ORIGINAL ARTICLES

Assessing The Impact Of COVID-19 Inactivated Vaccination Doses on Male Fertility in Assisted Insemination with Husband's Perm (AIH) Cycle

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Background: *This study aimed to assess the impact of coronavirus disease 2019 (COVID-19) inactivated vaccination doses on male fertility.*

Methods. *A retrospective cohort study was conducted, including 595 assisted inseminations with husband's sperm (AIH) cycles involving 438 couples. Participants were categorized into three groups: the unvaccinated group, the 1 or 2 doses group, and the 3 doses group based on their vaccination status before insemination. Reproductive outcomes such as biochemical pregnancy, clinical pregnancy, ongoing pregnancy, and live birth were assessed across the different groups.*

Results: *The analysis revealed no significant differences in reproductive outcomes among the three groups. The rates of biochemical pregnancy, clinical pregnancy, ongoing pregnancy, and live birth were comparable among the unvaccinated group, the 1 or 2 doses group, and the 3 doses group (P=0.433, P=0.637, P=0.583, and P=0.539, respectively). Multivariate logistic regression analysis indicated that the doses of COVID-19 inactivated vaccine did not independently impact the reproductive outcomes of AIH cycles.*

Conclusion: *The administration of COVID-19 inactivated vaccine doses did not adversely affect male fertility in AIH cycles.*

BACKGROUND

China had used inactivated vaccine, adenovirus and recombinant vaccine to prevent COVID-19, among which inactivated vaccine is the most commonly used in China.[18] Despite the understanding of the immune response elicited by inactivated vaccines and the safety and efficacy data obtained from clinical trials, current guidelines from globalorganizations do not impose restrictions on the use of COVID-19 inactivated vaccines for couples planning pregnancy or undergoing assisted reproductive technology (ART).[3,6,14,15,16] However, many infertile couples were still concerned about whether the vaccination would affect the outcome of the ART pregnancy.

Artificial insemination with husband sperm (AIH) involves the preparation of sperm from husband and artificially inseminates into the partner's uterus around ovulation. This is a relatively natural fertilization process compared to in vitro fertilization embryo transfer (IVF-ET.[1,12] AIH has emerged as a primary treatment option for unexplained and male factor infertility. Previous research has indicated that the administration of the

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COVID-19 inactivated vaccine to women, the dosage received, and the timing between vaccination and AIH did not impact female fertility.[18] In addition, whether men received covid-19 inactivated vaccine and the interval between vaccination and AIH did not affect AIH reproductive outcomes.[13] However, to the best of our knowledge, there was currently a lack of information on the doses of male COVID-19 inactivated vaccine and clinical outcomes of assisted reproduction. This retrospective cohort study was conducted to investigate the association between male COVID-19 inactivated vaccine dosages and AIH outcomes.

Materials And Methods

Patients

The retrospective cohort study was carried out at the Department of Reproductive Medicine, Yuncheng Central Hospital affiliated to Shanxi Medical University (Shanxi, China). Couples receiving AIH treatment between January 2021 and December 2022 were included in the study. Inclusion criteria included: (1) Infertility period ≥1 year; (2) Normal uterine cavity, and at least one fallopian tube is unblocked (confirmed by hysterosalpingography or laparoscopy).

The exclusion criteria were as follows: (1) The cycle was cancelled due to non-dominant follicles after treatment or the total motile sperm count (TMSC) after processing was less than 10*106; (2) No response; (3) Receiving non-inactivated vaccines or unknown vaccines; (4) Endometrial thickness less than 7mm on the day of insemination; (5) Abstinence days outside of 2 to 7 days.

