Fluoroscopic-guided hysteroscopic tubal cannulation results in high technical success and pregnancy rates comparable with the more traditional laparoscopically guided hysteroscopic tubal cannulation

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Objective: To compare women with proximal tubal obstruction (PTO) undergoing hysteroscopic tubal cannulation with fluoroscopic guidance vs. laparoscopic guidance.
Design: Retrospective cohort study.
Setting: All fluoroscopically-guided hysteroscopic tubal cannulations were performed in an ambulatory suite. All laparoscopically-guided hysteroscopic tubal cannulations were performed in a hospital operating room.
Patients: Infertile women with unilateral or bilateral PTO on hysterosalpingography who failed selective salpingography in the radiology suite and had a planned laparoscopy or hysteroscopy in the operating room for defects seen on sonohysterography were studied.
Intervention: All women had a Novy catheter system positioned hysteroscopically to cannulate the occluded fallopian tube(s). Women undergoing fluoroscopically guided hysteroscopic tubal cannulation (FHTC), which used contrast and C-arm pelvic imaging at an ambulatory center, were compared with those undergoing hospital-based laparoscopically guided hysteroscopic tubal cannulation (LHTC) with laparoscopic visualization.
Main Outcome Measurements: Tubal cannulation success; bilateral cannulation success; tubal perforations; post-FHTC non–in vitro fertilization (non-IVF) intrauterine pregnancies; days from procedure to pregnancy for non-IVF intrauterine pregnancies; and time to non-IVF pregnancy hazards ratio.
Results: A total of 76 infertile women undergoing either FHTC (34 women) or LHTC (42 women) between 2015 and 2019 were included. Demographic variables were similar among the 2 groups. A total of 31 (92%) of 34 of patients undergoing FHTC and 36 (86%) of 42 of patients undergoing LHTC had at least one tube successfully cannulated. In total, 30 (78%) of 34 of patients undergoing FHTC and 32 (79%) of 42 patients undergoing LHTC had all occluded tubes successfully cannulated. Tubal perforation occurred in 1 (3%) of 34 FHTC cases and 3 (7%) of 42 LHTC cases. A similar percentage of non-IVF treatment-induced intrauterine pregnancies were achieved in the FHTC and LHTC groups (10/34 [29%] vs. 12/42 [29%]). Among patients who conceived without IVF, time from procedure to pregnancy was lower in the FHTC group (101 $\pm$ 124.6 days) compared with the LHTC group (228 $\pm$ 216 days). There was a significant difference in time to pregnancy when only those who conceived were considered (hazard ratio, 9.39; 95% confidence interval, 2.42–36.51); however, there was no significant difference when all subjects regardless of pregnancy outcome were analyzed (hazard ratio, 1.48; 95% confidence interval, 0.64–3.446).

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Conclusion: Fluoroscopically guided hysteroscopic tubal cannulation is a safe, effective, incision free procedure that results in comparable rates of tubal patency and intrauterine pregnancies as LHTC. This technique should be considered in women undergoing treatment of PTO when operative laparoscopy is not otherwise indicated. (F S Rep® 2024;5:205–10. ©2024 by American Society for Reproductive Medicine.)

Key Words: Proximal tubal obstruction, fluoroscopically guided hysteroscopic tubal cannulation, laparoscopically guided hysteroscopic tubal cannulation, in vitro fertilization

Tubal disease is responsible for 25%–35% of female infertility, with 10%–25% of these cases because of proximal tubal obstruction (PTO) (1). In 1977, the first transcervical cannulation using selective salpingography was performed by injecting the contrast medium directly into the fallopian tube (1, 2). Technological advances and further development of cannulation instrumentation allowed for the first transcervical balloon tuboplasty in the 1980's (2). In 1988, Novy et al. (3) introduced the use of transcervical cannulation of the proximal oviduct using hysteroscopic cannulation under laparoscopic guidance. Patency was demonstrated in 11 (91.7%) of 12 obstructed tubes after hysteroscopy fallopian tube cannulation. We recently reported a novel technique, fluoroscopically guided hysteroscopic tubal cannulation (FHTC), demonstrating a 90% successful cannulation rate and a 34.5% pregnancy rate without in vitro fertilization (IVF) treatment (4).

