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Original Research Article

A prospective observational study comparing two embryo-transfer catheters and techniques to evaluate their impact on pregnancy outcomes

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ABSTRACT

Background: The procedure of embryo transfer (ET) is a critical determinant of success in the field of assisted reproductive technology (ART), and the choice of transfer catheter may influence pregnancy outcomes. Although soft ET catheters are generally preferred because of their atraumatic design, metallic catheters may offer technical advantages in selected cases with challenging cervical anatomy. This prospective observational study compared pregnancy outcomes between the Edwards-Wallace soft catheter and the Easy Flex metal catheter.
Methods: Thirty-two women undergoing intracytoplasmic sperm injection (ICSI)/ *in vitro* fertilization (IVF) treatment at Risaa IVF Centre, New Delhi, between November 2025 and May 2026 were enrolled. Patients were allocated into two equal groups (n=16 each) based on the ET catheter selected according to findings from a mock ET. Baseline demographic characteristics, ovarian reserve parameters, stimulation characteristics, embryological outcomes, and β-hCG confirmed pregnancy rates were compared. The primary outcome was a positive pregnancy test measured by serum β-hCG test performed 14 days after ET.
Results: Baseline clinical characteristics, ovarian reserve markers (AFC and AMH), gonadotropin requirements, oocyte yield, fertilization rates, blastocyst formation and development, and the number of embryos transferred were same among the two groups and was statistically insignificant ($p>0.05$). Positive serum β-hCG test was observed in 8 of 16 patients (50.0%) in the Easy Flex metal catheter group and 7 of 16 patients (43.8%) in the Edwards-Wallace group. No statistically significant difference in pregnancy outcomes was identified between the groups (OR=1.29, p=1.000).
Conclusions: The Easy Flex metal catheter and the Edwards-Wallace soft catheter demonstrated comparable clinical performance with respect to positive pregnancy outcomes following IVF/ICSI. These findings suggest that catheter selection may be guided by procedural considerations and operator preference rather than expected differences in pregnancy rates. Large scale randomized controlled trials and studies are required to validate these findings.

Keywords: Embryo transfer, IVF, ICSI, Embryo transfer catheter, Edwards-Wallace catheter, Easy Flex metal catheter, Assisted reproductive technology, Pregnancy outcome

INTRODUCTION

The process of embryo transfer (ET) is widely recognized as one of the most important and critical steps in the field of ART, directly influencing the success and final outcome of IVF cycles. Despite substantial advances in ovarian stimulation protocols, quality of embryo culture systems, and improved laboratory techniques, implantation rates remain suboptimal, making ET a key determinant of treatment outcome. Although embryo quality, chromosomal abnormalities, and developmental competence contribute significantly to implantation

failure, several procedural factors associated with ET have also been shown to affect the final outcome in terms of clinical pregnancy rates.

Several studies have shown increases in clinical pregnancy rates resulting from improvements in various aspects of the ET technique, including cervical cleaning, a full bladder, a dummy or mock transfer either before starting ovarian stimulation or immediately before ET, pretreatment cervical dilatation in difficult cases, and ultrasound guidance.[1-11]

The type of ET catheter has also been the subject of considerable discussion. Soft catheters, including the Edwards-Wallace and Cook catheters, have generally been associated with higher pregnancy rates than rigid or semi-rigid catheters because they minimize endometrial trauma and reduce uterine contractions during transfer. Consequently, soft catheters have become the preferred choice in routine clinical practice.

Many large retrospective studies have reported higher clinical pregnancy rates with "soft" ET catheters such as the Cook catheter and the Wallace catheter compared with "hard" embryo catheters such as the TDT (Tight difficult transfer) catheter, Frydman catheter, Tomcat catheter, Tefcat catheter, and Rocket ET catheter.[12-16]

However, difficult ETs caused by cervical stenosis, tortuous cervical canals, or anatomical variations may necessitate the use of metallic or reinforced catheters that provide greater stability and facilitate passage through the cervical canal. In such situations, the technical advantages of metallic catheters may outweigh concerns regarding increased rigidity. Nevertheless, it remains unclear whether the choice of catheter independently influences pregnancy outcomes or whether the underlying procedural difficulty is the primary determinant of success.