493 couples (667 cycles) were treated with AIH. These couples were further screened according to the above exclusion criteria. Finally, 595 AIH cycles (438 couples) were included in the study. The 595 AIH cycles were divided into two groups based on male COVID-19 inactivated vaccination status. The unvaccinated group included men who were not vaccinated or were vaccinated after insemination, including 329 AIH cycles (240 couples). The vaccinated group included men who were vaccinated prior to insemination, including 266 AIH cycles (198 couples). The vaccinated group was subdivided into 2 subgroups by vaccination doses prior to insemination. The 1 or 2 doses group included men who received 1 or 2 doses of the vaccine prior to insemination, including 149 AIH cycles (114 couples). The 3 doses group included men who received 3 doses of the vaccine prior to insemination, including 117 AIH cycles (84 couples) (Figure 1)

We followed up enrolled couples with vaccination information by telephone. Baseline clinical features and reproductive outcome data were collected from the Department of Reproductive Medicine database. Patient general information such as female ag, male age, female body mass index (BMI), Antral follicular count （AFC）, Gravidity, Parity, Miscarriage, Ectopic, type of infertility, infertility duration, infertility factors, cycle number, treatment cycle type, dominant follicle number, endometrial thickness on the day of insemination, abstinence duration, total motile sperm count (TMSC) after processing were recorded. Infertility factor was divided into pelvic-tubal factor, ovulation disorders and low ovarian reserve, male factor and other factors. Type of infertility were divided into primary and secondary. Treatment cycle type was divided into controlled ovarian stimulation (COS) cycle and natural cycle. Vaccination status included the doses received by the male partner and the interval between the last vaccination and insemination in the vaccinated group.

This study was approved by the Ethics Committee of Yuncheng Central Hospital affiliated to Shanxi Medical University. (No. YXLL2023009)

AIH protocol

Natural cycle: From the 8th to 10th day of the menstrual cycle, vaginal B-ultrasound was used to monitor follicle development and endometrial thickness. Maximum follicle diameter<10mm, monitor once every 3 to 4 days. When the dominant follicle diameter was 10 to 14mm, the patient was monitored once every 2 days, and the patient was instructed to monitor the urine LH test strip by himself. When the dominant follicle diameter was ≥14mm, B-ultrasound monitoring was performed once a day, and urine LH test strips

