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*RESEARCH ARTICLE*

# PREVALENCE OF MENSTRUAL CHANGES FOLLOWING COVID -19 VACCINATION AMONG THE WOMEN ATTENDING THE MCH , AL AHSA SAUDI ARABIA

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## Abstract

**Background:** Coronavirus disease (COVID-19), a highly infectious disease caused by the SARS-CoV-2 virus has taken the form of pandemic throughout the world and is a major public health problem. The effect of COVID-19 infection on menstruation cycle might be the adverse effect on the complex interplay of hormones that interact with immune, vascular and coagulation systems whose interaction can influence menstrual bleeding and severity of menstruation symptoms. However with the roll out of the COVID 19 vaccine among the younger age group, many complaints were received at the health centers regarding the change to their menstruation cycle. The present study was conducted to assess the effect of different types of Covid-19 vaccine on the menstruation cycle of the women.

**Material and Methods:** It was a cross sectional prospective study in which data were collected by interviewing the women attending the MCH hospital and who are vaccinated by COVID 19 vaccination. The study sample contained 344 women. The sampling was done randomly by selecting every second eligible patient attending the out-patient department of Obs. and Gynaecology.The data were collected in the data collection form specially designed for this study. The data were entered and analyzed by using the SPSS, version 21.Descriptive statistics were presented using counts, proportions (%), mean ± standard deviation whenever appropriate. Descriptive statistics (e.g. number, percentage) and analytic statistics using Chi Square tests (?2) to test for the association and/or the difference between two categorical variables were applied. A p-value equal to or less than 0.05 was considered statistically significant.

**Results:** A total of 314 subjects participated in study. The mean age of the participants was 29.56 years± Std. Dev. 8.29 years. Majority of the participants (67.5%) were married. Eighty six percent of the participants were immune by third dose while only 1% was immune by first dose and 7.6% by 2 doses of Covid-19 Vaccine. Almost forty six percent (45.9%) of the participants did not experience any change in their menstruation cycle after vaccination while 21.7% experienced irregular menstruation cycle and 15.9% experienced severe pain during the menstruation period. Minority of the participants complained about the heavy bleeding (7.6%), light bleeding and fewer days of period time (6.7%) and missed period without pregnancy (2.2%). Menstrual

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changes was significantly higher among the age group of 45-54 years of age as compared to 35-44 years , 25-34 years and 15-24 years of age group (90% vs. 51.95% vs.52.63%vs.52.69%, P=0.042). The menstrual cycle change was significantly more prevalent among the unmarried participants than married and divorced participants (60.42% vs. 50.94% vs.50%, P=0.045).Menstrual change was also significantly more among the participants with Type 2 diabetes as compared to those with no disease , hypertension and hypothyroidism (75% vs.50.57 vs.69.23 vs. 50%, P=0.043). The menstrual change was significantly more among the participants who were immune by first dose than those with second and third dose (80.0%vs.51.28% vs.53.70%, P=0.038). Conclusion: The present study has shown that there was evidence to support that following vaccination for COVID-19, menstrual disturbance do occur. Except Moderna vaccine the subjects in the present study had menstrual cycle irregularities regardless of the vaccine type. The presence of Type 2 Diabetes, hypertension, immunity by one dose, unmarried women and those with already irregular period were found to be the possible associated factors for the menstrual irregularities in our study. However, more specific studies such as case control are needed to validate the results of the present study.



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## Introduction:-

Coronavirus disease (COVID-19), a highly infectious disease caused by the SARS-CoV-2 virus has taken the form of pandemic throughout the world and is a major public health problem. According to the latest report more than 500 million have been affected by this infection and more than 8 million already died. [1]

COVID 19 develops a life threatening situation especially in those patients who are suffering from chronic diseases such as diabetes, hypertension, obstructive pulmonary disease, malignancies, HIV and cardiovascular disease. However morbidities associated with COVID- 19 infection known as post covid19 syndrome is posing a real threat to the health of the population. The enormous physical and mental stress caused by COVID-19 infection not only has downstream effects on the reproductive health including the regularity of the menstrual cycle. Study suggests that around 50%-70% of patients may experience minor or even major symptoms up to 3-6 months after recovering from COVID-19 and is observed more in those patients who had moderate or severe form of the infection .[2]

