

## Speculum-Free Embryo Transfer: Can It Be A New Modality?

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### Abstract

The present study aims to determine the effect of using Cusco's speculum during frozen embryo transfer (FET) in patients undergoing Assisted Reproductive technique (ART) procedure. A total of 200 patients were randomly selected, all of whom underwent In-Vitro fertilization and embryo transfer (IVF-ET) with their own gametes. The patients were divided into two groups: Group A, where Cusco's speculum was used during FET, and Group B, where it was not used. Both groups underwent the same protocol for FET and the procedure was performed by the same clinician. Three parameters were evaluated: ease of the procedure, patient's comfort level by assessing pain sensation, and pregnancy rates as determined by serum beta-hCG levels. The results showed that while the ease of the procedure was comparable in both groups, patients in Group B reported significantly less discomfort or pain. Additionally, Group B had a higher pregnancy rate (62.37%) compared to Group A (55%).

The use of Cusco's speculum was found to provide better visualization and control during ET, but it also caused increased discomfort for patients and slightly attenuated ultrasound visualization. Conversely, not using the speculum reduced patient discomfort and enhanced ultrasound visibility but had a marginally higher risk of catheter dislodgement.

In conclusion, the decision to use Cusco's speculum during ET should be individualized based on the patient's anatomy, comfort level and clinician experience, as both approaches have their respective advantages and disadvantages.

**Keywords:** IVF, FET, Cusco's Speculum, Speculum-Free Transfer

### 1. Introduction

The journey of In-Vitro Fertilization followed by Embryo Transfer (IVF-ET) began in 1978 by Patrick Steptoe and Sir Robert Edwards in a small country-side hospital in London. Since 1987 when the Society for Assisted Reproductive Technology (SART) and 1997 when the CDC began to report the outcomes of ART procedures, success rates of pregnancy for various clinics have improved significantly [1].

Given the magnitude of the problem of subfertility as we come across in the present scenario, IVF-ET is no longer a "sophisticated treatment of choice". As the need of ART has been increasing worldwide, the requirement of more accurate methods and protocols to increase the success rate, have become a necessity.

The last 30 years have borne witness to significant advances in the field of ART, with many spheres having undergone improvement. However, ET, the critical final step in an IVF cycle, has remained largely technically unchanged since first described in 1984 [2]. The goal of a successful ET is to deliver the embryo(s) atraumatically to the endometrial cavity that maximizes the chance of implantation. There has been little consensus within the scientific community regarding evidence-based guidelines to optimize ET success rate and there is no universal protocol for ET till date. Much of the published data on prognostic factors of success after ET are conflicting, inconclusive, or confounded by variables due to differing techniques that are unable to be controlled in a reliable manner [3-6].

There are various ways of Embryo transfer (ET) – depending upon whether it's Day -03 transfer, Day-05 transfer or blastocyst transfer,

frozen or fresh transfer. Depending upon the route there may be – vaginal route of transfer or transabdominal transfer. Unless needed, most of the cases of embryo transfer are done now-a-days transvaginally under trans-abdominal ultrasound guidance with a soft outer catheter with an inner catheter with a guide. In this study, we have modified the transvaginal route of embryo transfer or ET under transabdominal ultrasound guidance.