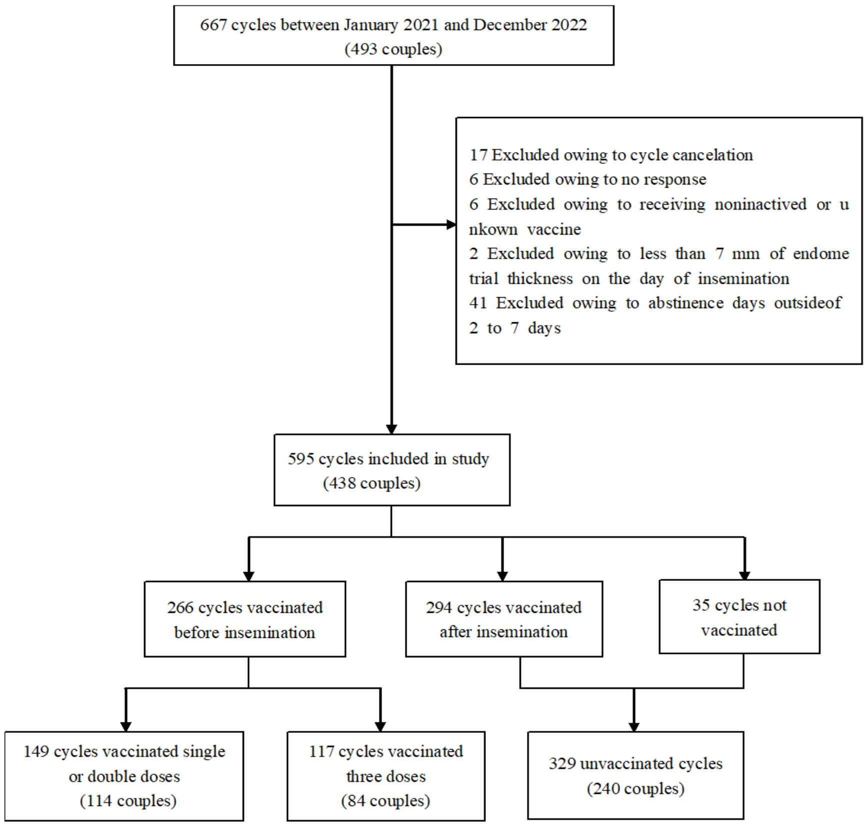

FIGURE 1
Study flowchart

or blood LH, E2 and P values were monitored at the same time. When the urine LH test strip was positive or weak positive, the patient would return to the doctor, and the blood LH, E2 and Pvalues would be measure. If a spontaneous LH peak (more than 3 times higher than the basal LH) occurred, the follicle diameter was ≥18mm, and the serum E2 level reached an average of 180~250pg /ml per mature follicle (it should be noted that the E2 level was consistent with the number of follicles), AIH would be performed within 24 hours. If there was no LH peak, follicle diameter was ≥18mm and serum E2 level reached an average of 180~250pg /ml per mature follicle (it should be noted that E2 level was consistent with the number of follicles), AIH was performed within 36 hours after HCG5000~10000IU. AIHcould also be performed immediately after HCG injection and B ultrasound confirmation of ovulation.

COS: On the 3rd to 5th day of menstruation, B ultrasound was used to evaluate the endometrial thickness, monitor the number of antral follicular count (AFC), and patients were given letrozole (LE; Jiangsu Hengrui) 2.5~5 mg, once a day for 5 days. The development of follicles and endometrial thickness were monitored by B-ultrasound starting from the 10th day of the menstrual cycle. When the diameter of the dominant follicle was 12~14 mm, the monitoring of follicles and endometrial thickness was conducted every 2 days. When the dominant follicle diameter was ≥14 mm, the monitoring of follicles and endometrial thickness was conducted every day, meanwhile the serum luteinizing hormone (LH), estradiol (E2) and progesterone (P) levels were monitored once a day. When the diameter of the dominant follicle was ≥18 mm and the serum E2 level reached an average of 180~250pg/ml per mature follicle, the follicle maturity was indicated (it should be noted that the E2 level was consistent with the number of follicles), HCG was given 5 000~10 000 U (Zhu Zhu Lizon), and AIH was administered within 36 h.

Sperm processing: The husband was instructed to abstain from sex for 2~7 days before sperm extraction. Sperm was extracted by masturbation and was optimized by density gradient centrifugation after complete liquefaction at room temperature. 15 ml conical centrifuge tube (Falcon, USA) were added with 1.0 ml 80% gradient solution, an equal amount of 40% gradient solution was slowly added to the top of the gradient solution, then fully liquefied sperm was slowly added to the top of the gradient solution. The supernatant in the conical tube was discarded after centrifuging 300 g for 20 min, leaving a little precipitation. A gametic buffer (GB; Cook, Australia) was added to another 15ml conical centrifuge tube, the precipitation was added into a centrifuge tube containing GB. Discard the supernatant and leave about 0.5 ml of the precipitation for mixing after centrifuging 200 g for 5 min. The sperm concentration and motility were observed by makler plate, and the TMSC after processing was calculated

Intrauterine insemination: After the nurse verified and determined the identity of the female patient, she was instructed to empty the bladder, take the lithotomy position, and scrubthe vulva with sterile saline. The surgeon opened the vagina with a speculum, scrubbed the vagina with sterile saline, checked the names of the female patient and the spouse with the nurse again. 0.5 ml of sperm was sucked out to 1 ml of sterile syringe with an artificial insemination tube (Shenzhen Huan Ho). According to the anterior and posterior positions of the uterus, the sperm suspension was slowly injected into the uterine cavity, and the artificial insemination tube and speculum were slowly removed 1 min later. Luteal support and pregnancy judgment: Take progesterone capsule (Zhejiang Xianju) orally 200 mg/d after ovulation. For patients with low estrogen levels before ovulation, oral supplementation of estradiol valerate tablets (Guangzhou Baier) 1 to 2 mg once a day could be done. After the pregnancy was confirmed by blood β-HCG positive test 14 to 16 days after surgery, the drug was continued to be used until 8 to 10 weeks of pregnancy The primary outcome indicator of this study was live birth (live delivery at 24 weeks of gestation or above), and the secondary outcome indicators included biochemical pregnancy (serum β-HCG level was greater than 10 mIU/ml on 14 to 16 days after surgery), clinical pregnancy (visible pregnancy capsule by ultrasound examination on 35 days after surgery, including ectopic pregnancy) and ongoing pregnancy (intrauterine pregnancy of more than 12 weeks confirmed by vaginal ultrasound).