The available evidence from prospective studies remains limited and, in many cases, inconclusive because of relatively small sample sizes and methodological differences. Therefore, the present prospective observational study was conducted to compare the clinical performance of the Easy Flex metal catheter and the Edwards-Wallace soft catheter by evaluating positive pregnancy outcomes following ET in women undergoing IVF treatment.

METHODS

In this prospective study, conducted at our private fertility clinic Risaa IVF Centre, New Delhi, India during a period occurring between November 2025 and May 2026.

The study included a total of 32 participants as per the inclusion and exclusion criteria.

The study included certain inclusion criteria- female age between 25-40 Years, male age between 25-45 years, women with regular ovulatory menstrual cycles every 21-35 days, bilateral ovaries present, no chronic medical illness in the male or female Partner, no current or past disease affecting ovaries or gonadotropin production and release, or sex steroid secretion, clearance or excretion in the female partner, not on any current hormone therapy (either male or female partner).

The study also included certain exclusion criteria - infertility caused by severe male factor, interruption of ART cycles at any phase, patients lost to Follow-up and Patient not willing to participate in the study.

Ethical clearance was taken prior to onset of study from the requisite ethical board.

The patients were primarily divided into two groups as per the type of catheter that would be used for the procedure of ET: Easy Flex metal catheter group (group 1) and Edwards-Wallace embryo catheter (group 2).

The choice of catheter to be used for the final ET procedure was made based on the difficulty encountered during a mock ET.

Each group had a total of 16 patients. All the patients signed written and informed consent forms and were made aware of the study.

The primary outcome was defined as a positive pregnancy test confirmed by measurement of serum ß-human chorionic gonadotrophin (ß-hCG) blood test. All the patients included in the study underwent this test 14 days after the ET procedure. Positive pregnancy test was considered once the value detected was above the 25 mIU/mL.

We also collected the following data: age, cause of infertility, antral follicular count (AFC), anti Müllerian hormone (AMH), total gonadotropin dose, number of retrieved Cumulus Oophorus Complexes (COC's), oocytes at metaphase II (M2 Oocytes), fertilized oocytes in 2 PN (2 Pronuclei), embryos generated, blast status, number of embryos transferred and beta-hCG outcomes (Table I). Each woman included in the study underwent sampling procedure by standard venipuncture on cycle day 2 or day 3 to understand baseline hormonal profile. The antagonist protocol was used for controlled ovarian stimulation. At an average, stimulation was conducted for 10 days in both the groups. Both groups received dual trigger (recombinant hCG 6500 IU and Triptorelin 0.2 mg subcutaneously). Oocyte retrieval was conducted 35 hours post trigger administration.

Follicles were collected post retrieval and divided into two equal groups based on the retrieval method used. Post collection, Cumulus-oocyte complexes (COCs) were cultured in single step media for physiological maturation till ICSI. COCs were denuded enzymatically under Hyaluronidase solution (80 IU/ml) followed by

mechanical removal by pipetting with Denupets (Vitromed). Metaphase II oocytes were evaluated and select under a stereomicroscope. Only oocytes in metaphase II were injected. The oocytes were incubated in single step media (Irvine CSCNX). In both groups, the ICSI procedure was performed on heated stage at 37°C under an inverted microscope (Olympus IX73) at 300-400X magnification. ICSI procedure was performed by Narishighe Micromanipulator system (Pneumatic based). Post-ICSI, injected eggs were cultured in Irvine CSCNX. Normal fertilization was defined as zygotes with 2 pronuclei, then fertilized oocytes were continuously cultured in Irvine CSCNX.

The Easy Flex metallic catheter set is a medical device typically manufactured in India and is there in the Indian Market since 2016, designed specifically for difficult ETs. It features a metallic-reinforced or malleable inner stylet/catheter that provides structural strength and improved handling during cervical passage.

Metallic shaft with malleable spring

The metal reinforcement or malleable mandrel made of rigid steel allows for better control, making it easier to guide the catheter through a difficult or tight cervical tract. It has been designed with a malleable spring and bulb tip for easy negotiation. The soft Malleable Spring gives easy entry to the cervical canal.

Key features

Multi-part design

The standard Easy Flex catheter set consists of-an outer metallic guiding catheter and the soft inner loading catheter.

Safety and comfort

The soft, flexible intrauterine catheter is designed to minimize trauma to the fundus.

Depth markings

The outer cannula usually includes markings to indicate the depth of insertion for precise positioning.

