Original Article

Comparative Study of Intrauterine Insemination Versus Fallopian Tube Sperm Perfusion in the Management of Non-Tubal Infertility

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Abstract

Background: Controlled ovarian hyperstimulation (COH) combined with intrauterine insemination (IUI) is a commonly used treatment modality for couples with non-tubal infertility. Fallopian tube sperm perfusion (FSP) is an alternative technique in which a larger volume of processed sperm suspension is injected under pressure while minimizing semen reflux through cervical sealing. This technique may increase the concentration of motile sperm reaching the fallopian tubes at the time of ovulation. The present study aimed to compare the effectiveness of standard IUI and FSP in the treatment of non-tubal infertility. **Material and Methods:** A total of 110 women with non-tubal infertility undergoing 110 stimulated cycles were enrolled in this prospective randomized study. Fifty-five patients underwent standard IUI following controlled ovarian stimulation with letrozole 2.5 mg (Group A), while 55 patients underwent FSP following the same stimulation protocol (Group B). Semen preparation was performed using the double-density centrifugation and swim-up technique in all cases. Insemination was performed 36–40 hours after human chorionic gonadotropin (hCG) administration. A volume of 0.5 mL inseminate was used for standard IUI, whereas 3 mL inseminate was used for FSP. **Results:** In Group A, 10 clinical pregnancies were achieved among 55 IUI cycles, resulting in a pregnancy rate of 18.2%. In Group B, 15 clinical pregnancies were achieved among 55 FSP cycles, resulting in a pregnancy rate of 27.3%. Clinical pregnancy was defined as the presence of a gestational sac with fetal cardiac activity on ultrasonography. "The clinical pregnancy rate was higher in the FSP group (27.3%) than in the IUI group (18.2%); however, the difference did not reach statistical significance." **Conclusion:** Fallopian tube sperm perfusion demonstrated a higher clinical pregnancy rate compared with standard intrauterine insemination in women with non-tubal infertility. FSP can be considered an effective alternative to conventional IUI in appropriately selected patients.

Keywords: Intrauterine insemination; Fallopian tube sperm perfusion; Non-tubal infertility; Controlled ovarian hyperstimulation; Clinical pregnancy.

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Introduction

Infertility is defined as the failure to achieve pregnancy after 12 months or more of regular unprotected sexual intercourse. It affects approximately 10–15% of couples of reproductive age worldwide and represents a significant medical, psychological, and social burden. It has been estimated that nearly one in seven couples experiences difficulty in conceiving. The evaluation of an infertile couple aims to identify abnormalities in either partner that may impair fertility and to guide appropriate treatment.[1-4]

Intrauterine insemination (IUI) is one of the most widely used assisted reproductive techniques for the treatment of selected cases of infertility. The procedure involves the placement of processed semen directly into the uterine cavity around the time of ovulation, thereby increasing the number of motile sperm available for fertilization. Owing to its simplicity, low cost, minimal invasiveness, and ease of performance, IUI is commonly employed as a first-line treatment option in couples with non-tubal infertility.[5-8]

The common indications for IUI include mild male factor infertility, unexplained infertility, cervical factor infertility, ovulatory dysfunction in conjunction with controlled ovarian stimulation, minimal or mild endometriosis, ejaculatory dysfunction, and certain coital disorders such as vaginismus. In addition, IUI is considered a safe and effective option for achieving pregnancy in serodiscordant couples affected by human immunodeficiency virus (HIV).[9-12]

Despite its widespread use, the pregnancy rates achieved with conventional IUI remain suboptimal. To improve the chances of fertilization, Fallopian Tube Sperm Perfusion (FSP) was introduced as a modification of standard IUI. FSP was first described by Kahn et al., who utilized a Frydman catheter to inject a larger volume of sperm suspension while preventing cervical reflux. In contrast to conventional IUI, which typically uses 0.5 mL of inseminate, FSP employs a larger volume of sperm suspension (approximately 3–4 mL) under gentle

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pressure, allowing spermatozoa to traverse the uterine cavity and fallopian tubes more effectively. This technique is believed to increase the concentration of motile sperm at the site of fertilization within the ampullary region of the fallopian tube.