One study suggests that the possible effect of COVID 19 infection on menstruation cycle might be the adverse effect on the complex interplay of hormones that interact with immune, vascular and coagulation systems whose interaction can influence menstrual bleeding and severity of menstruation symptoms.[3]Kezhen Li et al who performed study on the post COVID infected women has found that 25% of the studied patients presented with menstrual volume change while 28% with menstrual cycle change ( such as decreased volume 920% and prolonged cycle (19%).[4]

However with the roll out of the COVID 19 vaccine among the younger age group, many complaints were received at the health centers regarding the change to their menstruation cycle. An editorial published in BMJ has claimed that 30000 subjects suffering from menstrual changes or unexpected vaginal bleeding following Covid -19 vaccination been reported via the yellow card surveillance scheme run by the UK Medicine and Healthcare Products Regulatory Agency (MHRA). This editorial also quoted an American cohort study conducted by US vaccine adverse event reporting system (VAERS) which showed that in adjusted models, the first dose of vaccine did not have effect on timing of the subsequent period, while the second dose was associated with a delay of 0.45 days (98.75% confidence interval 0.06 to 0.84).Most affected were those individuals who received both doses of the vaccine in the same cycle, experiencing a 2.32 day (98.75% CI 1.59 to 3.04) delay to their next period. Among this group, 10.6% experienced a change in cycle length of more than 8 days, which is considered clinically significant, compared with 4.3% in the unvaccinated cohort (P<0.001). In all groups, cycle lengths returned to normal by two cycles after vaccination.[5]One Jordanian study has reported that about 66.3% of the participants in the study who took COVID 19 vaccination had menstrual symptoms post- vaccination.[6]

Very few studies have been conducted to assess the effect of COVID 19 vaccination on the menstruation cycle of the women. To find out the changes in the menstruation cycle among the young women who had been vaccinated by COVID 19 vaccination and are attending the MCH hospital.

## Material and Methods:-

It was a cross sectional prospective study in which data were collected during the 2 months' time from February 2022 to April 2022 by interviewing the women attending the MCH hospital and who are vaccinated by COVID 19 vaccination. All the young patients attending the outpatient's clinics of the hospital for any reasons and are vaccinated by COVID-19 vaccination during the specific time period were the study population. The patients with active menstrual cycle and are vaccinated by COVID-19 vaccination was the inclusion criteria..Menopausal women even if they are vaccinated by COVID-19 vaccination were excluded from the study. According to previous study the prevalence of menstrual changes post vaccination among the menstruating women was 66% (Nadia Muhaidat).The sample size was calculated using a Fisher"s formula by cited by Mugenda & Mugenda (1999)[14]; $n = Z^2pq/e^2$ where

n = the desired sample size ,Z = the standard normal deviate at 95% confidence level (1.96) ,P = the estimated proportion of the target population , 66% of whom may be suffering from menstruation changes documented by Nadia Muhaidat et al,2022 and q = 1-p.The calulated sample size was 344 women who were vaccinated by different type of Covid-19 vaccines. The sampling was done randomly by selecting every second elligible patient attending the out patient department of Obs. and Gynecology till the sample size was achieved. The data were collected in the data collection form specially designed for this study. Section 1: consisted of the demographic characteristics of the study subjects (such as age, education, marital status, health condition. The section 2: collected the information on the menstrual cycle, COVID-19 infection status, COVID-19 vaccination status, Type of COVID-19 vaccine administered menstruation cycle change after vaccination or infection, and menstruation cycle change duration. The data were entered and analyzed by using the statistical package for social sciences, version 21 (SPSS, Chicago, IL, USA).Descriptive statistics were presented using counts, proportions (%), mean ± standard deviation whenever appropriate. Descriptive statistics (e.g. number, percentage) and analytic statistics using Chi Square tests ($\chi 2$) to test for the association and/or the difference between two categorical variables were applied. A p-value equal to or less than 0.05 was considered statistically significant. An approval letter from the research committee of the Al Ahsa region was taken before starting the research. Consent was also taken from each participant of the study.