In our current study, we report on a single surgeon's contemporaneous success rates for achieving tubal patency in PTO as well as non-IVF treatment-induced pregnancy rates when comparing laparoscopic vs. fluoroscopic tubal guidance during hysteroscopic tubal cannulation and assessment. To our knowledge, this is the first study to investigate the time to non-IVF treatment-induced intrauterine pregnancy in FHTC vs. laparoscopically guided hysteroscopic tubal cannulation (LHTC).

MATERIALS AND METHODS

This retrospective study included all women who had undergone FHTC or LHTC between 2015 and 2019 during their fertility workup and treatment by a single reproductive surgeon (S.R.). Inclusion criteria were women with infertility with either unilateral or bilateral PTO aged 18–44 years. We excluded subjects with bilateral distal tubal occlusion, severe male factor infertility, or other indications, requiring the subject to go directly to IVF treatment. Hysterosalpingography (HSG) was performed on nearly all patients by an interventional radiologist (S.R.). If tubal occlusion was seen, then fluoroscopic selective salpingography was attempted using a curved catheter, performed without anesthesia. When fluoroscopic selective salpingography failed and when proximal obstruction was noted and no hydrosalpinx was seen, they were offered FHTC, using fluoroscopic guidance for hysteroscopic tubal cannulation. This technique, as described below, is separate from widely known fluoroscopic guidance for tubal cannulation often performed in the radiologic suite. When laparoscopy was otherwise indicated, they were offered LHTC. A finding of a unilateral hydrosalpinx, a positive chlamydia serology, or when a markedly damaged tube was seen with PTO, the patient was then indicated for laparoscopy with LHTC.

At the time of the study, all women undergoing FHTC had an indication for hysteroscopic tubal cannulation under fluoroscopic guidance on the basis of HSG findings. Patients underwent laryngeal mask airway anesthesia in the dorsal lithotomy position, with intravenous propofol and an inhalation agent to facilitate uterine relaxation. Then, the hysteroscope was placed in the uterine cavity, and the ostia was visualized. Indicated hysteroscopic procedures, such as polypectomy and lysis of adhesions to find the ostia, were performed before tubal cannulation. Extensive myomectomy, or extensive metroplasty, was sometimes delayed and performed after tubal cannulation to allow for completion without bleeding or intravasation. The Novy catheter system, Cook G17478 (Cook Medical, Bloomington, IN), was placed through a visualizable ostia or an obstructed ostia where an ostia was presumed to be located. The C-arm was then maneuvered into position over the uterus and fallopian tubes. A single image confirmed the location of the catheter. Hypaque contrast dye (Amersham Health, Inc., Princeton, NJ) was then injected under real-time fluoroscopic imaging. If no contrast was seen entering the fallopian tube, then tubal cannulation was performed with a 3-French inner catheter and a 2-French inner guidewire snaked through the outer catheter and inserted laterally through the intramural and into the isthmic portions of the fallopian tube using direct wire visualization. Repeat contrast injection was performed. If perforation was suggested by contrast spillage directly intraperitoneally and around the uterine cornual region without visualization of the fallopian tube, then the procedure was halted on that side. When the contrast flowed into the fallopian tube without suggestion of perforation, we assessed for dilation-free spill and loculation.

For the LHTC group, women underwent laparoscopy for one of several indications: pelvic pain, expected endometriosis, ovarian cysts, fibroids (intramural and subserosal), suspected pelvic inflammatory disease (history of a positive chlamydia serology in association with infertility), and abnormalities on HSG (distal tubal abnormalities). For the LHTC group, all subjects underwent general anesthesia with intubation. A 5-mm port and laparoscope were inserted through the umbilicus using the open-entry technique (5). Additional 5-mm pelvic lateral ports were placed as needed. Once all indicated laparoscopic procedures were completed, all patients underwent chromopertubation using both low-pressure flow and obstruction of one tube to see when injected dye flowed in the contralateral tube. Chromopertubation was performed with a

TABLE 1

Demographics of subjects.

