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Fluoroscopically-Guided Hysteroscopic Tubal Cannulation: A Procedure for Proximal Tubal Obstruction

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ABSTRACT

Objective(s): To evaluate the cannulation success rate, cumulative pregnancy, and time to intrauterine pregnancy rate following fluoroscopically-guided hysteroscopic tubal cannulation (FHTC) for infertile subjects with proximal tubal obstruction.

Methods: This retrospective study evaluated subjects with unilateral or bilateral proximal tubal obstruction on hysterosalpingography, who failed concomitant selective salpingography and subsequently underwent FHTC at the time of a hysteroscopy performed for findings seen on sonohysterography. FHTC employed a Novy Catheter (CooperSurgical, Inc, Trumbull, CT.) with or without the 3 French inner catheter and guidewire, to cannulate the occluded fallopian tube(s), followed by the injection of Hypaque™ (Amersham Health, Inc, Princeton, NJ.) contrast under C-arm imaging. Technical success rates, complications, post-procedure pregnancies, and average time from surgery to pregnancy were evaluated.

Results: Thirty-two women between January 1, 2017 and December 31, 2019 met the entry criteria and underwent FHTC. Of those women with bilateral obstruction, 6/6 (100%) of subjects achieved at least unilateral patency, while patency was achieved in 23/26 (88.5%) subjects with unilateral obstruction. Twenty-nine of 32 (90.6%) subjects had at least one tube successfully cannulated with 34/38 (89.5%) of proximally obstructed tubes opened. Asymptomatic tubal perforation occurred in 1/38 tubes (2.6%). Ten subjects (34.5%) achieved intrauterine pregnancies without in vitro fertilization in an average of 64.9 days from the procedure. There were no multiple pregnancies and one ectopic pregnancy.

Conclusion(s): FHTC is a safe, effective, incision free procedure that results in 90% of tubes successfully cannulated, and an observed short time to intrauterine pregnancy.

Key Words: Fallopian tube, Fluoroscopy, Hysterosalpingography, Infertility, In Vitro fertilization, Pregnancy, Tubal cannulation, Tubal obstruction, Tubal pregnancy.

INTRODUCTION

Tubal factor infertility accounts for 25% to 35% of female infertility and10% to 25% of tubal obstruction reflects proximal tubal obstruction (PTO).[1] In developed countries, tubal occlusion is most commonly caused by endometriosis, salpingitis due to chlamydia and other infections, salpingitis isthimica nodosa, as well as postsurgical adhesions, including scarring after a dilation and curettage.[2] After pelvic infection the fallopian tubes can become damaged with the rate of tubal infertility reported to be 12%, 23%, and 54% after one, two, and three episodes of pelvic inflammatory disease, respectively.[3,4] The standard screening test for tubal factor infertility is hysterosalpingography (HSG), which is conventionally performed in a radiology suite using fluoroscopy. If proximal tubal obstruction is found, then fluoroscopically guided selective salpingography can be attempted. Typically, these procedures are performed in the radiology suite with a balloon tip catheter introduced into the uterus through the cervical os. High pressure contrast is injected and if there is no tubal patency a catheter without a guidewire (selective salpingography) is placed into the tubal ostium to attempt recanalization of the obstructed tubes. Fluoroscopic tubal cannulation can also be performed with conventional 4 – 5 French catheters with a guidewire.[5] Advancing a

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guidewire or catheter beyond the ostium may require anesthesia and more advanced interventional radiology skills.

In a review of selective salpingography, the success rate ranges from 62% to 90% with rare complications.[3,4] If a patient cannot tolerate this procedure or distal tubal disease cannot be ruled out, then laparoscopically guided hysteroscopic tubal cannulation performed under general anesthesia has typically been the next step.

In the operating room, laparoscopy can be used to look for pelvic adhesions, distal disease and can guide hysteroscopic cannulation of the tubes via laparoscopic-guided hysteroscopic tubal cannulation (LHTC). LHTC patency rates have been reported between 54.2% and 90.2%, also with low rates of postprocedural complications.[4,5] Tubal factor infertility is most successfully treated with in vitro fertilization (IVF), but cannulation is a lower cost and less intensive alternative for women with PTO to potentially conceive without IVF.