## Results:-

A total of 314 subjects participated in study making the response rate of 91%.The mean age of the participants was 29.56 years± Std. Dev. 8.29 years. Majority of the participants (67.5%) were married while 30.6% were unmarried and only 1.9% was divorced. More than fifty percent of the participants (54.8%) were graduate followed by 18.8% each who were primary and secondary educated. A minority of the participants were post graduate (5.4%0 and post doctorate (2.2%).Majority of the participants (83.1%) were healthy without any disease while 10.1% were suffering from Type 2 diabetes , 4.1% were suffering from hypertension and 2.5% were suffering from hypothyroidism. The three fourth of the participants (75.6%) had regular menstruation cycle while 24.2% had irregular menstruation. The majority of the participants (49%) had one time infection of Covid-19 followed by those who were exposed to Covid-19 but without symptoms or taking PCR (40.4%).eight percent of the participants were exposed to Covid-19 infection with symptoms but without taking PCR. Only 2.5% of the participants were infected by Covid-19 infection for more than one time. The details of the demographic and Covid-19 infection status of the participants are shown in table 1.

**Table 1:-** Showing the demographic and Covid-19 infection status of the participants.

| Variables | No. | % |
|---|---|---|
| Age<br>29.56 years± Std. Dev. 8.29 years<br>Age group | | |
| 15-24 years | 93 | 29.6 |
| 25-34 years | 133 | 42.4 |
| 35-44 years | 77 | 24.5 |
| 45-54 years | 11 | 3.5 |
| Education | | |

| | | |
|---|---|---|
| Primary | 59 | 18.8 |
| Secondary | 59 | 18.8 |
| Graduate | 172 | 54.8 |
| Post graduate | 17 | 5.4 |
| Post doctoral | 7 | 2.2 |
| Marital Status | | |
| Unmarried | 96 | 3.6 |
| Married | 212 | 67.5 |
| Divorced | 6 | 1.9 |
| Health Status | | |
| No any disease | 261 | 83.1 |
| Type 2 Diabetes | 32 | 10.2 |
| Hypertension | 13 | 4.1 |
| Hypothroidism | 8 | 2.5 |
| Menstrual Cycle | | |
| Regular | 238 | 75.8 |
| Irregular | 76 | 24.2 |
| Covid-19 infection status | | |
| One time infection | 154 | 49.0 |
| More than one time | 8 | 2.5 |
| Exposed with symptoms without taking PCR | 25 | 8.0 |
| Exposed without symptoms or Taking PCR | 127 | 40.4 |

