

Use of Versapoint to refashion the cervical canal to overcome unusually difficult embryo transfers and improve *in-vitro* fertilization-embryo transfer outcome: A case series

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ABSTRACT

BACKGROUND: Smooth atraumatic embryo transfer is paramount for the success of *in-vitro* fertilization (IVF). In difficult cases, cervical canal manipulation may be required. **AIM:** To see if surgical correction of the cervical canal or cervical canal refashioning could improve ease of embryo transfer. **SETTING:** Private infertility and IVF hospital. **Design:** Prospective study. **MATERIALS AND METHODS:** Patients: 11 women with failed 1-3 IVF cycles with history of extremely difficult embryo transfers (ETs) despite undergoing cervical dilatation in the cycle prior to IVF. **INTERVENTIONS:** Operative hysteroscopy using Versapoint for refashioning of the cervical canal. **MAIN OUTCOME MEASURES:** Ease of ET in the subsequent IVF cycle. Secondary outcome measure was to assess reproductive outcome. **RESULTS:** Easy and atraumatic ET in the IVF cycle after procedure in 100% patients. PR was 46.5%. **CONCLUSIONS:** Use of Versapoint for refashioning the cervical canal can improve the quality of ET and PR.

KEY WORDS: Cervical stenosis, embryo transfer, hysteroscopy, *in vitro* fertilization, Versapoint

INTRODUCTION

Embryo transfer (ET), the final step in the *in-vitro* fertilization/intracytoplasmic sperm injection (IVF/ICSI) procedure is an important independent factor affecting implantation and pregnancy. The importance of a smooth atraumatic embryo transfer in IVF-ET has been highlighted by many authors.^[1,2] A number of studies have established the fact that a difficult or traumatic ET reduces pregnancy rates (PRs).^[3,4] During a difficult transfer there is trauma to the endocervix and endometrium resulting in bleeding. Blood in the endometrial cavity compromises implantation. Blood and mucus on the transfer catheter are associated with lower PRs.^[5] Difficult transfers also lead to myometrial contractions which can lead to expulsion of the embryo.^[6] There is also an increased possibility of carrying infection into the endometrial cavity.

Cervical canal negotiation may be extremely

hard or even impossible at times. In such patients, an alternative approach or an intervention is warranted. Many interventions have been suggested to overcome this problem such as use of rigid transfer catheters,^[7] use of a metal outer sheath, use of dilator to negotiate the cervix at oocyte retrieval or ET.^[8] In case of a perceived difficulty, cervical dilatation has been done prior to the IVF cycle.^[9] In patients where this fails, Laminaria tents^[10] or a Mallecots catheter^[11] has been left *in situ* after cervical dilatation to maintain perpetuity of result. Transmyometrial transfers^[12,13] and zygote intrafallopian transfer (ZIFT)^[14] have also been advocated to surmount this predicament. Surgical intervention using a resectoscope to create a smooth cervical passage has been performed by a few physicians.^[15,16]

Aim of the study

To see if surgical correction of the cervical canal or cervical canal refashioning using Versapoint could improve ease of embryo transfer.

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MATERIALS AND METHODS

A prospective study was conducted between January 2009 and February 2010 at a private infertility clinic. It included 11 women with history of an extremely difficult and traumatic embryo transfer despite undergoing cervical dilatation just prior to the IVF cycle. Negotiation of the cervical canal during embryo transfer had to be carried out ultimately using a metal outer sheath. The transfer catheter used was from Labotech Germany. Both the outer and inner transfer catheters were covered with blood. None of the patients had achieved pregnancy in any of their IVF/ICSI attempts.

Grading of difficulty was done by giving points for each of the following problems faced [Table 1]. Use of Tenaculum - 1, use of rigid catheter (TDT) - 1, use of metal outer sheath - 2, Use of Dilator - 2, blood on outer catheter - 1, blood on inner catheter - 2. The transfer was designated an easy transfer if the score was between 0 and 1, moderately difficult transfer if the score was ≥ 2 and extremely difficult if the score was ≥ 5 .

Patient profile: Patients included were in the age group of 25–40 years. Cause of infertility was male factor in two patients - one had obstructive azoospermia (CBAVD) and had undergone Testicular Sperm Aspiration-Intracytoplasmic sperm injection (TESA-ICSI) thrice prior to this procedure. Four patients had unexplained infertility; one had poor ovarian reserve, two patients had endometriosis and two had tubal factor infertility [Table 2]. Of the 11 patients, nine suffered from primary infertility and two had secondary infertility. Of the two secondary infertility cases one had undergone salpingectomy for right-sided ectopic pregnancy and the other had suffered a spontaneous abortion at 7 weeks. Five patients had history of a previous surgery, two of them had undergone a myomectomy, one a salpingectomy and two patients had been operated for ovarian endometriosis. Number

Table 1: Score given for level of difficulty during embryo transfer

Intervention used	Score
Use of tenaculum	1
Use of rigid catheter (TDT)	1
Use of metal outer sheath	2
Use of dilator	2
Blood on outer catheter	1
Blood on inner catheter	2

Table 2: Etiology of infertility

Cause of infertility	No. of patients
Male factor	2
Unexplained Infertility	4
Poor Ovarian Reserve	1
Endometriosis	2
Tubal factor	2

of previous failed IVF cycles ranged from 1 to 3. A prior hysteroscopy done at our center or elsewhere had revealed the following cervical canal abnormalities.