In this study, we present a minimally invasive and technically novel surgical technique that treats PTO: fluoroscopic-guided hysteroscopic tubal cannulation (FHTC). FHTC is performed using the same type of equipment as LHTC (i.e., a selective ostial salpingography catheter and if needed, a guidewire), to cannulate the occluded fallopian tube(s), but includes the injection of contrast dye with fluoroscopic imaging from a mobile C-arm X-ray system to assess tubal patency. FHTC can be conveniently performed at the time of hysteroscopic surgery for a uterine factor. Also, it avoids laparoscopic guidance that is used during conventional LHTC. Our primary outcome was to evaluate FHTC for safety and efficacy. Secondary outcomes included pregnancy, intrauterine pregnancy, and miscarriage rates.

METHODS

Patients who underwent FHTC between January 1, 2017 and December 31, 2019 were evaluated for safety and efficacy. Inclusion criteria consisted of patients with infertility aged 18 – 44, unilateral or bilateral PTO on HSG, and the desire to undergo tubal cannulation to attempt to open their obstructed tube(s). Exclusion criteria included mid or distal tubal occlusion, or another recognized indication (e.g., male factor) requiring moving directly to IVF. All patients had at least six months of follow-up for complications and pregnancy outcomes. Ongoing clinical pregnancy was defined as a fetal heartbeat on transvaginal ultrasound that persisted through the first trimester. All patients first had an HSG in the fluoroscopy suite with an unsuccessful transcervical tubal cannulation. This tubal cannulation was performed by a radiologist placing the Novy Catheter (CooperSurgical, Inc, Trumbull, CT.) to the level of the tubal interstitium. A guide wire was not introduced.

FHTC was performed at the time of a hysteroscopy, which all patients underwent for suspected uterine pathology such as polyps, fibroids, or adhesions identified on a sonohysterography. The sonohysterography was performed as part of the infertility work up and the FHTC was scheduled in the main operating room by a reproductive endocrinology and infertility specialist (REI) on a separate day as the failed fluoroscopic cannulation in the radiology suite. For each patient, a successful tubal cannulation via FHTC was defined as at least one obstructed tube being successfully cannulated during the procedure.

Informed consent for surgery was obtained from all patients including an explanation of the risks and benefits of FHTC and the alternative options to treat tubal factor infertility. The study was approved by the institutional review board.

Surgical Technique

All cases were performed by the senior author (MK). Patients were undergoing fertility related hysteroscopy either for intrauterine adhesions, retained pregnancy tissue, a congenital uterine anomaly (i.e., septum); an endometrial polyp, or a cavitary leiomyoma, or adenomyoma; or any combination thereof. Patients underwent laryngeal mask airway general anesthesia with intravenous propofol and an inhalation agent to facilitate uterine relaxation.[6] A 21 French hysteroscope (Karl Storz, KG, Tuttlingen) was inserted into the uterine cavity utilizing warmed Normal Saline as the distension media with graspers, biopsy forceps, tenaculum, scissors, and tubal cannulation catheters placed as needed through the operative channel. Procedures for polyps and intrauterine scarring or any completely intracavitary lesions were completed prior to unilateral or bilateral tubal cannulation, while if the ostia were visualized, myometrial procedures such as metroplasty, myometrial resection of myoma, adenomyosis, or retained products of conception were performed after cannulation to limit intravasation of the saline. Tubal cannulation was performed with a Novy Catheter (**Figure 1**). The outer catheter and metal stylet were inserted into the visualized ostium of the occluded fallopian tube. When scarring prevented visualization of the ostium the metal stylet was used to create a neo-ostium as the presumed cornual site of the tubal ostium. Once inserted, the C Arm was brought to the pelvic region and an initial single shot imaging was used to confirm appropriate location. At

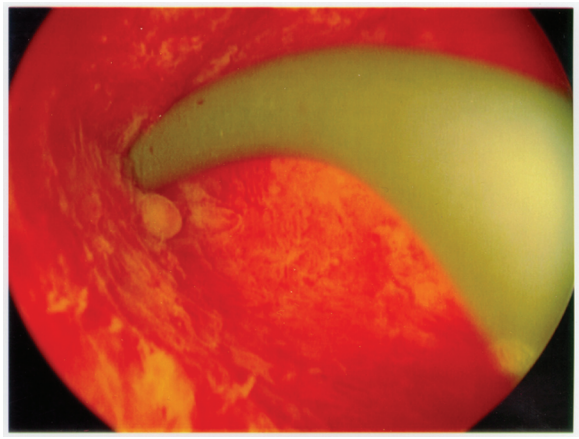

Figure 1. Hysteroscopic view of the tubal cannulation with the Novy Catheter inserted into left tubal ostium.