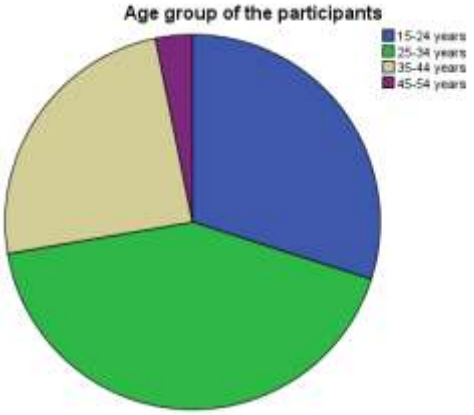


**Figure 1:-** Showing the age group of the participants

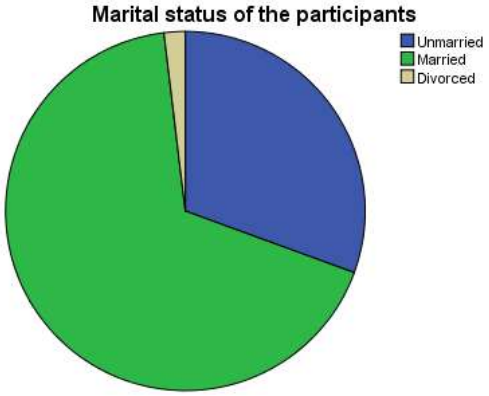


**Figure 2:-** Showing the marital status.

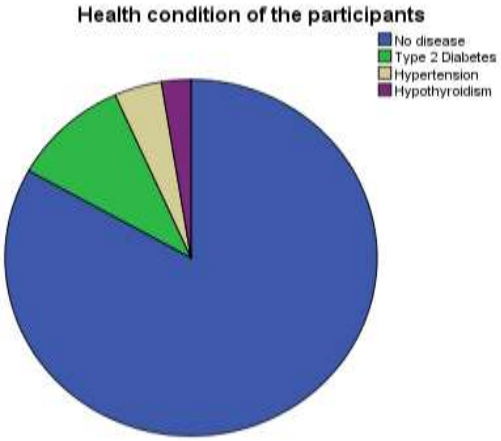


**Figure 3:-** Showing the health condition of the participant.

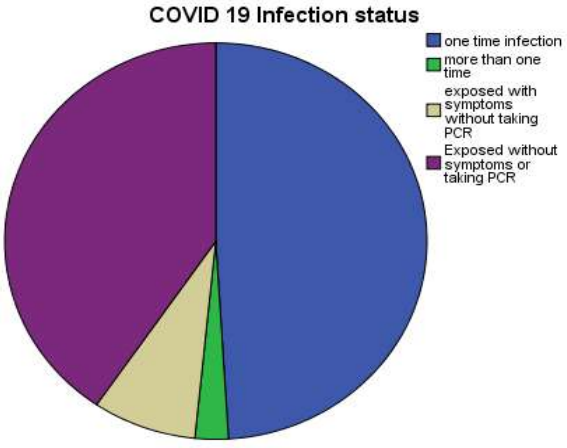


**Figure 4:-** Showing the Covid-19 infection status.

**Vaccination status of the participants:**

As far as the vaccination status of the participants is concerned, 86% of the participants were immune by third dose while only 1% was immune by first dose and 7.6% by 2 doses of Covid-19 Vaccine. More than sixty percent (60.2%) of the participants were vaccinated by Covid-19 vaccine by Pfizer while 29% were vaccinated by both Pfizer and Oxford vaccine. More than six percent (6.1%) of the participants were vaccinated by Pfizer and Moderna vaccines and 2.2% were vaccinated by three vaccine (Oxford Pfizer and Moderna).Minority of the participants were vaccinated by oxford and Moderna (1.3%),Oxford only (1%) and Moderna only (0.3%).The details of the vaccination status is shown in table 2.

**Table 2:-** Showing the details of the vaccination status of the participants.

| Variables | No. | % |
|---|---|---|
| Vaccination Status | | |
| Immune with first dose with one infection | 3 | 1 |
| Immune by first dose without infection | 2 | 0.6 |
| Immune by second dose with infection | 22 | 7 |
| Immune by second dose without infection | 17 | 5.4 |
| Immune by third dose with infection | 121 | 38.5 |
| Immune by third dose without infection | 140 | 47.5 |
| Type of vaccine given | | |
| Pfizer only | 189 | 60.2 |
| Pfizer and oxford | 91 | 29.0 |
| Pfizer and moderna | 19 | 6.1 |
| Oxford and Moderna | 4 | 1.3 |
| Oxford only | 3 | 1.0 |
| Moderna only | 1 | 0.3 |
| Pfizer oxford and Modema | 7 | 2.2 |

