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P-656 Effect of COVID-19 vaccination on clinical outcome in fully vaccinated infertile women undergoing IVF/ICSI cycles at tertiary care centre: prospective observational study

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**Study question:** Does immune response to COVID-19 vaccination affect the clinical outcome in fully vaccinated infertile women undergoing IVF/ICSI cycles?

**Summary answer:** COVID-19 IgG antibodies are present in follicular fluid post vaccination and higher immune response increases duration of gonado-trophins required and negatively impacts the IVF outcome.

What is known already: Recent studies assessed the influence of COVID-19 infection and mRNA COVID-19 vaccine on the stimulation cycle characteristics and embryological variables of patients undergoing IVF cycle and found no effect on the IVF outcome in their immediate IVF cycle after recovery, except for a decreased number of top quality embryos. One study reported infection or mRNA vaccine results in rapid formation of anti-COVID IgG which can be detected in follicular fluid. This immune response did not lead to any significant negative effect on ovarian follicular function. There is a possibility that COVID-19 infection might affect numerous fertilitylinked proteins.

**Study design, size, duration:** Prospective observational study, conducted at Division of Reproductive Medicine of tertiary care institute. After taking informed consent, 32 patients who satisfy the inclusion and exclusion criteria with history of receiving two doses of Covishield or Covaxin vaccine with atleast 2 weeks from last dose, were recruited for IVF/ICSI cycles from December 2021 to January 2022, for assessing COVID-19 IgG antibodies in their follicular fluid.

**Participants/materials, setting, methods:** Women of 21-40 years with normal ovarian reserve and normal uterine cavity were included, those with

history of COVID infection were excluded. All patients underwent GnRH antagonist protocol. Follicular fluid was collected at time of oocyte retrieval. After collecting oocytes, 400 microlitre of follicular fluid was stored at -80 and later thawed and analysed for SARS-CoV-2 IgG antibodies (ADVIA Centaur COV2G assay, Germany) which are expressed in index value and reported as reactive ( $\geq 1$  index).

Main results and the role of chance: Out of 32, 21 (65.6%) of the participants had received COVISHIELD (VI)and II (34.3%) received COVAXIN (V2). The mean gap between vaccine and the IVF cycle was 84.94  $\pm$  52.65 days. The mean COVID IgG antibody titres (Index) were significantly higher in VI, 28.77±33.50 (0.34 -100), than V2 2.28±3.74(0.05-13.23), p<0.001. Patients with higher antibody titres, required longer duration of ovarian stimulation, rho=0.42, p = 0.017. Patients with higher COVID IgG antibodies were negatively correlated with clinical pregnancy rate (20.9 0 $\pm$  29.68 vs 4.60  $\pm$ 6.28, p = 0.153). The time gap from the last dose of vaccine to IVF cycle had moderate negative correlation with percentage of grade-I embryos out of the total embryos fertilised (%), rho= -0.33, p = 0.068. Furthermore, higher gonadotropins doses were required in patients with high antibody titres, rho=0.25, p = 0.160, and amongst VI vs V2, total dose of gonadotropins required was 3802.38±742.92 vs 3422.73±564.52, respectively, p=0.115. COVID IgG antibody titres had weak negative correlation with number of grade-I embryos, rho= -0.16, p = 0.396. The time gap from the last dose of vaccine to IVF cycle had a weak negative correlation with number of grade-I embryos, rho=-0.28, p = 0.124.

**Limitations, reasons for caution:** The main limitation of this study is small sample size. However, the study is currently ongoing, and these are the interim results of the same. As prospective studies with larger sample size would be required to assess the effect of different COVID-19 vaccines in different populations on the IVF outcomes.

Wider implications of the findings: The present study confirms the presence of COVID IgG antibodies in follicular fluid in vaccinated women, and proves that COVISHIELD vaccinated patients had higher antibody titres. Higher antibody titres require longer duration of stimulation and result in poorer outcomes so a longer interval from vaccine to IVF should be recommended.

Trial registration number: NA