Luer lock handle

Features a secure Luer lock connection to safely attach to syringes during the transfer process.

Easy Flex inner catheter is specially designed for usage along with the Easy Flex steel catheter.

The catheter is made of flexible steel reinforcement which enables to smooth passage in case of the multiple distortions.

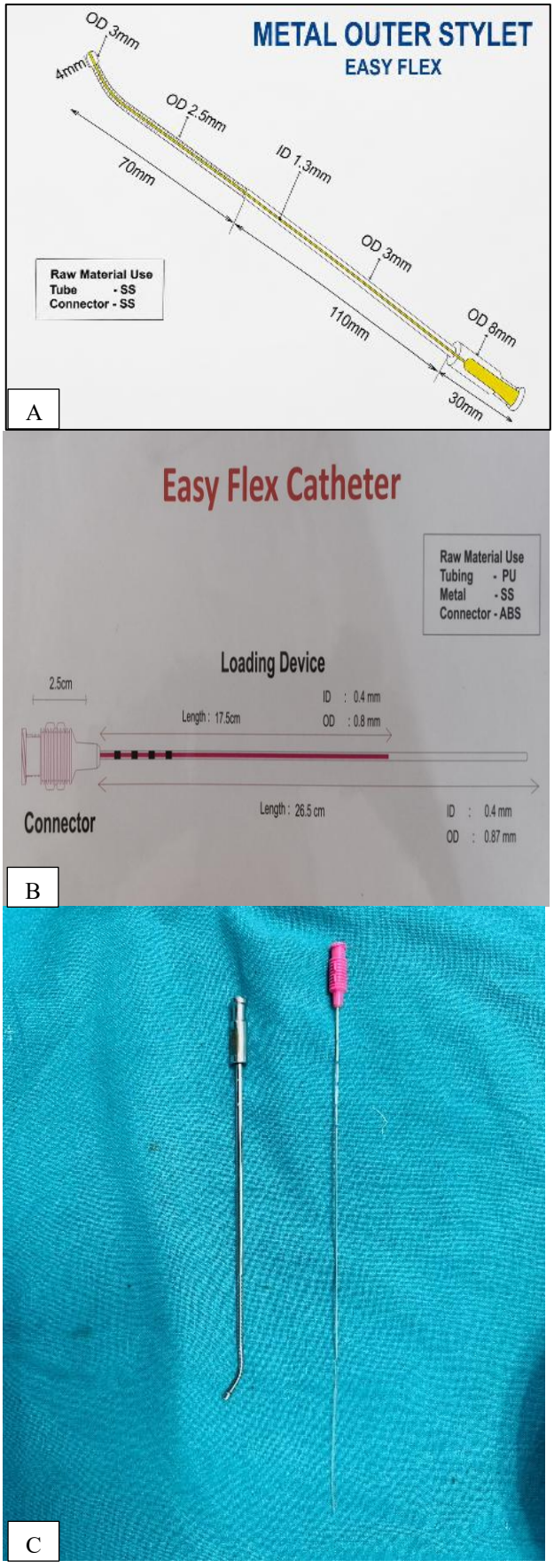

Figure 1 (A-C): Easy flex metal catheter set (outer and inner catheter).

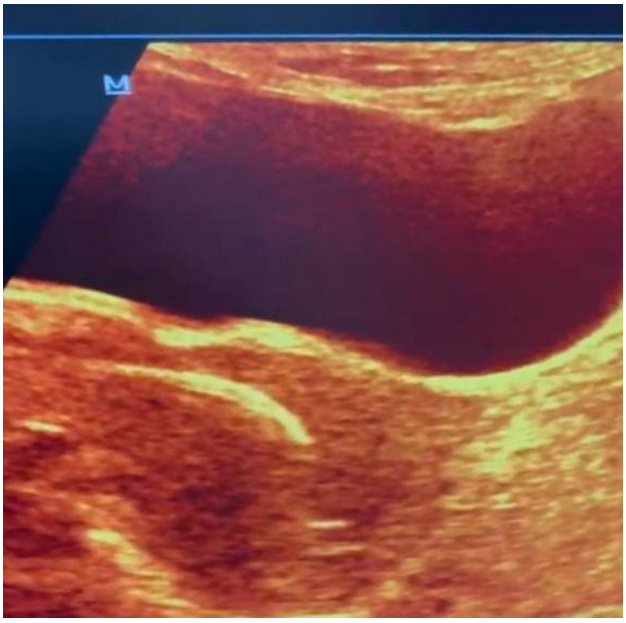

Figure 2: ET with easy flex metal catheter on ultrasound.