Several studies have evaluated the efficacy of FSP with varying results, and its role in the management of non-tubal infertility remains a subject of ongoing research. Therefore, the present study was undertaken to compare the clinical pregnancy rates achieved with Fallopian Tube Sperm Perfusion and conventional Intrauterine Insemination in women with non-tubal infertility undergoing controlled ovarian stimulation.[13,14]

Materials and Methods

Study Design and Setting: This prospective randomized comparative study was conducted in the Department of Obstetrics and Gynaecology, Command Hospital Eastern Command (CHEC), Kolkata, after obtaining approval from the Institutional Ethics Committee. Patient recruitment commenced Data collection and subsequent statistical analysis were performed during the study period.

Study Population: Women attending the Assisted Reproductive Technology (ART) outpatient department with primary non-tubal infertility were screened for eligibility. Eligible patients were counselled regarding the study protocol and written informed consent was obtained prior to enrolment.

A total of 110 women with primary non-tubal infertility fulfilling the inclusion and exclusion criteria were recruited.

Inclusion Criteria

1. Female age between 20 and 35 years.
2. Male age between 20 and 35 years.
3. Duration of infertility greater than one year.
4. Normal uterine cavity with bilateral tubal patency confirmed by hysterosalpingography or hysteroscopy and laparoscopy.
5. Normal semen parameters according to WHO guidelines or mild-to-moderate oligozoospermia (5–20 million sperm/mL).

Exclusion Criteria

1. Female age greater than 35 years.
2. Male age greater than 35 years.
3. Duration of infertility less than one year.
4. Unilateral or bilateral tubal blockage.
5. Severe male factor infertility with sperm count less than 5 million/mL or severe motility impairment.

Randomization:

Following enrolment, patients were randomized into two groups according to the calendar date of insemination. Patients undergoing insemination on even-numbered dates were assigned to the Intrauterine Insemination (IUI) group, whereas those undergoing insemination on odd-numbered dates were assigned to the Fallopian Tube Sperm Perfusion (FSP) group.

Group A comprised 55 patients undergoing standard IUI, while Group B comprised 55 patients undergoing FSP.

Ovulation Induction Protocol: All participants underwent controlled ovarian stimulation using letrozole 2.5 mg orally once daily from Day 2 to Day 6 of the menstrual cycle.

Baseline transvaginal ultrasonography was performed on Day 2 to exclude ovarian cysts. Follicular monitoring and endometrial assessment were performed on Days 7 and 10 of the cycle.

When at least one dominant follicle measured 18–20 mm in diameter and endometrial thickness reached 7–8 mm with a trilaminar appearance, ovulation was triggered using 5,000–10,000 IU of human chorionic gonadotropin (hCG) administered intramuscularly.

Insemination was performed 36–40 hours after hCG administration.

Semen Preparation

Semen samples were obtained after 2–5 days of abstinence by masturbation into sterile containers. Following liquefaction at room temperature for 30 minutes, semen analysis was performed according to WHO recommendations.

Sperm preparation was carried out using the double-density gradient centrifugation technique followed by the swim-up method. Post-wash sperm concentration and motility were recorded before insemination.

Insemination Procedure

All procedures were performed with the patient in the dorsal lithotomy position under aseptic conditions.

In Group A (IUI), 0.5 mL of processed sperm suspension was slowly injected into the uterine cavity using a standard IUI catheter.

In Group B (FSP), 3 mL of processed sperm suspension was injected using a sonohysterography catheter with an attempt to seal the cervix and facilitate sperm perfusion through the fallopian tubes while minimizing reflux.

Following the procedure, all patients rested for approximately 20 minutes and received luteal phase support with progesterone along with folic acid supplementation.

Outcome Measures

Primary Outcome

The primary outcome measure was clinical pregnancy rate.

Chemical pregnancy was defined as a positive urine pregnancy test performed 21 days after insemination.

Clinical pregnancy was defined as the presence of an intrauterine gestational sac with fetal cardiac activity confirmed on transvaginal ultrasonography during the first trimester.

Secondary Outcomes

1. Miscarriage.
2. Multiple pregnancy.
3. Ectopic pregnancy.
4. Ovarian Hyperstimulation Syndrome (OHSS).

Statistical Analysis

Data were entered and analysed using Statistical Package for Social Sciences (SPSS) version 20. Continuous variables were expressed as mean ± standard deviation, whereas categorical variables were expressed as frequencies and percentages.

Comparisons between groups were performed using appropriate statistical tests. A p-value of less than 0.05 was considered statistically significant.

