Renaissance of Surgical Recanalization for Proximal Fallopian Tubal Occlusion: Falloposcopic Tuboplasty as a Promising Therapeutic Option in Tubal Infertility

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ABSTRACT Study Objective: To assess the clinical effectiveness of falloposcopic tuboplasty in tubal infertility.
Design: Retrospective cohort study (Canadian Task Force classification II-3).
Setting: Infertility clinic.
Patients: Three hundred forty-five infertile patients (≥2y) with a diagnosis of proximal tubal occlusion, either bilateral or unilateral, between January 2005 and January 2011.
Intervention: Falloposcopic tuboplasty.
Measurements and Main Results: Medical records for 345 patients with a diagnosis of proximal tubal occlusion were reviewed. Of the 345 patients, 304 underwent falloposcopic tuboplasty, with successful recanalization achieved in 248 patients (81.6%). Ninety-one of the 304 patients (29.9%) became pregnant. Of these, 18 patients (19.8%) miscarried, and 4 (4.4%) had ectopic pregnancies in the recanalized tube. At 1-, 3-, 6-, and 9-month follow-up, the cumulative probability of conception was 23.1%, 50.6%, 73.6%, and 82.4%, respectively. Related complications included postsurgical infection (0.3%), perforation of the fallopian tube (1.3%), and accidental breakage of the catheter (4.9%) or the falloposcope (1.3%).
Conclusions: Falloposcopic tuboplasty is safe and effective for treatment of tubal infertility. The pregnancy rate after falloposcopic tuboplasty is comparable to that after in vitro fertilization, which suggests that it can be an alternative to in vitro fertilization in women with tubal infertility. Journal of Minimally Invasive Gynecology (2011) 18, 651–659 © 2011 AAGL. All rights reserved.

Keywords: Falloposcopic tuboplasty; Natural conception; Tubal occlusion

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Tubal obstruction has been recognized as a major cause of infertility since the 19th century. It is responsible for 20% to 30% of infertility in women worldwide and is the second most common cause of infertility after unexplained infertility [1]. Finding a solution for tubal obstruction, the lesions of which range from intrinsic intraluminal malformation of the cilia, mucosa, or muscularis to gross occlusion of the lumen, has preoccupied gynecologists for many years [1,2].

The concept of fallopian tube cannulation originated in the 19th century when Smith [3] introduced tools made of whale bone for use in treatment of proximal obstruction. Since then, various attempts to recanalize occluded fallopian tubes have been made; however, the results have varied greatly and have been criticized for lack of convincing evidence of efficacy [1]. As a result, tubal recanalization using a surgical approach has been almost abandoned [1]. However, there is no doubt that, if left untreated, complete bilateral tubal obstruction hinders conception [4].
Tubal cannulation reemerged in the 1990s for treatment of cornual obstruction. Falloposcopy, first developed in the early 1990s, was originally a diagnostic device for direct visualization of the fallopian tube lumen [5–9], but provided no therapeutic value for occluded tubes. With refinement of falloposcopy, the technique of falloposcopic tuboplasty was developed as an endoscopic catheterization procedure for treatment of occluded fallopian tubes [10,11]. In 1997, the US Food and Drug Administration approved the falloposcopic tuboplasty catheter system. In Japan, the Ministry of Public Health has listed falloposcopic tuboplasty as an approved treatment for occluded fallopian tubes, and since 1998, 70% of the cost of the procedure has been covered by National Medical Insurance.

Falloposcopic tuboplasty has not yet achieved widespread clinical acceptance [12]. In the 1980s, in vitro fertilization (IVF) emerged, and has quickly spread worldwide. As IVF became the first choice for treatment of tubal infertility, tubal recanalization attracted less interest from gynecologists. However, there is a considerable population of patients with tubal infertility who do not wish to abandon trying for natural pregnancy and want to recover tubal patency for subsequent natural conception [2]. Hence, we would like to reintroduce falloposcopic tuboplasty as a potential therapeutic option in women with tubal infertility. Previously, in a short communication, we reported a case series of falloposcopic tuboplasty with a successful recanalization rate of 94.8% and a clinical pregnancy rate of 28.9% [2]. In the present report, we retrospectively reviewed the medical records of 304 patients with tubal infertility who underwent falloposcopic tuboplasty between January 2005 and January 2011. The technique, clinical outcomes, and risks were examined in detail. We hope the present report will prompt physicians engaged in treating infertility to reconsider tubal recanalization.