- I. False passage in the cervix with acute angulation of the uterus in three patients,
- II. A tortuous cervical canal with a fibrotic internal cervical OS in five and
- III. A severely fibrotic internal OS in three patients.

In the women with a severely fibrotic OS, dilatation had not been possible beyond size 7 of a Hegar dilator. Two of the patients with a tortuous cervical canal and fibrotic internal OS had undergone cervical dilatation twice before ET - once prior to IVF and once on the day of OPU, because a mock transfer tried on that day failed. In these two patients, ET had been carried out under general anesthesia, despite that it was very difficult and traumatic. Not all dilatations and IVF-ET procedures were done at our center but records of previous procedures were available.

Intervention

Consent for operative hysteroscopy was obtained from the patients after discussing the nature of the surgery. The procedure of cervical canal refashioning was performed under general anesthesia. Patients were taken into the theater with a full bladder in case ultrasound guidance was required to access the uterine cavity. A Versapoint electrode (twizzle electrode) with a 1.9 mm Versascope (Gynecare division, Johnson and Johnson) was used for the procedure. The Versapoint electrode works on bipolar energy, so saline was used as the distension media. Versascope sheath has a small diameter (3.5 mm) and it can be inserted into the cervical canal without prior dilatation or with minimal dilatation. In two patients the canal was extremely tortuous and fibrotic and it was not possible to negotiate with the delicate Versascope. Cervical dilatation was achieved under ultrasound guidance in these women and the Versapoint twizzle electrode was introduced through the operating channel of an operating hysteroscope (Olympus).

For women with a false passage and acute angulation of the uterus [Figures 1 and 2], the tissue between the actual cervical canal and false passage was cut thus leaving a clean path which could be negotiated with an ET catheter. For the problem of a severely fibrotic OS, 1 or 2 linear releasing incisions were made with the Versapoint electrode, extending from the posterior aspect of the internal OS towards the external OS for approximately 1 cm [Figure 3]. In patients who had a tortuous cervical canal, several projecting ridges [Figure 4a and b] were seen arising from the anterior, posterior and/or lateral walls of the cervical canal. The hysteroscope was introduced into the uterine cavity and then withdrawn towards the external OS. As



Figure 1: False passage in the cervix seen posterior to the internal OS

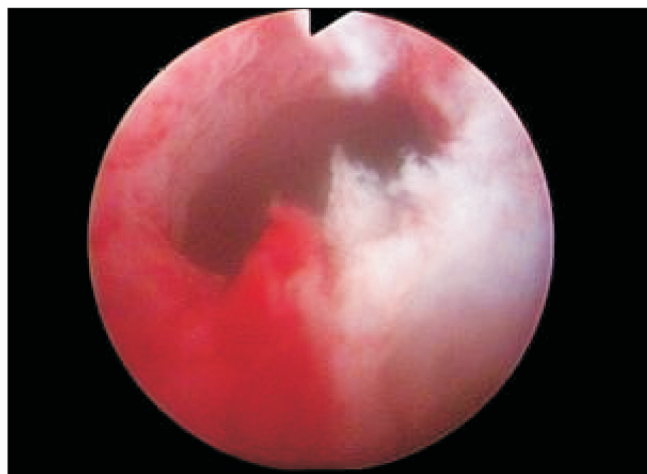


Figure 2: Acute angulation of the uterus: Cervical canal directed anteriorly and endometrial cavity directed posteriorly creating a hump at the level of the internal OS