Results

Table 1: Table- Comparison of study between IUI Group and FSP Group

S. No	Parameter	IUI Group	FSP Group	P Value	Significance
A	Primary Outcome				
1	Chemical Pregnancy (UPT Positive)	12	18	0.20	Not significant
2	Clinical Pregnancy (TVS-FCAPresent)	10	15	0.26	Not Significant
B	Secondary Outcome				
1	Abortion	4	3	0.696	Not Significant
2	Multiple Pregnancy	0	1	0.315	Not Significant
3	Ectopic Pregnancy	0	1	0.315	Not Significant
4	OHSS	1	1	1.00	Not Significant

Table 2: Comparative analysis of recent studies on IUI and FSP with Present Study.

Study	Col Gs Shekhawat	C.M. Farquhar et ali	Cantineau AEP et al RCT, Cochrane review	Present study
Design	Prospective randomised study	Multicentric Randomised control trail	16 RCT'S Cochrane collaboration	Prospective comparative study
Patient	200 nontubal infertility couple	417 nontubal infertility	1855 primary infertility women	110 non tubal primary infertility women
Intervention	Ovulation induction - follicular monitoring & HCG inj as follicle size 18-20mm followed by IUI or FSP after 34-36 hrs.	Ovulation induction by different methods at different centers. followed by HCG trigger followed by insemination of washed semen	Ovulation induction followed by HCG as follicle reach appropriate size and procedure after 34-36 hrs	Ovulation induction by letrozole 2.5mg. followed by follicular monitoring - HCG trigger for follicular rupture given 34-36 hrs before procedure. Double inseminate density gradient swim up technique washed semen by IUI or FSP.
outcome measures	Clinical pregnancy rate IUI-22(11.95%) FSP-48(21.81%)	Live birth IUI-27(12.9%) FSP-21(10.1%)Clinical Pregnancy-IUI-30(14.3%) FSP (11.6%)	Farquhar2013 Clinical PregnancyIUI-30/211 & 24/206.	Clinical pregnancy-IUI (10) FSP (15)statistically not significant difference
Results	For nontubal subfertility, statistical results (p-value <0.05) indicate clear benefit for FSP over IUI.	There was no evidence of an improvement in live birth rates, with FSP compared to IUI.	No evidence of statistically significant deference noted between IUI & FSP	No evidence of statistically significant deference noted between IUI & FSP

Overall the he above tabulated studies suggest that in women with nontubal infertility can be treated with either of the 2 artificial insemination technique FSP appear betterhavingbetter outcome than standard IUI. Implication for research - Further research is required to prove better efficacy of FSP technique over standard IUI.

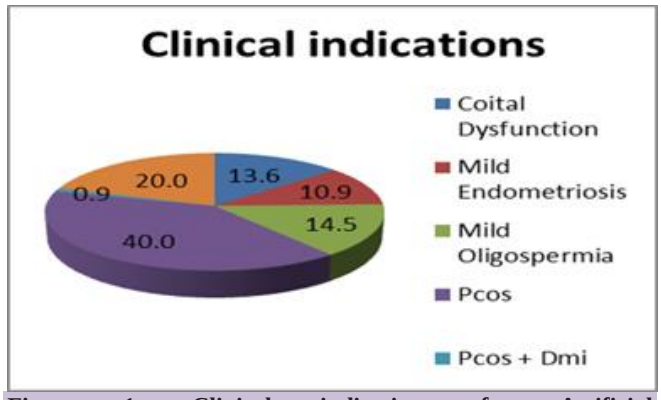

Figure 1: Clinical indications for Artificial insemination(IUI/FSP)

Discussion

The present prospective randomized comparative study was conducted to evaluate and compare the effectiveness of Intrauterine Insemination (IUI) and Fallopian Tube Sperm Perfusion (FSP) in the management of primary non-tubal infertility.[15-20]

The baseline demographic characteristics of both groups were comparable with respect to age, duration of infertility, tubal status, and semen parameters, thereby minimizing potential confounding factors and allowing an objective comparison of treatment outcomes.

The mean age of women included in the study was 28.19 ± 2.80 years, which is comparable to that reported by Shekhawat et al. and Farquhar et al,[18,21]Similarly, the mean duration of infertility and semen characteristics in our study were comparable to those reported in previous studies evaluating artificial insemination techniques.

In the present study, all patients underwent controlled ovarian stimulation with letrozole followed by hCG trigger and insemination 36–40 hours later. Uniform ovarian stimulation and semen preparation protocols were employed in both groups to reduce treatment-related bias.