## 2. Materials & Methods

Most common method of embryo transfer is transvaginal route under transabdominal ultrasound guidance with a Tomcat or Wallace Catheter or Frydman Catheter. Most commonly used one is a Tomcat Catheter. The catheter used for Embryo transfer usually contains a soft outer sheath with rounded tip, and hard inner catheter with a stellate attached to outer end and the inner end contains a soft fine siliconized tube attached to it, though which the embryo is gently placed over the endometrium. There are many methods to prepare the endometrium, irrespective of the procedure the final process of embryo transfer is the same. The female patient is placed on a table with a bladder semi-filled in a modified lithotomy position. Initial position of the uterus is checked trans-abdominally. The inner vaginal canal and then the outer portion of the vulva is cleaned with sterile normal saline solution. Then a Cusco's speculum is introduced inside the vagina with an aim to position the external os of the cervix in mid-position. The outer sheath of the Embryo Transfer catheter is then introduced via the cervical canal inside the endometrial cavity in an optimum position. The inner catheter is then introduced under transabdominal ultrasound guidance to check the passage of the catheter and to determine the optimum placement of catheter tip to determine the embryo placement. The inner catheter is then passed on to the embryologist who loads the catheter with the embryo. Then the "loaded" catheter is gently passed on to the clinician performing the transfer. The embryo is transferred under TAS and the empty catheter is then passed on to the embryologist again to check whether the embryos have been placed in the endometrial cavity in an optimum position. After transfer is done, transabdominal ultrasound shows the properly placed embryo as a hyper-echoic dot due to presence of air-bubble and media inside the cavity.

### 3. Aim of Study

The aim of our study was to determine the effect of use of Cusco's speculum during Embryo Transfer.

### 4. Study Population

200 patients getting prepared for frozen embryo transfer were chosen randomly. The study population included patients who underwent IVF-ET with their own gamete.

#### 4.1 Inclusion Criteria:

- Couple who underwent IVF-ET with their own gamete only; i.e. with self-sperm and self-oocyte.
- All the women partner underwent FET or Frozen Embryo Transfer.
- Protocol for FET was DR-HRT or Down-Regulation followed by Hormone Replacement Therapy Protocol.

- Method of Embryo Transfer chosen was Transvaginal route under Transabdominal Ultrasound guidance.
- Two Day-05 Blastocysts were transferred in each woman, one of which was Grade 4AA. Grading was done by the same embryologist, the senior most embryologist of our clinic.
- All the Embryo-Transfers were done by same clinician, the senior most clinician of our clinic.
- Post-Embryo Transfer support medications were same in all.
- ET catheter used were made by Cooper Surgical and same in all.

#### 4.2 Exclusion Criteria:

- Couple undergoing IVF with Donor Gamete.
- Previous History of Difficult Transfer.

### 5. Study Population:

200 couples were chosen using the above criteria. We divided the study population into two study groups of 100 each.

#### 5.1 Group A: FET utilizing Cusco's Speculum

In this study group 100 patients were chosen randomly from the study population. The patients were placed in a modified lithotomy position with bladder semi-full. After cleaning the vaginal canal and outer genitalia with sterile normal saline, antiseptic dressing and draping were done. A sterile Cusco's speculum was introduced inside the vaginal canal to expose and position the External OS of cervix in optimum position. The outer sheath of the ET catheter was introduced inside the endometrial cavity under transabdominal ultrasound guidance. Then the inner catheter was introduced and position was checked. Afterwards the inner catheter was handed over to the embryologist for loading of the embryos. The Cusco's speculum was in-situ. After the embryos were loaded, the inner catheter was again introduced inside the uterine cavity via the outer catheter under TAS. Under TAS, the embryo was placed in optimum position. The inner catheter was checked whether it was clear or not. After getting a positive signal from the embryologist and ultrasound picture when it was affirmed that the embryo transfer has been done properly inside the cavity – the Cusco's speculum was removed. The patient rested for 15 minutes in the OT table – before she was transferred to bed. All of the 100 patients underwent a similar procedure.

#### 5.2 Group B: FET without Cusco's Speculum

In this study group 100 patients were chosen randomly from the study population. The patients were placed in a modified lithotomy position with bladder semi-full. After cleaning the vaginal canal and outer genitalia with sterile normal saline, antiseptic dressing and draping were done. A sterile Cusco's speculum was introduced inside the vaginal canal to expose and position the External OS of cervix in optimum position. The outer sheath of the ET catheter was introduced inside the endometrial cavity under transabdominal ultrasound guidance. Then the inner catheter was introduced and position was checked. Then the Cusco's speculum was removed leaving the outer sheath of ET catheter in-situ. The inner catheter was then handed over to the embryologist for loading of the embryos. After the embryos were loaded, the inner catheter was again introduced inside the uterine cavity via the outer catheter