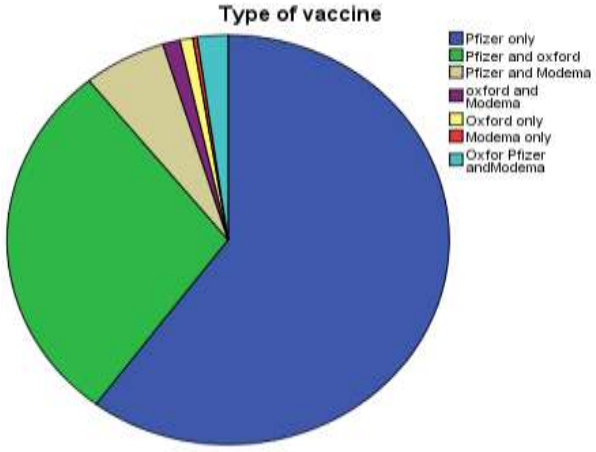


**Figure 5:-** Showing the vaccination stats of the participants.

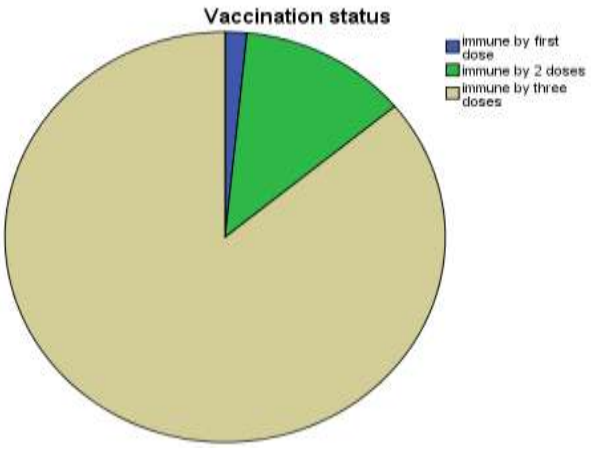


**Figure 6:-** Showing different vaccine given.

**Menstruation changes after Covid-19 vaccination**:

Almost forty six percent (45.9%) of the participants did not experience any change in their menstruation cycle after vaccination while 21.7% experienced irregular menstruation cycle and 15.9% experienced severe pain during the menstruation period. Minority of the participants complained about the heavy bleeding (7.6%), light bleeding and fewer days of period time (6.7%) and missed period without pregnancy (2.2%). Fifty one percent of the participants did not have any change in the menstruation period while 22.6% reported that they had the change in the period time since 6 months and 14.3% of the participants seek medical advised for the change of timing of their menstrual cycle. The details of the changes in the menstruation cycle after Covid-19 vaccination is shown in table 3.

**Table 3:-** Showing the details of the changes in the menstruation cycle after Covid-19 vaccination.

| Variables | No. | % |
|---|---|---|
| Post vaccination menstruation change | | |

| | | |
|---|---|---|
| No change | 144 | 45.9 |
| Severe pain during the period | 50 | 15.9 |
| Irregular period | 68 | 21.7 |
| Heavy bleeding | 24 | 7.6 |
| Missed period without pregnancy | 7 | 2.2 |
| Mild bleeding with short time of period | 21 | 6.7 |
| Menstrual cycle change duration | | |
| No change | 160 | 51.0 |
| More than 6 months | 38 | 12.1 |
| Less than 6 months | 71 | 22.6 |
| Needed medical advice | 45 | 14.3 |