Statistical analysis

SPSS 26.0 software (IBM) was used for statistical analysis. The continuous variables did not conform to the normal distribution after testing by the Shapiro Wilk (S-W) method, were expressed as the median (25th percentile, 75th percentile) [M (P25, P75)], and Kruscarl-Wallis H(K-W) test was used for comparison among groups. Categorical variables were expressed as frequency or rate, and comparisons among groups were made using Pearson's chi-square test or Fisher's exact test. The biochemical pregnancy rate, clinical pregnancy rate, ongoing pregnancy rate and live birth rate among different vaccine dose groups in the AIH cycle were compared. Then a multivariate logistic analysis regression model was performed, controlling for female age, female BMI, AFC, infertility factors, treatment cycle type, dominant follicles, endometrial thickness on the day of hCG administration, TMSC after processing, to analyze the effect of male vaccination dose on pregnancy outcome. Using unvaccinated cycles as the reference, the adjusted risk ratio (RR) and 95% confidence interval (CI) were calculated for biochemical pregnancy, clinical pregnancy, ongoing pregnancy and live birth. Next, a generalized estimating equation (GEE) was used to examine the relationship between individual factors and the outcome of ongoing pregnancy, controlling for multiple cycles within the same couple. RR and 95% CI were calculated for candidate factors. Two-tailed $P<0.05$ was considered statistically significant.

RESULTS

From January 2021 to December 2022, data from 595 AIH cycles in 438 couples were included in our study. There were 266 cycles in the male vaccinated group and 329 cycles in the male unvaccinated

Table1: Demographic Characteristics and vaccination status per artificial insemination cycles with husband sperm stratified by vaccination doses prior to insemination.

Variables	Unvaccinated group	Vaccinated group		*P*-value
		1 or 2 doses	3 doses	
No.of cycles	329	149	117	
Female age, median (IQR), y	28(26,30)	29(27,31)	29(27.5,31.5)	0.006
male age, median (IQR), y	29(27,31)	29(28,31)	31(29,34)	0
Female BMI, median (IQR), kg/m^2	22.6(20.2,25.4)	22.4(20.2,25.8)	23.9(21.2,26.4)	0.014
Total antral follicle count （AFC）	17(12,24)	17(11,21)	16(12,22)	0.235
Gravidity, n (%)				0.577
0	235(71.4)	108(72.5)	78(66.7)	
1	63(19.1)	27(18.1)	30(25.6)	
≥2	31(9.4)	14(9.4)	9(7.7)	
Parity, n (%)				0.471#
0	295(89.7)	138(92.6)	101(86.3)	
1	33(10.0)	10(6.7)	15(12.8)	
≥2	1(0.3)	1(0.7)	1(0.9)	
Miscarriage, n (%)				0.22
0	254(77.2)	115(77.2)	96(82.1)	
1	61(18.5)	23(15.4)	19(16.2)	
≥2	14(4.3)	11(7.4)	2(1.7)	
Ectopic, n (%)				0.168#
0	326(99.1)	149(100.0)	117(100.0)	
1	3(0.9)	0(0.0)	0(0.0)	
Type of Infertility, n(%)				0.308
Primary	254(77.2)	112(75.2)	82(70.1)	
Secondary	75(22.8)	37(24.8)	35(29.9)	
Infertility duration, median (IQR), y	3(2,4)	2 （2,3）	3(1.5,4)	0.005
Infertility factors, n(%)				0.001
Pelvic -tubal factor	70(21.3)	18(12.1)	10(8.5)	
Ovulation disorders and low ovarian reserve	155(47.1)	60(40.3)	48(41.0)	
Male factor	25(7.6)	14(9.4)	12(10.3)	
Others	79(24.0)	57(38.3)	47(40.2)	
Cycle number, n(%)				0.267#
1	240(72.9)	114(76.5)	84(71.8)	
2	77(23.4)	34(22.8)	28(23.9)	
≥3	12(3.6)	1(0.7)	5(4.3)	
Treatment cycle type, n(%)				0.269
Natural	35(10.6)	17(11.4)	19(16.2)	
COS	294(89.4)	132(88.6)	98(83.8)	
Dominant follicle number, n(%)				0.088
1	264(80.2)	131(87.9)	100(85.5)	
2	65(19.8)	18(12.1)	17(14.5)	
Endometrial thickness on the day of insemination, median (IQR), mm	10(8.5,11)	9.6(8.25,11)	9.4(8.45,10.65)	0.636
Abstinence duration, median (IQR), y	3(3,4)	3(3,5)	4(3,5)	0.274
TMSC after processing, median (IQR),10^6	24(15.75,35)	24(14,33)	24(16,32)	0.817
Male partner doses of vaccination, n (%)				0.000
0	321(97.6)	18(12.1)	5(4.3)	
1 or 2	8(2.4)	116(77.9)	22(18.8)	
3	0(0.0)	15(10.1)	90(76.9)	
Female interval between the last dose and insemination, n (%)				0.408
< 3 months	1(12.5)	16(12.2)	8(7.1)	
≥3 months	7(87.5)	115(87.8)	104(92.9)	
Male interval between the last dose and insemination, n (%)				0.847
< 3 months	/	19(12.8)	14(12.0)	
≥3 months	/	130(87.2)	103(88.0)	