under TAS. Under TAS, the embryo was placed in optimum position. The inner catheter was checked whether it was clear or not. After getting a positive signal from the embryologist and ultrasound picture when it was affirmed that the embryo transfer has been done properly inside the cavity. The patient rested for 15 minutes on the table – before she was transferred to bed. Out of 100 patients in this group – all of the 97 patients underwent the procedure as planned. In the case of 3 patients, due to difficulty the Cusco’s speculum was kept in-situ during the whole procedure. These 3 patients were excluded from the study group.

## 6. Results

Three parameters were checked between two groups -

- Ease of the Procedure
- Patient’s Comfort Level
- Effect on outcome of FET, i.e. pregnancy positivity rate checked by Beta-hCG Level.

It was found that except in the three excluded cases in Group B, “ease” of the procedure was the same in both groups as experienced by our senior most clinician during embryo transfer.

The patients felt more comfort in Group B than Group A. Patients felt more comfort, less vaginal fullness, less discomfort or pain in Group B than group A. The overall patient’s satisfaction level was more in Group B than Group A. We used Visual analog scale (VAS) (Pain Scale) for this purpose.

Beta-HCG was checked in both groups after 14 days from Embryo Transfer to check the outcome of the procedure. In Group A, 55 patients were pregnancy positive out of 100 (Pregnancy Positivity Rate: 55%). In Group B, 58 patients were pregnancy positive out of 93 women. (Pregnancy Positivity Rate: 62.37%)

## 7. Statistical Methods

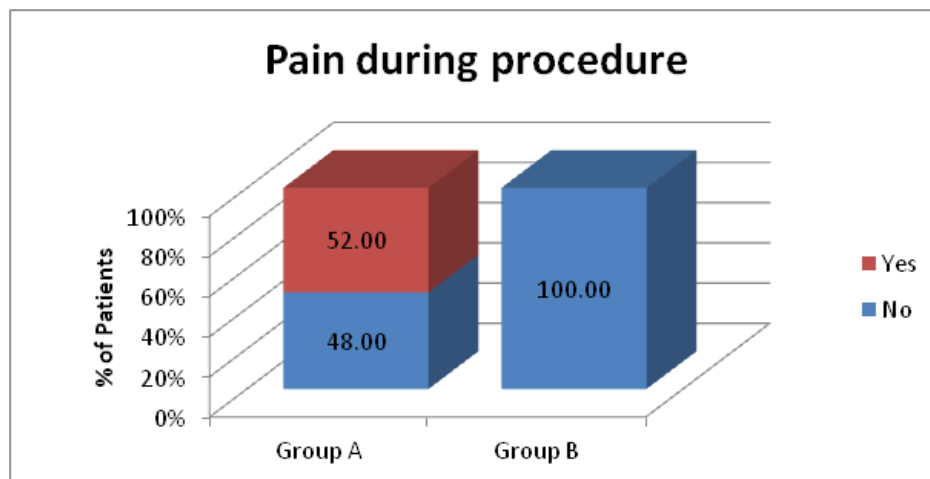
Categorical variables are expressed as Number of patients and percentage of patients and compared across the groups using Pearson’s Chi Square test for Independence of Attributes/ Fisher’s Exact Test as appropriate.

The statistical software SPSS version 25 has been used for the analysis.

An alpha level of 5% has been taken, i.e. if any p value is less than 0.05 it has been considered as significant.

