

Do the Covid-19 Vaccines Affect the Reproductive Parameters of Men?—A Northern Saudi Experience

MJ Alenzi, EE Ikpi¹, AS Alshlash, SM Alkhaldi¹, ZN Aljazi¹, M Alrawili², S Alanazi³, JA Alenazi²

Department of Surgery, Jouf University, ¹Department of Urology Prince Mutaib Bin Abdulaziz Hospital, ³Medical Student, College of Medicine, Jouf University, Sakaka, ²Department of Radiology, Ministry of Health, Alqurayat, Saudi Arabia

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ABSTRACT

Background: The COVID-19 vaccine acceptance is a psychological behavior influenced by many factors, including fear of an adverse effect on the reproductive system. **Aims:** The aim of this study is to assess the COVID-19 vaccines effect on reproductive parameters among the male population of northern Saudi Arabia. **Patients and Methods:** We conducted a prospective cohort study among 100 volunteers who received two doses of COVID-19 vaccines. A pre- and post-vaccination blood sample was collected and analyzed for testosterone, prolactin, and follicle-stimulating hormone (FSH). Semen samples were also collected and analyzed. The Wilcoxon signed-rank test was used to compare the values between pre- and post-vaccination. **Results:** Of the 100 samples analyzed, there was a significant increase in progressive sperm motility after the second dose of vaccination, but the increase was within the physiological limits (pre-55.03 [42.00–61.75] vs. post-57.50 [42.25–63.00], $P = 0.008$). Similarly, a significant increase in serum testosterone level after the second vaccination dose was observed (pre-380.65 [301.60–485.73] vs. post-410 [318.18–505.35], $P = 0.016$). **Conclusion:** These preliminary results show that the COVID-19 vaccines do not have any adverse effect on the reproductive parameters of men. A prospective long-term follow-up study will be necessary on all WHO -approved COVID vaccines to determine their long-term effect on men’s reproductive health. The future follow-up study could strengthen our findings and encourage the men who have vaccine hesitancy to take due to fear of its effect on reproductive parameters.

KEYWORDS: COVID-19 vaccines, reproductive parameters, sperm count, testosterone

INTRODUCTION

Coronavirus disease (COVID-19) is a highly communicable disease caused by the SARS-CoV-2.^[1] The world is still in the grip of the COVID-19 pandemic even after 20 months of the outbreak. As of October 2021, worldwide, around 238 million confirmed cases of COVID-19, including more than 4.8 million deaths, were reported to the World Health Organization (WHO).^[2] Currently, numerous methods, such as social distancing, face masks, hand hygiene, and vaccination against COVID-19, have been recommended by the WHO and Centre for Diseases Control and Prevention (CDC) to prevent the spread of COVID-19.^[3,4]


Vaccines have played a critical role in controlling several infectious diseases in the past.^[5,6] Though the features are difficult to measure, controlling the COVID-19 pandemic will need the vaccine shots that prevent the viral spread.^[7] Unfortunately, several myths and misconceptions about vaccines have hindered the control of some of the major infectious diseases such as polio.^[8,9] The WHO has issued an emergency use listing of some

Address for correspondence: Dr. MJ Alenzi, Department of Surgery, College of Medicine, Jouf University, P.O. Box-72388, Saudi Arabia. E-mail: mja@ju.edu.sa

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vaccines to control the current COVID-19 pandemics. While trials have shown several COVID-19 vaccines to have high levels of efficacy but like all other vaccines, COVID-19 vaccines will not be 100% effective. The WHO is working to help ensure that approved vaccines are as effective as possible to have the most significant impact on the pandemic.^[10]

Community acceptance of the vaccines is essential for controlling the COVID-19 pandemic.^[11] A study done by Hornsey *et al.*^[12] found that vaccine acceptance is a psychological behavior that is influenced by a wide range of factors. Identifying the hindering factors for COVID-19 acceptance and instituting necessary interventions is required to implement a safe and trusted vaccination program.^[13] However, there are several myths and misconceptions about COVID-19 vaccines in social media and public discussions. One of such myths is the believe that COVID-19 vaccines have adverse effects on male reproductive parameters.^[14] Currently, the world is still grappling with the challenges of managing the COVID-19 pandemic, worsened by the ever-changing variation of the virus as it rapidly spreads around the globe.^[15,16] Vaccination against the COVID-19 is considered one of the most prominent pillars for controlling the current pandemic. Unfortunately, several myths and misconceptions, including its effect on fertility, lead to hesitancy among several people to take the COVID-19 vaccination. Factual and scientific information that is evidence based with essential facts about the vaccine will help to end this crisis, as stated by Global Alliance for Vaccines and Immunization (GAVI).^[17] Hence, this study was planned to assess COVID-19 vaccines' effect on reproductive parameters among the male population in the Al-Jouf region of the KSA.

