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# Effect of Pfizer/BioNTech and Sinovac/CoronaVac Vaccines on Semen Parameters in Infertile Patients with Idiopathic Infertility: A Single-center Cohort Study

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**What's known on the subject? and What does the study add?**

Although it has been shown in many studies that COVID-19 vaccines have significantly reduced the risk of mortality and morbidity from the disease, vaccine hesitancy still exist among some individuals due to concerns about potential impacts on male fertility. Our study contributes to existing research by investigating the effects of COVID-19 vaccines on male fertility and semen paramaters, spesifically comparing the Sinovac/CoronaVAC and Pfizer/BioNTech vaccines and their impacts on semen parameters. The findings show that inactive and mRNA vaccines do not have a clinically meaningful affect on semen parameters in infertile men. Therefore, both vaccines can be considered safe for men's reproductive health.

## Abstract

**Objective:** We investigated the effects of Coronavirus disease-2019 (COVID-19) vaccines on semen parameters in patients with idiopathic infertility who visited our urology clinic.

**Materials and Methods:** Patients who visited our andrology clinic between January 2021 and April 2022 after the vaccines were made available for the population aged 18 years and above were included in the study. Sperm parameters of patients before and after vaccination with two doses of Pfizer/BioNTech and Sinovac/CoronaVac were retrospectively evaluated and compared using the hospital's patient information system. Semen samples obtained from the patients were evaluated in our andrology laboratory. The age, body mass index (BMI), semen analyses, and intervals between the two doses of vaccines and the second semen analysis of the patients were recorded. Spermogram data before and after vaccination of 65 patients, including 17 Sinovac/CoronaVac and 48 Pfizer/BioNTech COVID-19 vaccinated patients, were divided into two groups and compared in terms of semen volume, semen pH, total sperm count, sperm motility, and morphology.

**Results:** There was no significant difference in terms of the vaccine interval, BMI, or age between the groups. Although no significant differences were found in terms of volume, pH, total motility, and percentage of motile sperm, the total sperm count and sperm count per milliliter decreased significantly in the Sinovac/CoronaVac group and increased significantly in the Pfizer/BioNTech group. Before and after vaccination, a decrease in total sperm count was observed in the Sinovac/CoronaVac group and a decrease in pH was observed in the Sinovac/CoronaVac and Pfizer/BioNTech groups.

**Conclusion:** Our findings show that the total sperm count and the sperm count per milliliter decreased significantly among idiopathic infertile patients who received Sinovac/CoronaVac but increased significantly among those who received Pfizer/BioNTech COVID-19 vaccines

**Keywords:** Andrology, COVID-19, infertility, Pfizer/BioNTech, Sinovac, spermogram

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## Introduction

The novel Coronavirus disease-2019 (COVID-19) was declared the second pandemic of the 21st century by the World Health Organization (WHO) on March 11, 2020 (1) . It has been shown that severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), a new strain from the Coronaviridae family, causes COVID-19. Although the disease can be asymptomatic, it can also cause symptoms such as cough, fever, and chest discomfort. In severe cases, it can result in respiratory distress syndrome and death (2,3). Some studies have also reported negative effects of the disease on the male reproductive system (4-7).

To minimize the severity of the disease and its negative social and economic impacts during the COVID-19 pandemic, various types of vaccines have been produced, and vaccination programs have been initiated in some countries with emergency use approval. It has been shown that the inactivated vaccine Sinovac/CoronaVac, which is derived from a live virus, creates neutralizing antibodies against the SARS-CoV-2 virus in rats, mice and non-human primates, and phase 3 studies of Sinovac/CoronaVac have been conducted in Turkiye, Brazil and Indonesia. An interim analysis of studies in Turkiye reported the vaccine's efficacy as 91.25% (8). This inactivated vaccine began to be used in Turkiye and other countries in early January 2021 (9).

Considering the negative effects of live virus vaccines on fertility, similar results may also arise with inactivated vaccines, such as Sinovac/CoronaVac. Concerns about the potential negative effects of vaccines on human fertility and infant health are increasing, and this concern is becoming the most important reason for hesitancy toward vaccines (10). The SARS-CoV-2 mRNA vaccine (Pfizer/BioNTech), which contains BNT162b2, a modified RNA nucleoside in a lipid nanoparticle formulation, generates high levels of SARS-CoV-2 neutralizing antibody titers specific to the antigen with two doses of 30 microgram (g). The vaccine prevents infection at over 95% efficacy, with an average follow-up period of 2 months after the second dose (11). Despite emergency use approval in the United States of America (USA), 56% of individuals reported that they did not want to receive this vaccine, primarily because of concerns about possible negative effects on fertility (12,13). The Pfizer/BioNTech vaccine began to be used in Turkiye on April 2, 2021 (14).