this point injection of Hypaque™ contrast dye (Amersham Health, Inc, Princeton, NJ.), was performed under real-time fluoroscopic imaging. If no fill of the fallopian tube was seen then a 3 French inner catheter with a 2 French inner guidewire was snaked through the initial outer catheter and was probed laterally into the intramural and isthmic portions of the fallopian tube. Repeat contrast injection was performed and images were saved and reviewed following the completion of the procedures. If a perforation was suggested by intraperitoneal contrast around the uterine cornual region without visualization of the fallopian tube, the procedure was halted on that side. All procedures were performed completely and solely by the senior author, with Accreditation Council for Graduate Medical Education certificates in both REI and minimally invasive gynecologic surgery specialist. This included all hysteroscopic procedures, tubal cannulation, C-arm placement with assistance of radiology technician, and interpretation of the radiologic images.

Postoperatively, patients were discharged after 30 – 60 minutes in the recovery room and were advised to return to work the following day.

RESULTS

There were a total of 32 patients who underwent FHTC, with a mean (standard deviation [SD]) age of 37 (40.7) years, and a mean (SD) duration of infertility of 2.2 years (1.8). There were six patients with bilateral and 26 patients with unilateral PTO based on preoperative HSG. Patients who underwent FHTC for bilateral and unilateral cannulation had no difference in the mean (SD) duration of infertility, 1.1 (1.7) vs. 2.4 (1.9) years. The breakdown of intrauterine pathology included the following: 16/32 (50%) patients having polyps, 6/32 (19%) fibroids, 8/32 (25%) synechia or scar tissue, and 13/32 (41%) a septum. Many of the patients had more than one pathology.

Success rates for bilateral tubal cannulation and unilateral cannulation were 100% and 88.5% respectively (**Table 1**).

As noted above there was one intraoperative perforation noted. The perforation was peri-isthmic and was identified based on viewing intraperitoneal contrast around the uterine cornual region without visualization of the fallopian tube. The procedure was terminated and not rescheduled at another time because patency was achieved on the contralateral tube. No postoperative complications occurred. Three out of 32 (9.4%) patients who underwent FHTC, proceeded directly to IVF and did not attempt to conceive naturally or via intrauterine insemination despite the fact that 2/3 of those patients (660.7%) had successful tubal cannulations. Twelve of the remaining 29(410.4%) patients had a positive β human chorionic gonadotropin

Table 1.
Tubal Cannulation Results

Parameter	n	Percentage
Bilateral Cannulation Success (per patient)	6/6	100.0%
Unilateral Cannulation Success (per patient)	23/26	88.5%
Success in achieving tubal patency (per tube)	34/38	89.5%
Perforations (per tube)	1/38	2.6%
Post-FHTC non-ART IU pregnancies*	10/29	34.5%
Bilateral Cannulation Post-FHTC non-ART IU pregnancies	3/6	50.0%
Unilateral Cannulation Post-FHTC non-ART IU pregnancies	7/23	30.4%

*Out of patients attempted to conceive through non-ART methods: 29 patients.
Abbreviations: ART, assisted reproductive technology; IU, intrauterine.

result via ovulation induction with intrauterine insemination (6 patients) or ovulation induction with timed intercourse (6 patients). There were no multiple pregnancies. A single ectopic pregnancy occurred in the contralateral patent tube in a woman with unilateral PTO. The tubal pregnancy was located in the ampullary portion of the tube and was treated by laparoscopic salpingectomy. All patients were counseled about risk of ectopic and desired to avoid IVF understanding this risk. One out of 29 (30.4%) patients had a biochemical pregnancy loss. Ten out of 29(340.5%) achieved intrauterine pregnancies, however 3/10(300.0%) had a miscarriage. The ongoing clinical pregnancy rate was 7/29(240.1%) (**Table 2**).