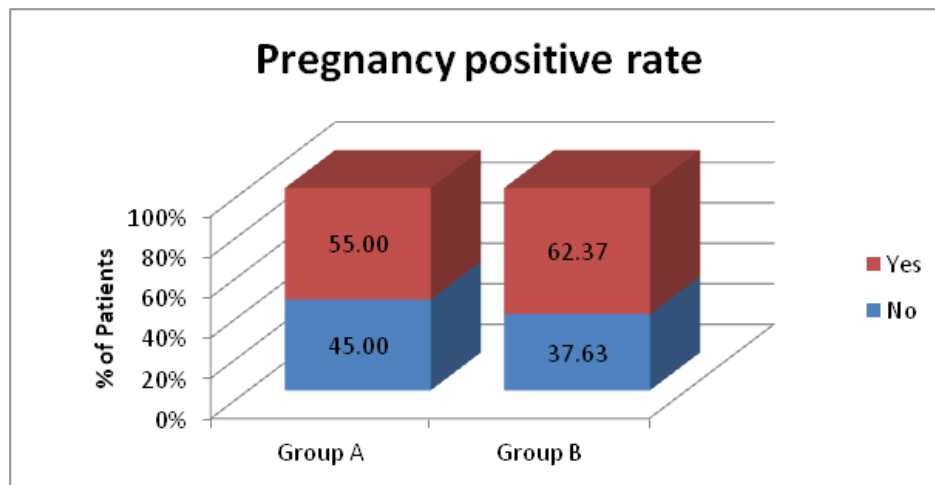
		Group		Total		
		Group A	Group B		p Value	Significance
Pain during procedure	No	48(48)	93(100)	141(73.06)	<0.001	Significant
	Yes	52(52)	0(0)	52(26.94)		
Total		100(100)	93(100)	193(100)		

**Table 1: Data Analysis Using Fisher's Exact Test**



		Group		Total		
		Group A	Group B		p Value	Significance
Pregnancy positive rate	No	45(45)	35(37.63)	80(41.45)	0.299	Not Significant
	Yes	55(55)	58(62.37)	113(58.55)		
Total		100(100)	93(100)	193(100)		

**Table 2: Data Analysis Using Pearson’s Chi Square Test for Independence of Attributes**



## 8. Discussion

The most commonly performed ET techniques: trial with transfer, afterload, or direct. For trial with transfer, the procedure begins with passage of a trial catheter up to or just through the internal os. The embryo(s) are then loaded into the same or a different catheter and the transfer is performed. For afterload, the inner catheter is placed approximately 1 cm beyond the outer sheath; the outer and inner sheaths are then advanced together until the leading tip reaches or is just beyond the level of the internal os; then the inner catheter is removed; the loaded catheter is then passed through the outer sheath to the desired location within the endometrial canal. For direct ET, the catheter is immediately loaded with embryo(s) and advanced directly through the internal os to the desired place within the cavity.

All steps of the ET procedure addressed in the survey by ASRM were analyzed for concordance among the respondents. Of the 48 total steps of ET practice analyzed, 10 of them were considered highly conserved with at least 85% of respondents having the same answer.

There were five steps of the procedure in which respondents indicated highly discordant practice occurring among 40%–56% of respondents: [a] presence of standard ET protocol; [b] universal use of patient relaxant medication of ET; [c] use of warmed speculum; [d] straight versus rotating direction of catheter removal; and [e] patient remaining supine for less than or greater than 15 minutes after transfer [7].

In our study we have tried to work on this and find out even more accurate method to optimize embryo transfer. The use of Cusco's speculum during embryo transfer with different techniques, can have both advantages and disadvantages compared to not using it.

### 8.1 Using Cusco's Speculum

#### 8.1.1 Advantages:

- **Visualization:** Cusco's speculum allows for better visualization of the cervix physically, which can help in accurately positioning the embryo transfer catheter.
- **Control:** The speculum helps in maintaining cervical stability

during the procedure, reducing the risk of accidental dislodgement of the catheter.

- **Dislodgement of the Catheter:** As the whole procedure is done with the speculum inside the vagina under direct physical vision, there may be less chance of dislodgement of the catheter.