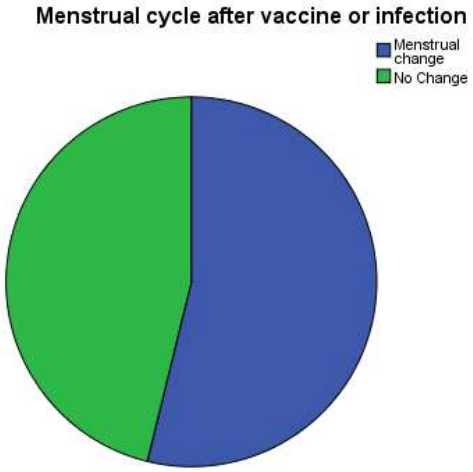


**Figure 7:-** Showing the menstrual changes in the participants.

**Association of the change in menstrual cycle with different demographic factors of the participant.**
Menstrual changes was significantly higher among the age group of 45-54 years of age as compared to 35-44 years , 25-34 years and 15-24 years of age group (90% vs. 51.95% vs.52.63%vs.52.69%, P=0.042). The menstrual changes were more among the participants who were primary educated than those with secondary education, graduate , post graduate and post doctorate but it was not statistically significant (59.32% vs.55.93% vs.54.07% vs.41.18%, P=0.176). The menstrual cycle change was significantly more prevalent among the unmarried participants than married and divorced participants (60.42% vs. 50.94% vs.50%, P=0.045).Menstrual change was also significantly more among the participants with Type 2 diabetes as compared to those with no disease , hypertension and hypothyroidism (75% vs.50.57 vs.69.23 vs. 50%, P=0.043). The participants who were already having irregular period were significantly more affected by the menstrual cycle changes than those with regular period (71.05% vs.48.32%, P=0.000).The presence of the change in the menstrual cycle was more among the participants who were exposed to Covid-19 infection without symptoms or taking PCR than those exposed with symptoms without taking PCR, with more than one infection and with one infection but it was not statistically significant. (59.84% vs.48.0%vs.50%vs.50%, P=0.370). The menstrual change was significantly more among the participants who were immune by first dose than those with second and third dose (80.0%vs.51.28% vs.53.70%, P=0.038).The menstrual cycle change was more prevalent among the participants vaccinate by Moderna only than oxford and Moderna ,Pfizer and Moderna ,Pfizer and Oxford , Oxford, Pfizer and Moderna and Pfizer only but it was also not statistically significant (100% vs,75% vs.57.14% vs.42.11% vs.50.55% vs.56.61%, P=0.308).The details of the a**ssociation of the change in menstrual cycle with different demographic factors of the participant is shown in table 4.**

**Table 4:-** Details of the association of the change in menstrual cycle with different demographic factors of the participant.

| Variables | change in the menstrual cycle No.(%) | No change in the menstrual cycle No.(%) | P Value |
|---|---|---|---|
| Age group | | | 0.042 |

| | | | |
|---|---|---|---|
| 15-24 years | 49(52.69) | 44(47.31) | |
| 25-34 years | 70(52.63) | 63(47.37) | |
| 35-44 years | 40(51.95) | 37(48.05) | |
| 45-54 years | 10(90.0) | 1(10.0) | |
| Education | | | 0.176 |
| Primary | 35(59.32) | 24(40.68) | |
| Secondary | 33(55.93) | 26(44.07) | |
| Graduate | 93(54.07) | 79(45.93) | |
| Post graduate | 7(41.16) | 10(58.84) | |
| Post doctoral | 1(14.28) | 6(85.72) | |
| Marital Status | | | 0.045 |
| Unmarried | 58(60.42) | 38(39.58) | |
| Married | 108(50.94) | 104(49.06) | |
| Divorced | 3(50.0) | 3(50.0) | |
| Menstrual cycle | | | 0.000 |
| Regular | 115(48.32) | 123(51.68) | |
| Irregular | 54(71.05) | 22(28.95) | |
| Health Status | | | 0.043 |
| No any disease | 132(50.57) | 129(49.43) | |
| Type 2 Diabetes | 24(75.0) | 8(25.0) | |
| Hypertension | 9(69.23) | 4(30.77) | |
| Hypothroidism | 4(50.0) | 4(50.0) | |
| Covid-19 infection status | | | 0.370 |
| One time infection | 77(50.0) | 77(50.0) | |
| More than one time | 4(50.0) | 4(50.0) | |
| Exposed with symptoms without taking PCR | 12(48.0) | 13(52.0) | |
| Exposed without symptoms or Taking PCR | 76(59.84) | 51(40.16) | |
| Immune status | | | 0.038 |
| Immune by one dose | 4(80.0) | 1(20.0) | |
| Immune by two doses | 20(51.28) | 19(48.72) | |
| Immune by three doses | 145(53.70) | 125(46.30) | |
| Types of vaccine | | | 0.308 |
| Pfizer | 107(56.61) | 82(43.39) | |
| Pfizer and Oxford | 46(50.55) | 45(49.45) | |
| Pfizer and Moderna | 8(42.11) | 11(57.89) | |
| Oxford and Moderna | 3(75.0) | 1(25.0) | |
| Oxford Only | 0(0.00) | 3(100.0) | |
| Moderna only | 19(100.0) | 0(0.00) | |
| Pfizer ,Oxford and Modema | 4(57.14) | 3 | |