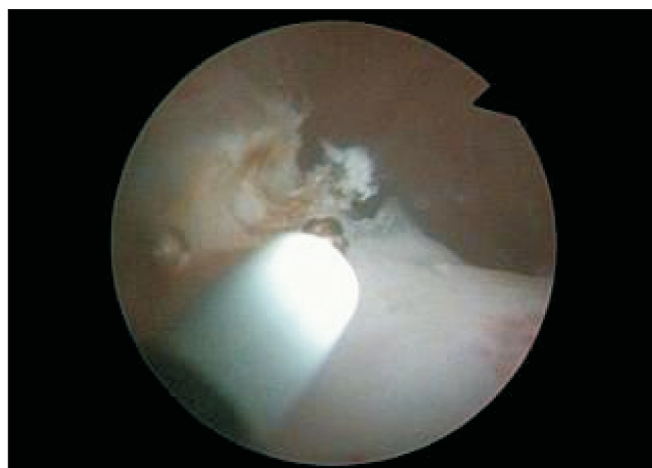


Figure 3: Linear releasing incision with Versapoint, extending from internal OS outwards for 1 cm approximately

the hysteroscope was moved outwards the cervical canal projections distorting linearity of the canal were visualized. Linear releasing incisions of approximately a centimeter were made into these projections and a straightening of the canal was achieved [Figures 5a and b]. Subsequent to the procedure, dilatation was done to further stretch the incised fibrous tissue, and it was now possible to dilate the cervix up to size 10/12 Hegar in even the most resistant cervix.

In patients where a Versascope was used, adequacy of the procedure was confirmed by introducing a dummy ET catheter before dilatation. There was no complication related to the procedure. A mock embryo transfer was performed 4–6 weeks later and the level of difficulty encountered was 0-1.

Main outcome measure(s)

Ease of ET in the subsequent IVF cycle. Secondary outcome measure was to assess reproductive outcome.

RESULTS

IVF-ET was done in all the patients within 3–4 months of the

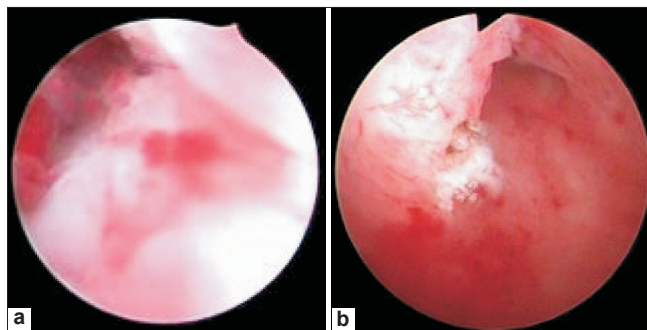


Figure 4: (a, b) Projection of tissue in to the cervical canal from right

procedure. The procedure was easy in 100% of the patients. The level of difficulty faced was '0' in 9 patients (81.9%) and '1' in 2 patients (18.2%) where we needed to stabilize the cervix with an Allis forceps without closing the ratchet. There was no blood on the inner or outer transfer catheter. Five of the 11 patients achieved pregnancy giving a PR of 46.5%. The implantation rate was 20%. Two of the patients have delivered; one had a normal delivery and one an LSCS for PIH. Three of the patients aborted 1) one had a blighted ovum 2) spontaneous abortion with a twin pregnancy and 3) missed abortion at 8 weeks.

DISCUSSION

Embryo transfer, a simple transcervical procedure is the final and most vulnerable step in IVF treatment. In a small subset of women however, performing an ET let alone an atraumatic one, can prove to be an arduous task. An incidence of 0.6%^[17] for difficult cervical canal negotiations has been quoted. The importance of a smooth atraumatic transfer is underscored by the fact that over the years there have been constant attempts to increase clinical pregnancy rates by improving ET technique and quality of catheters. Use of soft transfer catheters over rigid ones and use of ultrasound guidance for ET have been shown to increase

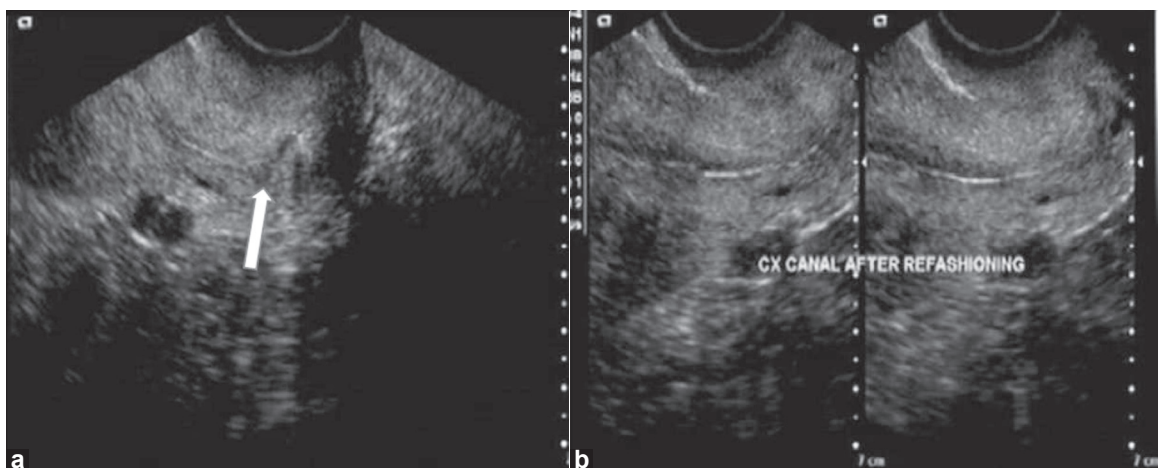


Figure 5: (a) Cervical canal angulation seen on ultrasound prior to procedure. Arrow points to the 'V' shape, (b) Curvature of the cervical canal after procedure. The canal has a less acute curvature after procedure

pregnancy rates significantly.^[18] Operator variability in ET has also been associated with a difference in pregnancy rates.^[19,20]