Parameter	FHTC, n (%)	LHTC, n (%)	*P* value
Number of subjects	34	42	
Mean age (y) (±SD)	37 (4.7)	35 (3.7)	.09
Mean duration of infertility	2.1 (1.9)	1.4 (1.5)	.09
HSG performed	34/34 (100%)	39/42 (92.9%)	.42
Unilateral occlusion on HSG	27/34 (79.4%)	20/39 (51.3%)	.01
Bilateral occlusion on HSG	6/34 (17.6%)	11/39 (28.2%)	.33
Abnormal uterine cavity	33/34 (97%)	38/42 (90%)	.26
Positive chlamydia serology	5/42 (11.9%)	1/34 (2.9%)	.15

FHTC = fluoroscopically guided hysteroscopic tubal cannulation; HSG = hysterosalpingography; LHTC = laparoscopically guided hysteroscopic tubal cannulation; SD = standard deviation.

Keltz. FHTC vs LHTC in proximal tubal block. F S Rep 2024.

Clearview manipulator, using very dilute methylene blue. When there was bilateral tubal patency, patients would not have been enrolled in this study. When there was bilateral PTO with normal distal tubes, they underwent bilateral LHTC. If a unilateral occlusion appeared, then the patent tube was obstructed to see whether further instillation and pumping action would overcome the obstruction. If the obstruction was still not overcome, then it would be counted as a unilateral obstruction. All indicated hysteroscopic procedures were first performed; however, no procedure requiring incisions was performed before tubal cannulation. We then placed the Novy catheter into the ostium, or presumed ostial area, and injected contrast. When the injected contrast failed to show tubal patency, we placed the 2-French wire over a 3-French catheter, further trying to insert them through the intramural and into the isthmic portions of the tube using direct wire visualization. We checked for patency on removal of the wire with injected dye. If perforation was suggested by contrast spillage directly intraperitoneally and around the uterine cornual region without visualization of the fallopian tube, then the procedure was halted on that side. We considered the procedure a technical success when there was contrast flow coming out of the distal fallopian tube on the laparoscopic view.

Those in the FHTC returned home the same day and were able to resume work the day after their procedure. The LHTC group returned home the same day of their procedure and were able to return to work 3–4 days later. All women had at least 6 months of observation for complications and pregnancy outcomes. Ongoing clinical pregnancy was defined as a fetal heartbeat on transvaginal ultrasound that persisted through the first trimester.

Procedural success, perforation rates, pregnancy rates, and time to intrauterine pregnancy were analyzed. The *t*-test and Wilcoxon rank sum analysis were used to compare continuous variables, and a Fisher's exact test was used for categorical variables. Kaplan-Meier analysis was used to compare times to pregnancy. Informed consent for surgery was obtained from all patients, including an explanation of the risks and benefits of LHTC and FHTC as well as the alternative options to treat tubal factor infertility. The study was approved by the institutional review board at Brown University.

RESULTS

A total of 76 infertile women undergoing either FHTC (34 women) or LHTC (42 women) between 2015 and 2019 were included, as listed in Table 1. Demographic variables were similar, although the FHTC group was older with a mean (±SD) age of 37 (±4.7) years, whereas the LHTC group had a mean age of 35 (±3.7) years (P=.09). The FHTC group had a mean (±SD) duration of infertility of 2.1 years (1.9), whereas the LHTC group had a mean (±SD) duration of infertility of 1.4 (±1.5) years (P=.09).

For the FHTC group, all subjects had attempted HSG; 34 (100%) of 34 subjects; however, one subject was unable to tolerate the procedure, thus the HSG was inconclusive and there was no confirmed occlusion. For the LHTC group, 39 (92.9%) of 42 subjects had an HSG performed, whereas all subjects had pathology indicating the need for hysteroscopy (P=.42). Of those with an HSG performed, in the LHTC group, 20 (51.3%) of 39 were found to have a unilateral occlusion, whereas 27 (81.8%) of 33 in the FHTC group had a unilateral occlusion (P=.01). Additionally, of those that had an HSG performed, the LHTC group was found to have 11 (28.2%) of 39 patients with a bilateral occlusion, whereas for the FHTC group, 6 (18.2%) of 33 patients had a bilateral occlusion (P=.33). For the LHTC group, there were 8 subjects who were found to not have an occlusion on HSG. However, all of these patients had other indications for laparoscopy. Therefore, at the time of laparoscopy, all patients underwent chromopertubation, and were found to have PTOs at that time that were unresponsive to our usual noncannulation techniques for tubal spasm as presented in the methods.