On average, patients achieved non-assisted reproductive technology (ART) intrauterine pregnancies in a mean (SD; range) time of 64.9 (30.3; 32 – 120) days following FHTC. Patients who underwent bilateral FHTC achieved non-ART spontaneous intrauterine pregnancies in a mean (SD; range) time of 70.8 (31.1; 36 – 120) days following the procedure. There was no statistically significant difference in intrauterine pregnancy rates or time to intrauterine pregnancy between patients with unilateral or bilateral PTO.

DISCUSSION

FHTC resulted in 90% of patients having their occluded tube successfully cannulated with one-third achieving a non-ART intrauterine pregnancy within an average of two months of the procedure. In contrast to LHTC, FHTC is performed with no incisions and requires a much shorter recovery time. FHTC may reduce postoperative pain, allowing for quicker recovery and more rapid return to normal activities, including sexual intercourse. Although postoperative pain scores were not specifically evaluated in this study, other data suggests that hysteroscopic postoperative pain scores are lower than laparoscopic pain scores. For example, a study comparing laparoscopic tubal sterilization with hysteroscopic tubal sterilization found lower pain scores with hysteroscopic tubal sterilization immediately postoperatively, 1 week and 4 weeks post procedure.[7] This may have contributed to a short mean time (64.9 days) to non-ART pregnancy.

Table 2.
Non-Assisted Reproductive Technology Pregnancies

	(n = 29)	%
Positive β human chorionic gonadotropin	12/29	41.4
Clinical pregnancy	10/29	34.5
Ongoing clinical pregnancy	7/29	24.1
Clinical miscarriage	3/10	30.0

FHTC provides a less costly fertility treatment option for patients with PTO especially when compared to IVF which may not be covered by insurance. The charge to the patient for the FHTC portion of the surgery is $1500, while the average cost and charge to the patient for IVF is $15,000 per cycle at our institution. Another report showed the cost of tubal cannulation was in the average of $750, with a range of $500 – $1000.[8] Importantly, IVF may not be covered for many patients whereas surgical treatment typically is. In addition, many couples prefer to avoid IVF and attempt natural means to conceive.

FHTC can be conveniently performed at the time of hysteroscopy, which all FHTC patients required due to uterine pathology. Hysteroscopy with tubal cannulation is relatively simple to perform with a quick learning curve as most REI physicians have extensive experience with hysteroscopic techniques. Additionally, the C-arm X-ray technology is simple to employ by the REI or radiology technician.

Our 90% success rate of achieving tubal patency and 34% clinical pregnancy within six months are comparable to reports of fluoroscopic guided tubal cannulation performed in the radiology suite under anesthesia as well as reports of LHTC. For example, Al-Omari et al. reports 100% tubal patency and 41% intrauterine pregnancy in a group of 61 women within one year of the fluoroscopic guided tubal cannulation performed with a guidewire.[9] A prospective cohort study of 49 women with unilateral or bilateral proximal tubal obstruction had a successful recanalization rate of 90.2% per tube and 88.9% per patient with a conception rate of 33.3% after LHTC.[8] Although success rates may be similar with various techniques the benefit of FHTC is that the patients did not require an abdominal incision or a separate radiologic procedure. They were already scheduled for hysteroscopy to repair other uterine pathology.

Limitations of this study include its retrospective nature limiting the assessment of patient selection criteria and randomized comparisons to other modalities such as laparoscopic guided tubal cannulation. In addition, a small number of patients subsequently decided to move to directly to IVF. This limited a full evaluation of the non-ART pregnancy success rates after FHTC. Although we cannot state that pregnancies in women with unilateral PTO were achieved in the previously blocked tube given

their longstanding infertility and pregnancy temporality related to the procedure it is likely that FHTC contributed to some of these pregnancies. Despite these limitations the procedure yielded fairly rapidly achieved high non-ART success rates suggesting the value of further prospective study into FHTC.

CONCLUSIONS

This retrospective study demonstrates that FHTC has a high technical success rate and a low complication rate. These results suggest this novel surgical technique is a viable alternative to conventional laparoscopically guided hysteroscopic tubal cannulation (LHTC), especially as an option in patients considering IVF.

In conclusion, FHTC is a safe, effective, incision free procedure that results in a 90% rate of tubal patency and, in our population, was associated with an average of two months to intrauterine pregnancy. This warrants further prospective studies, to compare cost and efficacy of FHTC vs LHTC.

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