METHODOLOGY

This prospective clinical study was carried out on an adult male population aged between 20 and 60 years in Al-Jouf province, northern Saudi Arabia, from April 2021 to September 2021. A total of 100 volunteers who were eligible to receive COVID 19 vaccines administered by the Ministry of Health, KSA, were enrolled in the study. The study enrollees comprised of the citizens and expatriate residents of the KSA and they either received the Pfizer–BioNTech BNT162b2 or Oxford–AstraZeneca vaccine ChAdOx1 nCoV-19. Of the 100 eligible participants, 44 received two doses of Pfizer–BioNTech BNT162b2, 32 received two doses Oxford–AstraZeneca ChAdOx1 nCoV-19, and 24 received mix and match vaccines (one dose Oxford–AstraZeneca ChAdOx1 nCoV-19 and another dose Pfizer–BioNTech BNT162b2).

The study was conducted after ethical approval from the Ministry of Health, Qurayat health affairs (approval no.: 065). A written informed consent was obtained from the participants for their willingness to participate in the study.

The participants were given a brief orientation about the study and abstinence from sex before giving the sample for testing. The data collected from the participants include age, smoking status, abstinence duration from sex, etc., Before the participants received the first dose of vaccines, blood samples for testosterone, prolactin, follicle-stimulating hormone (FSH), and semen were collected. These samples were considered as pre-COVID-19 vaccine samples. Next, blood and semen samples were collected after one month of the second dose of the vaccine. These samples were considered as post-COVID-19 vaccine samples. The WHO reference values for human semen parameters have been used for semen and hormonal parameters. We performed all reproductive parameters tests at the Qurayat General Hospital Laboratory, the Ministry of Health, KSA. This laboratory is certified by the Saudi Central Board of Accreditation of Healthcare Institute (CBAHI certificate no: QRT-MOH-HOS-258-0172-1118). A fully automated analyzer (cobas e 411) that uses an ElectroChemiLuminescence technology for immunoassay analysis was used for hormonal assays.

The present study included adult males aged between 20 and 60 years and those who were willing to participate. Those who were previously diagnosed with infertility and/or erectile dysfunction, those investigations suggestive of infertility from the pre-COVID-19 vaccine sample, and those who received only a single dose of vaccine were excluded from the study. Also, participants with symptoms suggestive of COVID-19 and/or who were positive for COVID-19 in the past 90 days were also excluded.

Statistical package of social science (SPSS) version 21.0 was used for data entry and analysis. Descriptive variables are presented as frequency and percentage, while quantitative values are presented as mean and standard deviation (SD) for socio-demographic details, and median and interquartile range (IQR) for reproductive parameters. After the normality assumption test, the “Wilcoxon signed-rank test” was used to compare pre- and post-vaccination values. A *P* value less than 0.05 was considered as statistically significant.

RESULTS

Table 1 presents the participants' mean age (37.89 ± 10.34), and pre- and post-vaccination abstinence duration (4.01 ± 1.20 and 3.78 ± 1.40).

Of the 100 samples analyzed, there was a slight and statistically significant increase in the median (IQR) of progressive motility of spermatozoa after the second dose of vaccination ($P = 0.008$). No other parameters showed a significant difference between pre- and post-vaccination samples [Table 2].

There is a slight and statistically significant increase in the median (IQR) level of serum testosterone after the second dose of vaccination ($P = 0.016$). No other parameters had shown a significant difference between pre- and post-vaccination samples [Table 3].

DISCUSSION

The present study assessed the short-term effects of COVID-19 vaccines on reproductive parameters among the male population in the Al-Jouf region of the KSA.