## Discussion:-

The present study was an attempt to assess the effect of Covid-19 vaccination on the menstruation cycle of the women.The present study has found that more than 50% of the Covid-19 vaccinated women were suffering from different type of menstruationproblem. In one west African case report study the researchers reported two incidents of heavy menstrual bleeding and one incident of inter-menstrual bleeding which were likely associated with COVID 19 vaccination. In the present study 7.6% of the vaccinated participants had heavy bleeding .[7] In one US cohort study, Change in menses length was not associated with vaccination.[5]In a UK study it has also reported menstrual changes after receiving all brands of vaccine. The same result is found in the present study where menstrual changes were experienced by all participants irrespective of what vaccines they have taken. This study also showed that **the women who received both doses of the vaccine in the same cycle experience, on average, a delay to their next period of 2 days.[8]**In the USA cohort study[5] the researchers have detected that covid -19 vaccination was associated with a less than one-day change in menstrual cycle length in the one to two cycles that followed the first and second vaccine doses, compared with pre-vaccine menstrual cycles. However in the present study we have found that minority of patients (6.7%) complained about the change in the duration of menstrual cycle. The

Netherlands Pharmacovigilance Centre Lareb has also reported a signal for COVID-19 vaccine-related menstrual disorder. In a large survey, this study has also found that as much as 77% of the Covid-19 vaccinated women were having menstrual disorders such as heavy blood loss, amenorrhea, dysmenorrhea and oligomenorrhoea. Out of 23 026 menstrual disorders, 79 were serious reports for which medical attention was needed in this study.[9] The present study also found that 14.3% of the participants had serious issue with the menstrual bleeding and had to seek medical advice .Moderna vaccine was associated with higher rate of menstrual disorder in this study as compared to Pfizer-BioNTechans Astra Zenica (238.7 per 100000 vs.148.2 per 100000 vs.44.3 per 100000 of the population). The present study has also revealed that the presence of menstrual disorder was more prevalent among the participants vaccinate by Moderna vaccine followed by a combination of Pfizer , Oxford + Modema, Pfizer, Pfizer + Oxford ,Pfizer + Moderna and Oxford + Moderna. In one Italian study Antonio Simone Laganà, et al also reported that 50-60% of the post Covid-19 vaccinated women were suffering from menstrual cycle irregularities regardless of the type of administered vaccine.[11]

In another United kingdom retrospective case control study Alexandra Alvergne et al has reported that 80% of the premenopausal vaccinated women did not report any menstrual cycle changes up to 4 months after their first COVID-19 vaccine injection but more than 50% of the individuals with Covid-19 infection status had OR of 1.61 towards the changes in the menstruation cycle.[10]Fifty percent each of the women infected by first and second Covid-19 infection were having the menstruation irregularities in the present study. However, almost seventy five percent of the women presented with the different types of menstrual irregularities in a Chinese study. Among the women having menstrual irregularities 25% presented with menstrual volume changes, 28% had menstrual cycle changes, mainly a decreased volume 20% and a prolonged cycle 19% in this study.[12] We did not find enough studies on Coved -19 vaccination effect on menstruation cycle and its relation with the different demographic characteristics to compare with or result.

## Conclusion:-

The present study has shown that there was evidence to support that following vaccination for COVID-19, menstrual disturbance do occur. Except Moderna vaccine the subjects in the present study had menstrual cycle irregularities regardless of the vaccine type. The presence of Type 2 Diabetes, hypertension, immunity by one dose, unmarried women and those with already irregular period were found to be the possible associated factors for the menstrual irregularities in our study. However, more specific studies such as case control are needed to validate the results of the present study.

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