The FHTC had a higher incidence of abnormal uterine cavities among subjects compared with the LHTC group, although statistically insignificant. The LHTC group had 38 (90%) of 42 subjects presenting with uterine pathology whereas the FHTC group had 33 (97%) of 34 subjects with uterine pathology (P=0.26). The FHTC group's intrauterine pathology included the following: 16 (50%) of 32 (patients had polyps, 6 (19%) of 32 fibroids, 8 (25%) of 32 synechia

TABLE 2

Tubal cannulation results.

Parameter	FHTC, n (%)	LHTC, n (%)	*P* value
≥One tube cannulation success	31/34 (91%)	36/42 (86%)	.47
Bilateral cannulation success (per patient)	30/34 (78%)	32/42 (79%)	.52
Perforations (per tube)	1/34 (3%)	3/42 (7%)	.42
Postoperative non-IVF IU clinical pregnancy	10/34 (29%)	12/42 (29%)	.94
Days from procedure to pregnancy for non-IVF IU pregnancies	101 ± 124.6	228 ± 216	.01

FHTC = fluoroscopically guided hysteroscopic tubal cannulation; IU = intrauterine; IVF = in vitro fertilization; LHTC = laparoscopically guided hysteroscopic tubal cannulation.

Keltz. FHTC vs LHTC in proximal tubal block. F S Rep 2024.

or scar tissue, and 13 (41%) of 32 septa. Many of the patients had more than one pathology. For the LHTC group, many patients underwent laparoscopy for endometriosis, with 24 (57%) of 42 subjects having known endometriosis, many with a concurrent infertility condition, i.e., Asherman's and polycystic ovary syndrome. Only 3 (9.4%) of 32 subjects undergoing FHTC had a known diagnosis of endometrioses; however, without laparoscopic confirmation, this value may be inexact. For additional intrauterine pathologies in the LHTC group, 11 (26%) of 42 patients had polyps, 10 (24%) of 42 fibroids, 7 (17%) of 42 synechia or scar tissue, and 10 (24%) of 42 a septum. Of the LHTC group 5 (11.90%) of 42 patients had a positive chlamydia serology, whereas 1 (2.94%) of 34 patients in the FHTC group had a positive chlamydia serology (P=.15)

In total, 31 (91%) of 34 patients with FHTC and 36 (86%) of 42 patients with LHTC had at least one tube successfully cannulated (P=.47) as shown in Table 2. A total of 30 (78%) of 34 patients with FHTC and 32 (79%) of 42 patients with LHTC had all occluded tubes successfully cannulated (P=.52). Tubal perforation occurred in 1(3%) of 34 FHTC cases as compared with 3(7%) of 42 LHTC cases (P=.42).

For the FHTC group, 19 (55%) of 34 patients had a positive pregnancy test, including pregnancies achieved with IVF, whereas in the LHTC group, 27 (64%) of 42 patients had a positive pregnancy test (P=.46). A similar percentage of non-IVF intrauterine pregnancies were achieved in the FHTC and LHTC groups. In the FHTC group 10 (29%) of 34 non-IVF intrauterine pregnancies were achieved, whereas in the LHTC group, there were 12 (29%) of 42 non-IVF intrauterine pregnancies (P=.94).

When analyzing pregnancy rates for those with unilateral occlusion between groups, results were similar. For the FHTC group, 7 (27%) of 26 patients had a non-IVF intrauterine pregnancy, whereas 8 (40%) of 20 patients in the LHTC group had a non-IVF intrauterine pregnancy (P=.35). In the case of bilateral occlusion, for the FHTC group, 3 (38%) of 8 patients and for the LHTC group 4 (18%) of 22 patients had a non-IVF intrauterine (IU) pregnancy (P=.28).