The Edwards-Wallace catheter (now primarily produced by Cooper Surgical as the Wallace Embryo Replacement Catheter) is a flexible, soft polyurethane catheter widely used in IVF to gently deposit embryos into the uterus. It remains the gold standard in many clinics, often used with an outer introducer sheath or stylet for difficult anatomy.

ET was performed by only one gynaecologist with over 15 years of experience to avoid operator bias.

RESULTS

The study groups were matched by age and the following variables: Age, antral follicular count (AFC), anti Müllerian hormone (AMH), Total gonadotropin initial, number of retrieved COC's, oocytes at metaphase II, fertilized oocytes in 2 PN, embryos generated, number of embryos transferred and beta-hCG outcomes were not statistically significant.

Statistical analysis was done by using Welch's two-sample t-test. Statistical significance was defined as $p<0.05$.

The most common cause of infertility among the couples in the study was the female factor infertility (PCOS) (31.25%, n=10), female factor (endometriosis and adenomyosis) (12.5%, n=4), female factor (tubal factor) (18.75%, n=6), male factor (21.875%, n=7) and unexplained (15.625%, n=5).

The baseline characteristics of the participants were comparable between the Metal and Wallace groups. The mean age was 32.00±2.22 years (median: 32.00) in the Metal group and 32.75±2.70 years (median: 33.50) in the Wallace group, with no statistically significant difference (p=0.397).

The mean antral follicle count (AFC) was 9.38±1.09 (median: 9.00) in the Metal group compared with 9.25±1.13 (median: 9.00) in the Wallace group (p=0.752).

Similarly, the mean AMH level was 1.83±0.28 (median: 1.85) in the Metal group and 1.82±0.22 (median: 1.80) in the Wallace group, with no significant difference (p=0.944). The mean total FSH dose was 1893.75±685.47 (median: 1687.50) in the Metal group and 1792.19±882.45 (median: 1575.00) in the Wallace group (p=0.719).

The mean total HMG dose was 1145.31±389.04 (median: 900.00) in the Metal group and 1285.94±482.61 (median: 1162.50) in the Wallace group (p=0.372). Overall, there were no statistically significant differences between the Metal and Wallace groups for age, AFC, AMH, total FSH dose, or total HMG dose.

Table 1: Basic demographic parameters for causes of infertility.

Cause of infertility	N	Percentage (%)
Female factor infertility-PCOS	10	31.25
Female factor-endometriosis and adenomyosis	4	12.50
Female factor-tubal factor	6	18.75
Male factor	7	21.875
Unexplained	5	15.625

Table 2: Comparison of baseline and laboratory outcomes between metal and Wallace groups.

Variables	Metal group	Wallace group	P value
Age (in years)	32.00±2.22; median 32.00	32.75±2.70; median 33.50	0.397
AFC	9.38±1.09; median 9.00	9.25±1.13; median 9.00	0.752
AMH	1.83±0.28; median 1.85	1.82±0.22; median 1.80	0.944
Total FSH dose	1893.75±685.47; median 1687.50	1792.19±882.45; median 1575.00	0.719
Total HMG dose	1145.31±389.04; median 900.00	1285.94±482.61; median 1162.50	0.372

Table 3: Comparison of embryological and primary outcomes outcomes between metal and Wallace groups.

Variables	Metal group	Wallace group	P value
COC	14.88±2.60; median 14.50	15.00±2.00; median 15.00	0.880
M2	8.19±1.64; median 8.00	8.69±1.66; median 9.00	0.399
2PN	7.69±1.40; median 7.50	8.38±1.67; median 9.00	0.217
Blast status	3.56±0.81; median 3.50	4.06±1.12; median 4.00	0.161
No of embryos transferred	2.00±0.00; median 2.00	2.00±0.00; median 2.00	Not applicable
Beta hCG outcome	Positive 8 (50.0%), Negative 8 (50.0%)	Positive 7 (43.8%), Negative 9 (56.2%)	OR=1.29 P=1.000

The embryological and clinical outcomes were comparable between the Metal and Wallace groups. The mean number of COC was 14.88±2.60 (median: 14.50) in the metal group and 15.00±2.00 (median: 15.00) in the Wallace group, with no statistically significant difference (p=0.880). The mean number of M2 oocytes was 8.19±1.64 (median: 8.00) in the Metal group compared with 8.69±1.66 (median: 9.00) in the Wallace group (p=0.399). Similarly, the mean number of 2PN embryos was 7.69±1.40 (median: 7.50) in the metal group and 8.38±1.67 (median: 9.00) in the Wallace group, with no significant difference (p=0.217).