#### 8.1.2 Disadvantages:

- **Discomfort:** The use of a speculum can cause discomfort or pain for some patients.
- **Invasiveness:** It is an additional invasive step in the procedure, which might not be necessary for all patients.
- **Visualization:** The speculum in-situ creates attenuation in TAS. Its makes visualization under TAS more difficult.

### 8.2 Not Using Cusco's Speculum

#### 8.2.1 Advantages:

- **Reduced Discomfort:** Avoiding the use of a speculum can make the procedure less uncomfortable for the patient.
- **Simplicity:** The procedure can be quicker and simpler without the need for additional equipment.
- **Better Ultrasound Visualization:** After removing the speculum, the utero-cervical canal becomes less angulated, and comes in a more or less single axis. The shadow of the anterior lip of the Cusco's speculum is also disappears after its removal – making the ultrasound picture clearer. So, the visualization becomes better.
- **Potential for Movement:** As the speculum is removed before the embryo transfer. There is less chance of movement of cervix after embryo transfer. So is the dislodgement of embryo.

#### 8.2.2 Disadvantages:

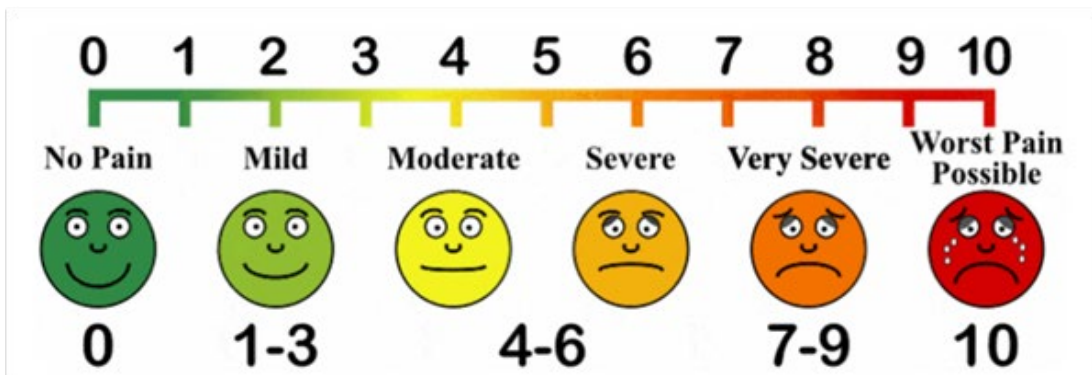
- **Dislodgement of the Catheter:** There is a slightly increased risk of accidental dislodgement of the catheter.

## 9. Conclusion

Embryo Transfer is an important step rather crucial step in IVF. The decision to use Cusco's speculum during embryo transfer depends on the individual patient's anatomy, comfort level, and the clinician's preference and experience. Both approaches have their pros and cons, and the choice should be tailored to the specific circumstances of each patient. Patient selection in this procedure

seems to be the most specific point for successful transfer. The speculum-less transfer can be more rewarding than the with-speculum transfer. However, a multi-centric study involving an AI-model comparing whole ultrasound video or still images maybe

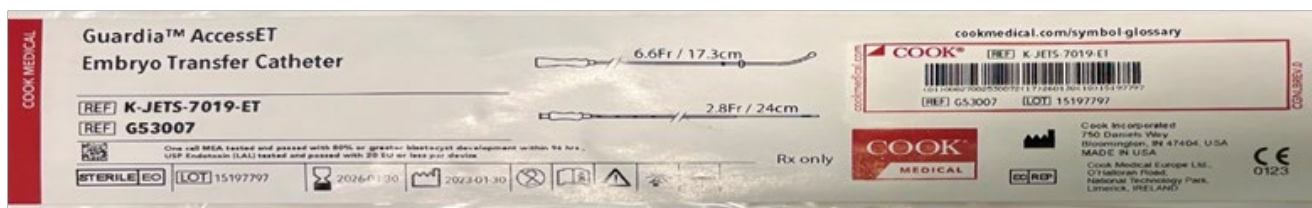
useful in drawing a better conclusion and making significant advancement in the Embryo transfer procedure bringing smile of joy to hundreds, if not thousands around the world.