After tubal cannulation, the FHTC group had 4 (11.8%) of 34 subjects continue to IVF directly, whereas the LHTC group had 2 (4.8%) of 42 subjects continue to IVF directly (P=.3); the remaining patients continued with intrauterine insemination or timed intercourse. For those that were not successful with non-IVF methods in the FHTC group and continued treatment all 9 (100%) of 9 continued to IVF and for the LHTC group all 16 (100%) of 16 subjects continued to IVF (P=0.1). A similar percentage of intrauterine clinical pregnancies, including patients who underwent IVF, were achieved in the FHTC and LHTC groups. In the FHTC group 17 (50%) of 34 intrauterine pregnancies were achieved, whereas in the LHTC group there were 26 (61.9%) of 42 intrauterine pregnancies (P=.30). Of the total clinical pregnancies achieved, in the FHTC group 3 (17.6%) of 17 pregnancies, resulted in miscarriage whereas in the LHTC group 3 (11.5%) of 26 patients resulted miscarriage (P=.8). All miscarriages were spontaneous abortions, except for one in the LHTC group, which was induced. Two ectopic pregnancies occurred, one in the LHTC group and the other in the FHTC group.

Among patients who conceived without IVF, days from procedure to pregnancy was significantly lower in the fluoroscopically guided group 101.45 ± 124.6 as compared with the laparoscopically guided group 228.2 ± 216 (P=.01). There was a statistical difference in time to pregnancy (excluding IVF pregnancies) when considering only those that successfully conceived (hazard ratio, 9.39; 95% confidence intervals [CIs], 2.42–36.51). However, there was no statistical difference in time to pregnancy when all subjects regardless of pregnancy were analyzed (hazard ratio, 1.48; 95% CI, 0.64–3.446). Additionally, the calculated relative risk for non-IVF intrauterine pregnancies is 1.01 (95% CI, 0.75–1.35), thus indicating no significant difference among the 2 groups.

Among patients who conceived with IVF, days from procedure to pregnancy was lower in the fluoroscopically guided group, 71.64 ± 52.71, as compared with the laparoscopically guided group 151.42 ± 85.2 (P=.0013). There was a statistical difference in time to pregnancy, including IVF pregnancies when considering only those that successfully conceived (hazard ratio, 2.907; 95% CI, 1.52–5.57). However, there was no statistical difference in time to pregnancy when all subjects regardless of pregnancy were analyzed (hazard ratio, 1.14; 95% CI, 0.62–2.11).

DISCUSSION

This study compares laparoscopically guided tubal cannulation with the novel procedure of fluoroscopically guided hysteroscopic tubal cannulation. It is evident that LHTC and FHTC are comparable in terms of tubal patency, perforations, and IU pregnancy rate, and there is a shorter time to pregnancy when employing FHTC. This may be because of

confounding variables, such as degree of tubal disease, endometriosis, or may be because of quicker recovery time with hysteroscopy than laparoscopy. Time to pregnancy is unlikely because of the fluoroscopic guidance itself. Further, FHTC can be conveniently performed at the time of hysteroscopy, which many fertility patients require because of uterine pathology (4). Hysteroscopy with tubal cannulation is relatively simple to perform as most reproductive endocrinology and infertility physicians have extensive experience with hysteroscopic techniques. Additionally, the C-arm roentgenogram technology is simple to employ by the reproductive endocrinology and infertility physicians or radiology technician. This benefit is in conjunction with the fact that FHTC is less invasive and further that hysteroscopic guidance has been shown to produce lower pain scores than laparoscopic guidance in other fertility procedures (6). Fluoroscopically guided hysteroscopic tubal cannulation would be preferred when hysteroscopy is indicated but laparoscopy is not necessary. Although fluoroscopically guided tubal cannulation at the time of HSG is still the least invasive option, it is rarely offered (7). Fluoroscopically guided hysteroscopic tubal cannulation is the preferred option if the fluoroscopic selective salpingography fails or the patient requires hysteroscopy for another indication. However, its use may be limited by the availability of a C-arm at hysteroscopic surgery centers.