The mean blastocyst status was 3.56±0.81 (median: 3.50) in the Metal group and 4.06±1.12 (median: 4.00) in the Wallace group; however, this difference was not statistically significant (p=0.161). The number of embryos transferred was 2.00±0.00 (median: 2.00) in both groups, and therefore no statistical comparison was applicable. Regarding beta-hCG outcome, 8 participants (50.0%) in the Metal group had a positive beta-hCG result, while 8 (50.0%) had a negative result. In the Wallace group, 7 participants (43.8%) had a positive beta-hCG result and 9 (56.2%) had a negative result. The odds ratio was 1.29, with a p-value of 1.000, indicating no statistically significant difference in beta-hCG positivity between the two groups. Overall, none of the assessed embryological or beta-hCG outcomes showed a statistically significant difference between the Metal and Wallace groups.

Comparing the efficacy of both catheters for the primary outcome, there was no significant difference (p>0.05) between the Easy Flex metal catheter and the Wallace catheters. The primary outcome showed no difference between the groups.

DISCUSSION

In previous literature, superiority of flexible catheters over rigid and semi-rigid ones has been well-established. Abou Setta et al in their review, concluded that flexible catheters have better pregnancy rates when compared to rigid catheters, and Ruhlmann et al demonstrated that the implantation rate is increased when using flexible catheters rather than semi-rigid ones. Several studies compared soft catheters.[17,18]

van Weering et al studied pregnancy rates comparing the TDT ET set and the Cook K-soft 5000 soft trans-universal ET set, and which found that pregnancy rates were significantly higher in the second group.[19]

Our study compared two types of ET catheters, with pregnancy rates of 50% for the Easy Flex Metal Catheter and 43.8%, for the Edwards-Wallace Catheter. We found no significant difference between the groups (p>0.05).

In our study, both the groups were matched by age, the patients underwent the same ovarian stimulation protocol and the same laboratory procedures were carried out among all subjects. There was no statistical significance among the two groups while comparing the total dose of gonadotropins and the study concluded that it did not impact our primary outcome (pregnancy rate): subsequent laboratory parameters following the controlled ovarian stimulation was similar for both groups. Thus, we had a homogeneity among various parameters while comparing both the groups of soft catheter and Easy Flex Metal catheter in hormonal and laboratory terms, which allowed us to assess whether there was a correlation between the type of catheter used for ET and the ß-hCG outcome.

Even though the present findings demonstrated comparable pregnancy outcomes between the two catheter groups., the study's small sample size limits statistical power and increases the possibility of error as well. Future multicentre randomized trials with live birth as the primary endpoint, together with implantation, miscarriage, and patient-reported outcomes, are needed to determine whether subtle differences exist between catheter systems across specific clinical subgroups.

We do believe that the main weaknesses of this study were the small sample size and the fact that it was not a randomized clinical trial (RCT).

CONCLUSION

In conclusion, this prospective study supported that the modern ET soft catheters like Edwards-Wallace Set and Metal Catheter set had a similar performance in ART procedures. Catheter choice may be based on other factors, rather than its performance on outcomes.

Although soft catheters are traditionally recommended, the absence of a statistically significant difference in this cohort suggests that appropriate catheter selection according to cervical anatomy can achieve satisfactory outcomes with either device. These observations are consistent with reports indicating that atraumatic ET, ultrasound guidance, and operator experience may exert a greater influence on success than catheter composition alone. From a clinical perspective, the ability to individualize catheter choice is important because difficult transfers have been associated with cervical trauma, bleeding, uterine contractions, and reduced implantation potential. In such situations, a reinforced metallic system can facilitate atraumatic passage while still allowing embryo deposition through a soft inner catheter.

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