#Fisher exact test was used.

group. In the male vaccinated group, there were 149 cycles in 1or 2 doses group and 117 cycles in 3 doses group. The vaccination coverage rate of maleseeking for AIH treatments was 44.7% (266/595). In the male vaccinated group, 56 percent of cycles (149/266) received 1 or 2 doses of the vaccine and 44 percent of cycles (117/266) received 3 doses of the vaccine. Table 1 summarizes demographic Characteristics andvaccination status per artificial insemination cycles with husband sperm stratified by vaccination doses prior to insemination. There were statistically significant differences in the female age, male age, female BMI, infertility duration, infertility factors in the three different male vaccination dose groups (P＜0.05). Other baseline characteristics did not differ significantly(P>0.05). In the three different male vaccination dose groups, male partner vaccination dose was statistically significant differences(P＜0.05). Interval between the last dose and insemination of male or female did not differ significantly in the three different male vaccination dose groups (P>0.05).

Table 2 shows the frequencies for reproductive outcome of artificial insemination with husband sperm stratified by vaccination doses prior to insemination.

There were no significant differences in Reproductive outcomes in the three different vaccination dose groups (24.0% in unvaccinated group, 18.8% in 1 or 2 doses group, 21.4% in 3 doses group for biochemical pregnancy rate, P=0.433; 18.8% in unvaccinated group, 16.8% in 1 or 2 doses group, 21.4% in 3 doses group for clinical pregnancy rate, P=0.637; 17.0% in unvaccinatedgroup, 13.4% in 1 or 2 doses group,17.1% in 3 doses group for ongoing pregnancy rate, P=0.583; 16.7% in unvaccinated group, 12.8% in 1 or 2 doses group, 15.4% in 3 doses group for live birth rate, P=0.539). Multivariable logistic regression analyses showed no independent influence of male vaccine dose on the reproductive outcomes of AIH cycles afteradjusted for female age, female BMI, total antral follicle count (AFC), infertility factors, treatment cycle type, dominant follicle number, endometrial thickness on the day of insemination, TMSC after processing [Adjusted RR(95%CI) 0.806(0.489-1.330) in 1 or 2 doses group, 0.993(0.579-1.703) in 3 doses group for biochemical pregnancy rate; Adjusted RR(95%CI) 0.928(0.545-1.581) in 1 or 2 doses group, 1.315(0.754-2.295) in 3 doses group for clinical pregnancy rate; Adjusted RR(95%CI) 0.807(0.453-1.435) in 1 or 2 doses group,1.129(0.619-2.057) in 3 doses group for ongoing pregnancy rate; Adjusted RR(95%CI) 0.780(0.434-1.399) in 1 or 2 doses group, 1.025(0.553-1.900) in 3 doses group for live

TABLE 2: Reproductive outcome of artificial insemination with husband sperm stratified by vaccination doses prior to insemination.