In our LHTC group, tubal patency, conception rate, and time to pregnancy were comparable with other studies. Prior studies have shown a recanalization rate of 80% with LHTC and up to 100% with all fluoroscopic radiologic techniques (8, 9). Further studies have shown an overall conception rate of 33% using LHTC (10). In our study, LHTC achieved an 86% recanalization rate and a 29% intrauterine pregnancy rate in FHTC we achieved 92% tubal patency and 29% non-assisted reproductive technology IU pregnancy. Other studies have shown a 27% clinical pregnancy rate after general tubal catheterization for unilateral and bilateral PTO (11, 12). Thus when using LHTC, we demonstrated success similar to what is currently in the literature.

In addition to comparing procedural approaches to PTO, it is also important to consider whether any PTO procedure is an appropriate alternative to IVF. Currently, there are no trials comparing pregnancy rates after tubal surgery with IVF (11). However, it may be beneficial to compare some of the advantages and disadvantages. Fluoroscopically guided hysteroscopic tubal cannulation provides a less costly fertility treatment option for patients with PTO when compared with IVF. The charge to the patient for the FHTC portion of the surgery is $1,500, whereas 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 $750, with a range of $500–$1,000 (10). At our institution, hysteroscopy is $1,500 and anesthesia is an additional $500, thus tubal cannulation can be up to $3,000 in total. Additionally some couples prefer to avoid IVF and attempt natural means to conceive.

The limitations of this study include that it is retrospective, thus we cannot eliminate all possible confounders between patients who underwent FHTC and LHTC, such as the higher rates of endometriosis among those in the LHTC group. The patients undergoing LHTC had more comorbidities, which may limit interpretation of the data (13, 14). However, intrauterine pathology was compared, and the FHTC group was found to have a higher incidence of abnormalities. Furthermore, in the LHTC group all pathology encountered via laparoscopy and hysteroscopy was corrected whereas in the FHTC group only hysteroscopically visualizable and treatable pathology was corrected. This may have provided an advantage to those in the LHTC group. An additional limitation of this study is that our patients initially underwent HSG to assess for tubal factor, which has a high false-positive rate. Although they additionally underwent selective salpingography at the time of HSG, this does not eliminate all false positives results. Additionally, a small number of patients subsequently decided to move directly to IVF. In our study, after tubal cannulation the FHTC group had 4 (11.8%) of 34 subjects continue to IVF directly, whereas the LHTC group had 2 (4.8%) of 42 subjects continue to IVF directly ($P=.3$). This limited a full evaluation of the non-assisted reproductive technology pregnancy success rates after FHTC. It is unknown whether pregnancies in women with unilateral PTO were achieved through the previously blocked tube.

CONCLUSION

To our knowledge, this is the first study comparing the novel procedure of FHTC and the more traditional LHTC for success rates in the treatment of PTO by a single provider. It demonstrates that FHTC has a high-technical success rate, a low-perforation rate, and a successful conception rate similar to LHTC both in our hands and when compared with prior literature. These results demonstrate that FHTC is a viable alternative to conventional laparoscopically guided hysteroscopic tubal cannulation, particularly among patients planning to delay IVF.

CRediT Authorship Contribution Statement

Martin Keltz: Conceptualization, Methodology, Investigation, Resources, Data curation, Writing - original draft, writing - review & editing, Project administration. **Sarah C. Rubin:** Conceptualization, Methodology, Software, Validation, Formal analysis, Writing - original draft, Writing - review & editing, Visualization. **Emma Brown:** Data curation. **Moses Bibi:** Writing - review & editing. **May-Tal Sauerbrun-Cutler:** Investigation, Writing - review & editing, Project administration, Supervision.

Declaration of Interests

M.K. has nothing to disclose. S.C.R. has nothing to disclose. E.B. has nothing to disclose. M.B. has nothing to disclose. M.T.S. has nothing to disclose.

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