Difficult ET defined as a problematic negotiation of the cervical canal, blood on the transfer catheter, a need to use rigid catheters or dilators, compromises pregnancy rates. Such procedures are more frequently associated with retention of embryos in the ET catheter and/or expulsion of the embryos. Mechanical activity due to physical stimulation is capable of relocating intrauterine embryos. Junctional zone contractions can be implicated in cases of IVF/embryo transfer failure or ectopic gestation.

Patients with history of extremely difficult ET procedures represent a small but significant group of IVF failures. Many techniques have been advocated to overcome this problem but have met with limited success. Cervical dilatation in a cycle prior to IVF and even at OPU has not helped significantly.^[21] Pregnancy rates with use of dilator to overcome cervical stenosis are low. Laminaria tents and Malecot catheter have been used to perpetuate the result of cervical dilatation but these techniques yield inconsistent results and there is a theoretical risk of introducing infection into the uterine cavity.

Procedures like ZIFT, GIFT (gamete intrafallopian transfer) where gametes are transferred directly into the fallopian tube thereby avoiding cervical canal negotiation, have been tried but due to their invasive nature have not gained popularity. In addition it is not possible to use such procedures in patients with tubal factor infertility. A transmyometrial approach to ET has been used successfully by some authors though others have found that pregnancy rates are lower than with the transcervical approach.^[22] With transmyometrial ET, it is extremely difficult to transfer the embryos to the uterine cavity atraumatically.

A surgical approach to cervical stenosis was proposed by Noyes 1999 in which cervical tissue was excised hysteroscopically with a resectoscope and a smooth cervical tract was created.^[15] An intrauterine Foley catheter was placed for an extended period after resection and a significantly improved PR was reported after the procedure.

Since use of a resectoscope necessitates a greater degree of dilatation which is a difficult proposition in these patients, we elected to see if we could refashion the cervical canal using the fine Versapoint twizzle without resorting to shaving the cervical tissue. Linear releasing incisions were made in the cervical tissue to widen the OS and straighten the cervical canal. Subsequent dilatation to 10-12H further stretched the fibrous tissue. To ensure perpetuity of result we performed a mock embryo transfer 4–6 weeks later. The transfer was smooth and showed that the fibrosis had not recurred.

Use of Versascope presented a problem in patients with a very tortuous cervical canal associated with an acute flexion of the uterus. Since the instrument is very delicate and might have broken we decided to dilate the cervix under ultrasound guidance and introduce the Versapoint electrode through the operating channel of an operating hysteroscope. Dilatation and introduction of this wider instrument was a technical challenge and required constant ultrasound guidance in order to avoid perforation.

Though pregnancy was not the primary outcome measure as there are many factors affecting pregnancy and implantation, we believe that a difficult embryo transfer may have played a part in the previous IVF failure of these patients. We achieved a pregnancy rate of 46.5% in this group which is slightly higher than our overall PR of 40.9%. There was one blighted ovum in the patient who had TESA–ICSI; she was 40 years old. It is well known that

there is a higher rate of oocyte aneuploidy at an advanced maternal age, in addition to this testicular sperm was used, these two factors could probably account for the blighted ovum. The fact that she had three failures prior to this with two ETs done under GA points to the fact that previous implantation failures may have been due to a traumatic ET. The second pregnancy loss was a missed abortion at 8 weeks. This was a case of secondary infertility who had history of an abortion earlier. The third loss was of a twin pregnancy at 7 weeks.

The ease of transfer which was our primary end point was achieved in all the patients. Two patients did need the use of an Allis forceps to stabilize the cervix but there was no blood on the catheter and the ET could be performed with a soft catheter very easily.

Concerns

The major concern we had was whether the procedure would lead to cervical incompetence. We examined the cervix frequently during pregnancy in the two patients who went to term. There was no funneling of the internal cervical OS or widening of the cervical canal. Further evaluation of this aspect is necessary and patient counseling regarding this possible complication should be done.

This study presents a simple and easy surgical approach to refashion the cervical canal thereby improving the quality of the ET procedure in patients who suffer from unusually difficult embryo transfers due to cervical canal abnormalities.

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