Variables	Unvaccinated group	Vaccinated group		P-value
		1 or 2 doses	3 doses	
Biochemical pregnancy, %(n)	24.0(79/329)	18.8(28/149)	21.4(25/117)	0.433#
Adjusted RR (95%CI)	ref.	0.806(0.489-1.330)	0.993(0.579-1.703)	
Adjusted P value	/	0.399	0.98	0.683*
Clinical pregnancy, %(n)	18.8(62/329)	16.8(25/149)	21.4(25/117)	0.637#
Adjusted RR (95%CI)	ref.	0.928(0.545-1.581)	1.315(0.754-2.295)	
Adjusted P value	/	0.784	0.335	0.523*
Ongoing pregnancy, %(n)	17.0(56/329)	13.4(20/149)	17.1(20/117)	0.583#
Adjusted RR (95%CI)	ref.	0.807(0.453-1.435)	1.129(0.619-2.057)	
Adjusted P value	/	0.465	0.693	0.626*
live birth, %(n)	16.7(55/329)	12.8（19/149）	15.4(18/117)	0.539#
Adjusted RR (95%CI)	ref.	0.780(0.434-1.399)	1.025(0.553-1.900)	
Adjusted P value	/	0.404	0.937	0.669*

#Reproductive outcome difference in three different vaccination dose groups before adjustment.
*Reproductive outcome difference in three different vaccination dose groups after adjustment.

birth].
The predictors in the GEE model for live birth were presented in Table 3. After controlling bias from multiple cycles within the same couple, male COVID-19 vaccine dose did not to predict the live birth of AIH cycles. The independent influence factor to predict live birth of AIH cycles was treatment cycle type.

Table 3: Adjusted binary logistic regression model for predictors of live birth of artificial insemination with husband sperm using generalized estimating equations.

Factors	**Adjusted RR (95%CI)**	***P*-value**
male vaccination doses prior to insemination		
0	ref.	
1 or 2	0.759(0.208-2.771)	0.676
3	2.121(0.518-8.690)	0.296
male partner vaccination doses prior to insemination		
0	ref.	
1 or 2	1.152(0.322-4.123)	0.827
3	0.349(0.079-1.553)	0.167
Female age, y	0.928(0.858-1.003)	0.061
Female BMI, kg/m^2	1.069(0.995-1.147)	0.067
Total antral follicle count（AFC）	1.025(0.980-1.072)	0.287
Infertility factors		
Pelvic -tubal factor	ref.	
Ovulation disorders and low ovarian reserve	1.148(0.561-2.352)	0.705
Male factor	0.411(0.100-1.690)	0.218
Others	0.905(0.431-1.901)	0.792
Treatment cycle type		
Natual	ref.	
COS	4.318(1.093-17.054)	0.037
Dominant follicle number		
1	ref.	
2	1.527(0.852-2.734)	0.155
Endometrial thickness on the day of insemination, mm	1.042(0.918-1.183)	0.525
TMSC after processing, median, 10^6	0.995(0.977-1.013)	0.56

DISCUSSION

This retrospective cohort study aimed to assess the impact of COVID-19 inactivated vaccine doses on male fertility within the AIH cycle. The findings revealed no significant effect on the clinical outcomes of AIH.