The primary outcome measure was clinical pregnancy rate. Clinical pregnancy was achieved in 10 of 55 women (18.2%) in the IUI group compared with 15 of 55 women (27.3%) in the FSP group. Similarly, chemical pregnancy was observed in 12 women in the IUI group and 18 women in the FSP group. The higher pregnancy rates observed in the FSP group suggest a potential advantage of Fallopian Tube Sperm Perfusion over conventional IUI in the treatment of non-tubal infertility.

The improved pregnancy outcome observed with FSP may be explained by the use of a larger volume of sperm suspension, which facilitates sperm transport through the uterine cavity and fallopian tubes, thereby increasing the concentration of motile sperm at the site of fertilization.[12,13] By reducing sperm reflux

and enhancing tubal exposure to spermatozoa, FSP may improve the likelihood of successful fertilization.

Our findings are in agreement with those reported by Shekhawat et al,[21] who demonstrated significantly higher pregnancy rates with FSP compared with conventional IUI and concluded that FSP offers a clinical advantage in selected infertile couples. Similar observations have been reported in studies suggesting that tubal perfusion with larger volumes of processed sperm may enhance fertilization potential.

However, not all published studies have demonstrated superiority of FSP. Farquhar et al., in a multicentric randomized controlled trial, reported comparable pregnancy rates between IUI and FSP and concluded that routine use of FSP could not be recommended over conventional IUI.[18] Differences in study population, ovarian stimulation protocols, semen preparation techniques, sample size, and inclusion criteria may account for the variation in outcomes among different studies.[7,18]

Regarding secondary outcomes, no statistically significant differences were observed between the two groups with respect to miscarriage rate, multiple pregnancy, ectopic pregnancy, or ovarian hyperstimulation syndrome. This suggests that FSP does not increase treatment-related complications when compared with conventional IUI.

The major strengths of the present study include its prospective randomized design, uniform ovarian stimulation protocol, standardized semen preparation technique, and comparable baseline characteristics between study groups. However, the relatively small sample size and single-centre design may limit the generalizability of the findings. Larger multicentric randomized controlled trials are required to further validate the observed benefits of FSP.[7,18,20]

Overall, the findings of the present study indicate that Fallopian Tube Sperm Perfusion may provide superior pregnancy outcomes compared with conventional Intrauterine Insemination in women with non-tubal infertility, while maintaining a comparable safety profile.

Limitations of the study

The present study was a prospective randomized comparative study conducted at a single tertiary care centre. Certain limitations should be considered while interpreting the results.

First, the sample size was relatively small, which may have limited the statistical power of the study and the generalizability of the findings. Second, participants were followed only up to 12 weeks of gestation following confirmation of clinical pregnancy. Therefore, important reproductive outcomes such as ongoing pregnancy rate, live birth rate, and perinatal outcomes could not be evaluated.

Furthermore, only a single cycle of Intrauterine Insemination (IUI) or Fallopian Tube Sperm Perfusion (FSP) was performed in each participant. In contrast, several published studies have evaluated cumulative pregnancy outcomes over multiple treatment cycles, which may provide a more comprehensive assessment of treatment efficacy.

Conclusion

The present prospective randomized comparative study evaluated the efficacy of Fallopian Tube Sperm Perfusion (FSP) and conventional Intrauterine Insemination (IUI) in women with non-tubal infertility undergoing controlled ovarian stimulation.

The clinical pregnancy rate was higher in the FSP group (27.3%) than in the IUI group (18.2%); however, the difference did not reach statistical significance.Still we can suggest that FSP may offer an advantage over conventional IUI in achieving pregnancy among appropriately selected women with non-tubal infertility.The improved outcomes associated with FSP may be attributed to the use of a larger volume of processed sperm suspension, facilitating enhanced sperm transport through the uterine cavity and fallopian tubes and increasing the likelihood of fertilization.

Although FSP is associated with higher procedural costs owing to increased media requirements and the use of specialized catheters, the higher pregnancy rates observed in the present study may justify its consideration as an alternative to standard IUI in selected cases.

No significant differences were observed between the two groups with respect to miscarriage, multiple pregnancy, ectopic pregnancy, or ovarian hyperstimulation syndrome, indicating a comparable safety profile.

Further large-scale multicentric randomized controlled trials with multiple treatment cycles, longer follow-up, and assessment of live birth rates are required to confirm these findings and establish the definitive role of Fallopian Tube Sperm Perfusion in the management of non-tubal infertility.

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Conflicts of interest

There are no conflicts of interest.

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