The present study revealed no significant difference in sperm count and sperm volume among the pre- and post-COVID-19 vaccinated individuals. Interestingly, a recently published study by Gonzalez *et al.*^[18] reported increased sperm counts and sperm volume among their study participants before the first dose and after the second dose vaccination. The variation in the parameters can be explained based on the duration of the abstinence period before taking the second sample in the two studies. In our study, the mean abstinence period is

lower in the second sample but more in the study done by Gonzalez *et al.*^[18]

Our study found a statistical increase in progressive sperm motility among the pre- and post-COVID-19 vaccinated individuals. This slight increase (55.03 vs. 56.50) is within normal limits. This finding is similar to the study done by Gonzalez *et al.*^[18] among 45 healthy individuals. Similar to our study, a study done by Safrai *et al.*^[19] in Israel on the impact of COVID-19 vaccine on sperm parameters revealed that vaccination does not negatively affect sperm parameters.

This study depicted a statistically significant increase in serum testosterone levels after the second dose of vaccination. However, these increased levels are within the physiological limits. This statistical change may be due to regression to mean and may not have clinical significance. Though researchers around the world are looking for long-term clinical evidence, it is a proven evidence that COVID-19 infections may affect fertility in men, including testicular damage, decrease in sperm count, and/or fragmentation of sperm DNA.^[20,21] In contrast to COVID-19 infections, vaccination does not produce any adverse significant effect on reproductive parameters among men.

The following limitations are to be considered while interpreting the present research. Firstly, the duration of follow-up is short period. Hence, these findings are not to be interpreted as long-term effects of COVID-19 vaccination. Also, this study included only two types of WHO-approved vaccines.

CONCLUSION

The present study did not find any transient/short-term adverse effects on sperm parameters and fertility hormones among the men who received two COVID-19 vaccination doses. A prospective long-term follow-up

Table 1: Study participants background details (n=100)

Variables	Mean±SD
Age (mean±SD)	37.89±10.34
Pre-vaccination abstinence duration (mean±SD)	4.01±1.20
Post-vaccination abstinence duration (mean±SD)	3.78±1.40
Smoking status	No (%)
Smoker	26 (26%)
Non-smoker	74 (74%)

Table 2: Semen parameters variation—pre- and post-COVID-19 vaccination

Parameters	Normal value range	Median (IQR)		P
		Pre-COVID-19 vaccination	Post-COVID-19 vaccination	
Semen volume (in mL)	>1.5	2.47 (1.86-3.34)	2.69 (1.93-3.29)	0.091
Sperm count (millions/mL)	20-120 millions/mL	36.60 (31.72-43.50)	37.90 (31.80-44.73)	0.087
Progressive motility sperm (%)	>40	55.03 (42.00-61.75)	56.50 (42.25-63.00)	0.008*

* Statistically significant value

Table 3: Hormonal assay—pre- and post-COVID-19 vaccination

Parameters	Normal value range	Median (IQR)		P
		Pre-COVID-19 vaccination	Post-COVID-19 vaccination	
Prolactin	2.64-13.3 ng/mL	4.55 (3.35-5.78)	4.64 (3.65-5.86)	0.072
FSH	1.5-12.4 mIU/mL	3.90 (2.88-5.50)	3.97 (2.80-5.10)	0.355
Testosterone	132-813 ng/mL	380.65 (301.60-485.73)	410 (318.18-505.35)	0.016*

* Statistically significant value

study will be necessary on all WHO-approved COVID vaccines to determine their long-term effect on men's reproductive health. The future follow-up study could strengthen our findings and encourage the men who have vaccine hesitancy to take due to fear of its effect on reproductive parameters.

It is important to note that more investigations are required to elucidate on the long-term effects of current vaccinations with the minimum duration of 3- to 6-month follow-up. Cultural inhibitions will continue to trail new innovations in treatment and preventive medication, but a scientific documentation of the facts, carried out in different regions of the world, will increase the confidence and acceptance of citizens to new treatment and preventive modalities.

Institutional review board statement

The present study was conducted after ethical approval from the Ministry of Health, Qurayat health affairs (approval no.: 065), Ministry of Health, Saudi Arabia.

Informed consent statement

A written informed consent was obtained from the participants for their willingness to participate in the study.

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Conflicts of interest

There are no conflicts of interest.

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