There is limited scientific evidence in the literature regarding the effects of different types of vaccines on semen parameters and male fertility. In this study, we investigated the effects of these vaccines on semen parameters because of their active use in Turkiye.

## Materials and Methods

We retrospectively investigated 118 sexually active male patients aged between 18 and 50 years whose partners had no problem and who attended Recep Tayyip Erdogan University Training and Research Hospital Andrology Laborotary between January 2021 and April 2022 and had received either Sinovac/CoronaVac vaccine (Group 1) or Pfizer/BioNTech vaccine (Group 2). Sixty-five patients were included in the study, and 53 patients who did not meet the inclusion criteria were excluded from the study (Figure 1). Ethical approval was obtained from the Recep Tayyip Erdogan University Non-Interventional Clinical Research Ethics Committee before the study (decision no: 2023/17 date: January 1, 2023). Anthropometric data of patients [age, body mass index (BMI)], the time of the second semen analysis after the second dose of vaccine, and semen analysis parameters (volume, pH, count, motility, and morphology) before and after two doses of vaccination were evaluated from the patient's files. Patients younger than 18 years old, older than 50 years old, using medication affecting spermatogenesis, diagnosed with endocrinological disease affecting spermatogenesis, presence of genetic disease, gender disorders, history of varicocele or cryptorchidism operations, having only one sample, and diagnosed with azoospermia according to the spermiogram analyzes were excluded from the study. After exclusion criteria, a total of 65 patients' data were recorded and analyzed Semen samples obtained by masturbation after 2-5 days of sexual abstinence were evaluated in the andrology laboratory by an experienced embryologist according to the guidelines of the WHO laboratory manual (6th edition) (Table 1) (15).

Patients who were azospermic (n=6), had not completed two doses of vaccine (n=6), or had a history of COVID-19 (n=41) were excluded from the study. The remaining 65 patients were divided into two groups: Group 1 (n=17) and Group 2 (n=48).

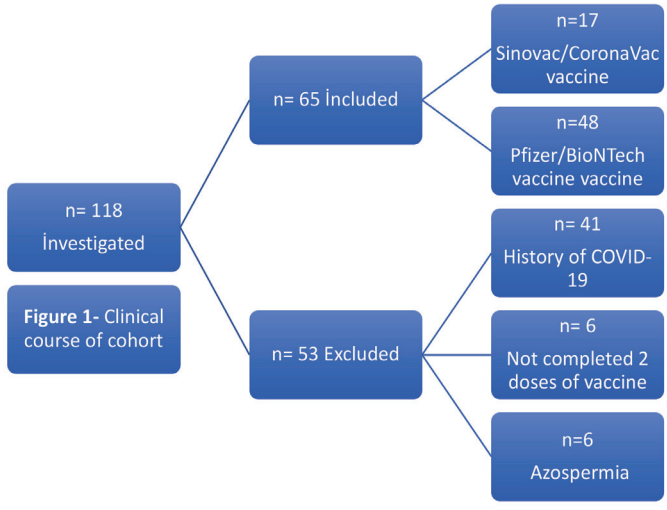


**Figure 1-** Clinical course of cohort

**Figure 1.** Clinical course of cohort

The pre-and post-vaccination BMI, semen volume, semen pH, sperm count per milliliter, total sperm count, sperm motility, and morphology values of patients in both groups were recorded and compared.

### Statistical Analyses

Statistical analysis was performed using IBM SPSS Statistics (SPSS Inc., Chicago, IL, USA) software. After normality analysis of continuous numerical variables, the data showing the normal distribution were calculated as mean ± standard deviation and median (minimum-maximum). Differences between groups were evaluated using the independent samples t-test or Mann-Whitney U test, depending on the distribution of the data. Within-group and between-group pre- and post-vaccination comparisons in Sinovac/CoronaVac and Pfizer/BioNTech groups were performed using the Wilcoxon Signed-Rank test. For sperm morphology, 4 normal morphology was considered normal, and 4 was considered pathological. The McNemar test was used for comparisons made by dichotomizing the data. A $p<0.05$ was considered statistically significant.

## Results

The mean ages of the patients in Groups 1 and 2 were calculated as 37±5 and 34±7 years, respectively. There was no significant difference between the groups in terms of BMI and duration. The mean time between vaccination and second semen analysis in Group 1 and Group 2 was 4±2.4 and 3.5±1.9 month (Table 2). No significant difference was found between Groups 1 and 2 in terms of volume, pH, total motility, the percentage of motile sperm changes, and morphology. We observed that the total sperm count (p=0.021) and sperm count per mL (p=0.014) significantly decreased in Group 1 and increased in Group 2 (Table 3).