COVID-19 vaccines mainly include inactivated virus vaccine, viral vector vaccine, and mRNA vaccine. Inactivated vaccine undergoes physical or chemical inactivation while preservingthe integrity of virus particles, utilizing the entire virus as a vaccine target. The targeted immune response of inactivated vaccines is usually humoral and cellular, with almost noreactivity, and therefore has a high safety.[10] Given its widespread use in China, reproductive medicine experts should consider the impact of the COVID-19 inactivated vaccine on fertility. Initial studies had found no association between inactivated COVID-19 vaccines and fertility rate. [2,4] Existing research had also focused on whether pregnancy need to be delayed after COVID-19 inactivated vaccination and the optimal interval to delay pregnancy.[11] Several studies have evaluated the potential sperm toxicity of the COVID-19 inactivated vaccine in men, with results indicating that vaccination with the COVID-19 inactivated vaccine does not adversely affect male sperm parameters, (including sperm volume, sperm concentration, total sperm count, forward motility sperm count, sperm morphology and sperm DNA fragmentation index, etc.).[5,7,9,17,13] conducted a study involving 4185 couples who underwent their first AIH treatment at 10 centers across 9 provinces in China between July 2021 and February 2022. Their findings revealed that the vaccination status of both men and women, the type of vaccination, and the interval between vaccination and AIH did not impact the success rate of artificial insemination. Another retrospective cohort study in 2022, involving 492 women undergoing artificial insemination with husband sperm (AIH) (725 cycles), concluded that vaccination with the COVID-19 inactivated vaccine, the vaccine dosage, and the time interval between the last vaccination and AIH did not have adverse effects on fertility within the AIH cycle.[18,13] conducted a study involving 4185 couples who received the first AIH treatment at 10 centers in 9 provinces in China from July 2021 to February 2022 and followed up the vaccination status of both men and women. Their findings revealed that the vaccination status of both men and women, the type of vaccination, and the interval between vaccination and AIH did not impact the success rate of artificial insemination. Another retrospective cohort study in 2022, involving 492women undergoing artificial insemination with husband sperm (AIH) (725 cycles), concluded that vaccination with the COVID-19 inactivated vaccine, the vaccine dosage, and the time interval between the last vaccination and AIH did not have adverse effects on fertility within the AIH cycle.[18] These studies indirectly reflect the safety of COVID-19 inactivated vaccine for reproductive health. However, existing studies had not addressed the effect of COVID-19 inactivated vaccination doses on male reproductive outcomes.

AIH is an effective method to study the influence of one factor on implantation. This approach offers a relatively natural fertilization process compared to IVF-ET, while also bypassing various factors that could affect conception in natural conception processes, such as ovulation and sperm selection.[8]

Our study was the first to assess the effect of COVID-19 inactivated vaccine doses on male reproduction using the AIH cycle as a model. In our grouping strategy, we went beyond simply categorizing men into vaccinated and unvaccinated groups by meticulously considering vaccination doses and employing a more stringent grouping methodology. In addition, our follow-up information on vaccination was more comprehensive, and we also followed up the data of female vaccination dose and interval between female vaccination and AIH while focusing on male vaccination status. Finally, the basic data of patients included in our study were also relatively perfect,including gravidity, parity, miscarriage, ectopic and abstinence duration. The study also hadsome limitations. First, the sample size was small, with approximately 90% of couples having an interval of 3 months or more between the last vaccine dose and insemination, which hindered the possibility of conducting a detailed stratified analysis of the interval between vaccination and AIH. Second, statistical bias exists in retrospective studies. Although factors related to AIH success were included in multivariate logistic regression to correct for confounding, and GEE model was used to control for bias caused by multiple cycles of the same couple, it was impossible to identify and control for all confounding variables. Third, the study focused on infertile couples undergoing AIH treatment and may not representative of couples who conceived naturally.

CONCLUSIONS

Our study was characterized by a rigorous design, utilizing the AIH cycle as a fertility model, implementing stringent inclusion and exclusion criteria, and employing the GEE model to account for confounding factors derived from cycle characteristics data.

This investigation yielded valuable insights into elucidating the impact of COVID-19 inactivated vaccine doses on male fertility. The results demonstrated that the dosage of the COVID-19 inactivated vaccine did not have a detrimental effect on male fertility within the AIH cycle.

DECLARATIONS

Ethics approval

This study involving human participants were reviewed and approved by Ethics Committee of Yuncheng Central Hospital affiliated to Shanxi Medical University (No. YXLL2023009).

Consent to participate

Written informed consent for participation was not required for this study in accordance with the National Legislation and the Institutional requirements.

Consent for publication

All authors in this paper consent to the publication of the work.

Conflict of interest

All authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Data availability

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Code availability

Not applicable.

Disclosure Statement

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Attestation Statement

Data regarding any of the subjects in the study has not been previously published unless specified.

Data will be made available to the editors of the journal for review or query upon request.

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