**Figure 1:** Visual Analogue Scale (Conventional). We used the same and asked patients for the level of discomfort she felt instead of pain



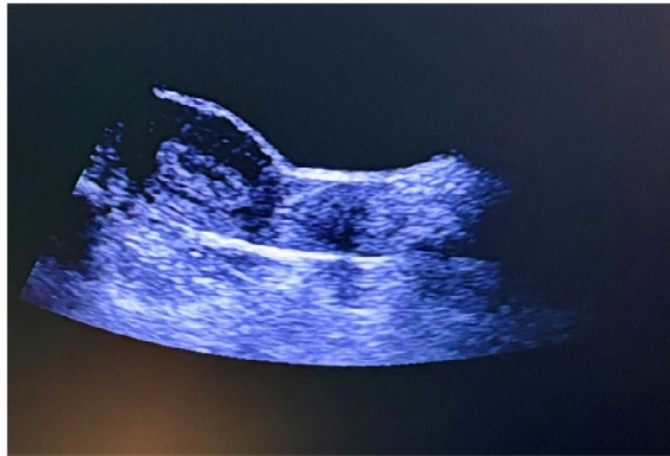
**Figure 2:** Cusco's Speculum



**Figure 3:** Back Panel of sealed packet of “Guardia AccessET” – Embryo Transfer Catheter



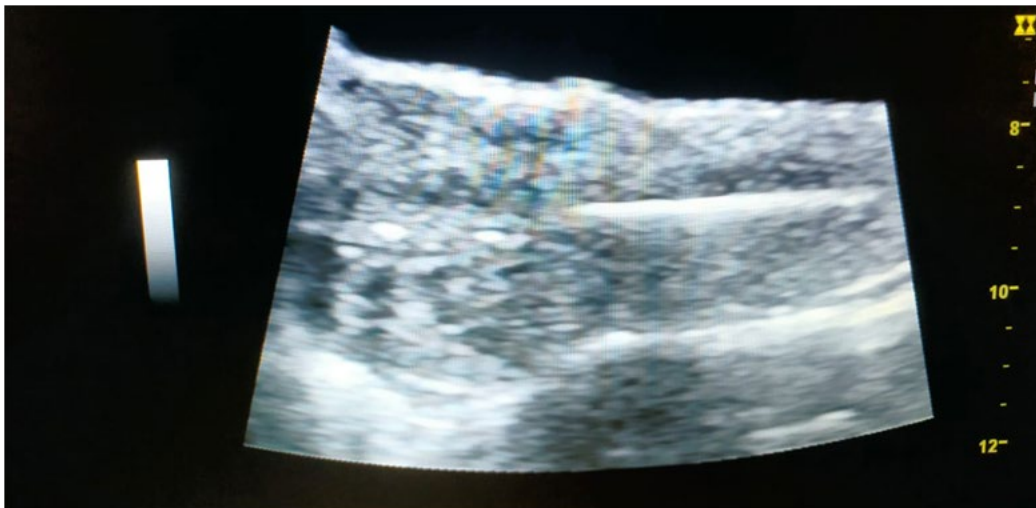
**Figure 4:** Embryo Transfer Catheter



**Figure 5:** Uterus with Cusco's Speculum in-situ. The Lips of the Speculum are visible as long hyper-echoic line- creating artifacts in Transabdominal Ultrasound image.



**Figure 6:** Trans-abdominal Ultrasound: Cusco's speculum was removed after introduction of the outer sheath. Better Visualization, the utero-cervical canal line is more significantly straightened than Cusco's speculum in-situ.



**Figure 7:** Transabdominal Ultrasound- without speculum. Better Visualization, better accessibility. More or less straight utero-cervical canal facilitating smooth passage of catheter. The outer catheter is visible as bright straight line.

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