**Table 1. Normal value according to the World Health Organization**

| | |
|---|---|
| **Semen volume (mL)** | **≥1.4** |
| pH | 7.2 |
| Total sperm number (millions/ejaculate) | ≥39 |
| Sperm concentration (millions/mL) | ≥16 |
| Total motility (PR+NP, %) | ≥42 |
| Progressive motility (PR, %) | ≥30 |
| Sperm morphology (normal form, %) | ≥4 |

PR: Progressive, NP: Non-progressive

**Table 2. Comparison of the demographic characteristics of the groups**

| | Group 1 (n=17) | Group 2 (n=48) | p-value |
|---|---|---|---|
| | Mean ± SD; Median (min/max) | Mean ± SD; Median (min/max) | |
| Duration (month) | 4 ±2.4 | 3.5±1.9 | 0.328 |
| BMI* | 25.9 (21.6-30.1) | 27 (20.2-47.3) | 0.135 |
| Age (year) | 37±5 | 34±7 | 0.073 |

*Body mass index, SD: Standard deviation, min: Minimum, max: Maximum

**Table 3. Intergroupdifferences in sperm parameters**

| | Group 1 (n=17) | Group 2 (n=48) | p-value |
|---|---|---|---|
| | Mean ± SD; Median (min-max) | Mean ± SD; Median (min-max) | |
| *Volume (mL) | 4 (1.8-6) | 3.8 (1.1-8.1) | 0.455 |
| **Volume (mL) | 4,1 (1.4-9.8) | 3.4 (1-7) | |
| *pH | 7.9 (6.9-8.5) | 7.8 (6.7-8.5) | 0.219 |
| **pH | 7.2 (7-8.1) | 7.3 (6.8-8.5) | |
| *Total sperm count (millions/ejaculate) | 125 (6-479) | 121 (0.3-848) | **0.021** |
| **Total sperm count (millions/ejaculate) | 102 (5-384) | 152 (0.3-827) | |
| *Sperm count per mL (millions/mL) | 36 (2-150) | 32 (0.1-210) | **0.014** |
| **Sperm count per mL (millions/mL) | 34 (1-105) | 43 (0.1-167) | |
| *Total motility (PR+NP, %) | 40 (18-65) | 42 (2-71) | 0.777 |
| **Total motility (PR+NP, %) | 38 (20-53) | 42 (1-63) | |
| *Progresifmotility (%) | 37 (15-62) | 40 (1-68) | 0.869 |
| **Progresifmotility (%) | 35 (16-48) | 38 (1-61) | |
| *Sperm morphology (normal/pathological) | 6/11 | 23/25 | 0.368 |
| **Sperm morphology (normal/pathological) | 8/9 | 17/31 | 0.397 |

*: Pre-Vaccination, **: Post-Vaccination, PR: Progressive, NP: Nonprogressive, SD: Standard deviation, min: Minimum, max: Maximum

In Group 1, no significant difference was observed in volume, sperm count per ml, motile sperm count, or total motility before and after Sinovac/CoronaVac vaccination. However, a statistically significant decrease was observed in pH (p=0.004) and total sperm count (p=0.019) due to the Sinovac/CoronaVac vaccine (Table 4). There was no significant difference in sperm morphology before or after the Sinovac/CoronaVac vaccine.

In Group 2, no significant differences were observed in volume, total sperm count, sperm count per mL, motile sperm count, or total motility before and after the vaccination. However, a statistically significant decrease was observed in pH because of the Pfizer/BioNTech vaccine (p<0.001) (Table 5). There was no significant difference in sperm morphology before and after administration of the Pfizer/BioNTech vaccine.

## Discussion

This study was designed to identify the potential effects of Sinovac/CoronaVac and Pfizer/BioNTech vaccines on male fertility. Compared with previous studies that reported a decline in semen parameters in active COVID-19 and recovered patients (16,17), our study showed a significant decrease in total sperm count and sperm count per milliliter in infertile patients after Sinovac/CoronaVac vaccination but an increase in these parameters after Pfizer/BioNTech vaccination.

Gonzales and colleagues examined the sperm parameters of 45 patients before and after two doses of COVID-19 mRNA vaccines and reported a significant increase in all sperm parameters at an average of 75 days after the second dose (Pfizer/BioNTech n=21 and Moderna n=24) (18). In contrast, Barda's study showed no negative effect on sperm parameters in patients who received two doses of Pfizer/BioNTech and were evaluated 72 days after the second dose, and that total sperm and total motile sperm counts increased significantly after the second dose (19). A study by Myriam Safrai evaluated sperm parameters in 72 patients an average of 71 days after the second dose of the Pfizer/BioNTech vaccine and reported that it did not affect sperm parameters in normospermic or infertile patients (20). Similarly, Reschini et al. (21) reported that there was no negative effect on sperm parameters or fertilisation rates after PfizerBioNTech (n=73) and Moderna (n=20) vaccinations. Gat and colleagues examined semen samples after two doses of Pfizer/BioNTech vaccine on days 15-45, 75-125, and 145 and reported that the decreased sperm concentration and total motile sperm count in the first two-time intervals improved in the third time interval (22). Abd and colleagues compared semen samples before and after the second dose of the Pfizer/BioNTech vaccine 90 days after vaccination and found impaired total sperm motility and progressive motility, but other parameters were normal (23). In our study, we did not observe any changes in sperm parameters

