Medicinal Products for Human Use (CHMP). Assessment report Comirnaty Common name: COVID-19 mRNA vaccine (nucleoside-modified). Procedure No. EMEA/H/C/005735/ 0000. [Internet], 2021. [cited 2021 Dec 27]. https://www.ema.europa.eu/en/documents/assessment-report/comirnatyepar-public-assessment-report\_en.pdf.
- 11. EMA/15689/2021 Corr.1\*1 (11 March 2021)
  Committee for Medicinal Products for Human Use (CHMP). Assessment report COVID-19 Vaccine Moderna Common name: COVID- 19 mRNA Vaccine (nucleoside-modified). Procedure No. EMEA/ H/C/005791/0000.[Internet], 2021. [cited 2021 Dec 27]. https://www.ema.europa.eu/en/documents/assessmentreport/spikevax-previously-covid-19-vaccine-moderna-eparpublic-assessment-report\_en.pdf.
- 12. EMA/94907/2021 (29 January 2021) Committee for Medicinal Products for Human Use (CHMP). Assessment report COVID- 19 Vaccine AstraZeneca Common name: COVID-19 Vaccine (ChAdOx1-S [recombinant]). Procedure No. EMEA/H/C/ 005675/0000. [Internet], 2021. [cited 2021 Dec 27]. https://www.ema.europa.eu/en/documents/assessment-report/ vaxzevria-previously-covid-19-vaccine-astrazeneca-eparpublic- assessment-report\_en.pdf.
- 13. EMA/158424/2021 (11 March 2021) Committee for Medicinal Products for Human Use (CHMP). Assessment report COVID- 19 Vaccine Janssen Procedure No. EMEA/H/C/005737/0000. [Internet], 2021. [cited 2021 Dec 27]. https://www.ema.europa.eu/en/documents/assessment-report/covid-19- vaccine-janssen-epar-public-assessment-report\_en.pd