**Table 4. Intragroup differences in sperm parameters of the Sinovac/CoronaVac vaccine (group 1)**

| | Pre-Vaccination | Post-Vaccination | p-value |
|---|---|---|---|
| | Median (min-max) | Median (min-max) | |
| Volume (mL) | 4 (1.8-6) | 4.1 (1.4-9.8) | 0.850 |
| pH | 7.9 (6.9-8.5) | 7.2 (7-8.1) | **0.004** |
| Total sperm count (millions/ejaculate) | 125 (6-479) | 102 (5-384) | **0.019** |
| Sperm count per mL (millions/mL) | 36 (2-150) | 34 (1-105) | 0.065 |
| Progressive motility (%) | 37 (15-62) | 35 (16-48) | 0.641 |
| Total motility (PR+NP, %) | 40 (18-65) | 38 (20-53) | 0.717 |
| Sperm morphology (normal/pathological) | 11/6 | 8/9 | 0.500 |

PR: Progressive, NP: Nonprogressive, min: Minimum, max: Maximum

**Table 5. Intragroup differences in sperm parameters of the Pfizer/BioNTech vaccine (group 2)**

| | Pre-Vaccination | Post-Vaccination | p-value |
|---|---|---|---|
| | Median(min-max) | Median(min-max) | |
| Volume (mL) | 3.8 (1.1-8.1) | 3.4 (1-7) | 0.064 |
| ph | 7.8 (6.7-8.5) | 7.3 (6.8-8.5) | **<0.001** |
| Total sperm count (millions/ejaculate) | 121 (0.3-848) | 152 (0.3-827) | 0.310 |
| Sperm count per mL (millions/mL) | 32 (0.1-210) | 43 (0.1-167) | 0.096 |
| Progressive motility (%) | 40 (1-68) | 38 (1-61) | 0.477 |
| Total motility (PR+NP, %) | 42 (2-71) | 42 (1-63) | 0.352 |
| Sperm morphology (normal/pathological) | 23/25 | 17/31 | 0.070 |

PR: Progressive, NP: Nonprogressive, min: Minimum, max: Maximum

before or after two doses of the Pfizer/BioNTech vaccine. Although normal sperm morphology decreased before and after vaccination, it was not statistically significant. Interestingly, the pH value was significantly lower after vaccination.

In a study of 128 individuals vaccinated with Sinovac/CoronaVac and Sinopharm inactivated vaccines in China, no difference in semen parameters was observed before or after the second vaccination within 90 days (24). In another study using Sinovac/CoronaVac vaccine, a slight decrease in motility and morphology was observed after the second dose, which was attributed to the length of time between semen collection before and after vaccination (10). Zhu Hong and colleagues examined semen parameters at an average of 60 days after inactivated vaccine administration in 43 healthy volunteers and observed no changes (25). In their study, Xia et al. (26) also showed that there was no difference in semen parameters or in vitro fertilization outcomes after vaccination with Sinovac (n=105) or Sinopharm (n=155) vaccines. In contrast to these studies, our study showed a decrease sperm count and pH values after Sinovac/CoronaVac vaccination.

In the first study in which Sinovac/CoronaVac and PfizerBioNTech vaccines were compared, we showed that sperm count per milliliter and total sperm count increased in favor of PfizerBioNTech. We did not detect any difference between the groups in other sperm parameters.

### Study Limitations

The major limitation of this study was the retrospective design. Single-center design, heterogeneous sample distribution among the groups, and lack of serum testosterone values were the other limitations of our study. Pre-vaccination evaluation in idiopathic infertile men, evaluation of the same patient cohort, and comparison of two different vaccine groups were the strengths of our study.

## Conclusion

We observed that the milliliter and total sperm count decreased in idiopathic infertile patients in the Sinovac/CoronaVac group, whereas it increased in the PfizerBioNTech group following COVID-19 vaccination. The findings show that inactive and mRNA vaccines do not significantly affect semen parameters in infertile men. Therefore, both vaccines can be considered safe for men's reproductive health.

### Ethics

**Ethics Committee Approval:** Ethical approval was obtained from the Recep Tayyip Erdogan University Non-Interventional Clinical Research Ethics Committee before the study (decision no: 2023/17 date: January 1, 2023).

**Informed Consent:** Retrospective study.

**Peer-review:** Externally peer-reviewed.

**Conflict of Interest:** No conflict of interest was declared by the author.

**Financial Disclosure:** The author declare that they have no relevant financial.

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