Materials and Methods

We retrospectively reviewed the medical records of patients with a diagnosis of tubal occlusion between January 1, 2005, and January 31, 2011. Indications for falloposcopic tuboplasty included infertility for at least 2 years, a diagnosis of either bilateral or unilateral proximal tubal occlusion, and regular menstrual cycle without other ovulatory disorders such as polycystic ovarian syndrome. Patients were excluded if their partner’s semen analysis demonstrated oligospermia or asthenozoospermia according to criteria of the World Health Organization [13]. Proximal tubal occlusion was diagnosed using either hysterosalpingography (HSG) or hydrotubation using dilute indigo carmine solution during laparoscopic surgery, as described elsewhere [14]. Because transient tubal occlusion may be induced by uterine and tubal contraction due to pain and may lead to misdiagnosis of tubal occlusion, occlusion was always confirmed using either HSG on 2 occasions or HSG and intraoperative hydrotubation on 1 occasion, as described previously [2]. In addition, HSG was always repeated to confirm the occluded side and portion in patients who were referred from another clinic because of tubal infertility (135 patients [39.1%]). Patients with midssegment or distal tubal obstruction and those who had previously undergone unilateral salpingectomy were excluded. After the diagnosis of proximal tubal occlusion was confirmed, all 345 patients were offered 2 therapeutic options, IVF or falloposcopic tuboplasty. Forty-one patients (11.9%) preferred IVF, and the remaining 304 patients (88.1%) decided to undergo falloposcopic tuboplasty. All 345 patients were included in this retrospective analysis. Written informed consent was obtained from each patient before the operation.

Falloposcopic tuboplasty was always performed bilaterally regardless of whether the tubal occlusion was bilateral or unilateral. Tubal recanalization was defined as successful only when the inner sheath of the linear eversion catheter was extended to its full length of 11 cm, giving a clear image of the intralumen of the tubes bilaterally. The procedure was considered to have failed if the ipsilateral tube remained occluded. Pregnancy was attempted by either timed intercourse or intrauterine insemination during the natural ovulatory cycle at any time after the surgery. Patients who received ovarian hyperstimulation were excluded from the study.

Procedure

All procedures were performed using a falloposcopic tuboplasty catheter system (Imagyn Medical, Inc., Laguna Niguel, CA). The optimal time to perform falloposcopic tuboplasty is during the mid-follicular phase of the menstrual cycle because the ostium can be visualized easily in the absence of blood and a thick endometrial lining [14–16]. Intravenous prophylactic antibiotic therapy is given just before surgery.

Patients were placed in the lithotomy position, and anesthesia was administered intravenously. A speculum was inserted into the vagina, and the posterior uterine cervix was grasped with a tenaculum firmly connected to the speculum via a specific attachment. The basic structure of the falloposcopic tuboplasty catheter system consists of 3 units: a charge-coupled device video camera with a light source, a falloposcope, and a linear eversion catheter (Fig. 1). The linear eversion catheter consists of inner and outer catheter bodies (0.8 and 2.8 mm in diameter, respectively) joined circumferentially at their distal tips via a distensible polyethylene membrane. This membrane is used as a pressurized balloon, and can be unrolled from within a plastic polymer cannula after the falloposcope is preloaded into its lumen (Fig. 2). The pressure in the enclosed balloon space is controlled at 2 to 10 atm (1 atm is equivalent to approximately 760 mm Hg) via an inflation device filled with normal saline solution.

The high-resolution falloposcope, outer diameter 0.6 mm, contains 6 light fibers, achieving a 5000-pixel image resolution. It passes through the central channel of the linear...
eversion catheter (i.e., in the middle of the balloon) and is connected to the charge-coupled device, video camera, and light source. As the balloon unrolls, it carries the falloposcope within the inner catheter into and along the tubal lumen to a full length of 11 cm, preventing the tube and falloposcope from damaging one another and negotiating the curves and strictures without exerting any shearing forces on the tube wall.

Once the tubal ostium is identified, the outer catheter is held in position and connected to the tenaculum. Then, the linear eversion catheter with the falloposcope inside it is gently advanced into the fallopian tube. When the inner catheter is pushed forward, 6 to 8 atm pressure is applied to the balloon using a fluid-filled syringe, resulting in linear eversion of the balloon into the fallopian tube. As a result, the falloposcope is carried forward at twice the speed of the balloon. Thus, attention must always be given to the falloposcope tip, which resides within the protective cover of the everting membrane, to prevent damage to the delicate endoscope [15,16].

After the inner sheath is extended to its maximal length of 11 cm, the inflation pressure is set at 2 atm, and the falloposcope is retracted gently until the balloon is placed completely inside the outer sheath. During this retrograde process, the tubal lining can be continuously imaged, and the recanalized portion can be observed clearly. A schema of the progress of the linear eversion catheter and release of tubal occlusion are shown in Fig. 3. When the balloon encounters an obstruction, it is felt as resistance to the forward advancement of the balloon. When this occurs, the inflation pressure is gradually increased to 8 to 10 atm to break down the adhesion inside the tubal lumen.

Patients are discharged either on the day of surgery or the following day, depending on their recovery from anesthesia.
Determination of IgG Antibodies to Chlamydia trachomatis

Before surgery, each patient was tested for serum IgG antibodies to *Chlamydia trachomatis* because chlamydial infection is a common cause of tubal occlusion [17]. The antibody was detected using a VIR-ELISA Anti-Chlamydia IgG Kit (Viro-Immune Labor-Diagnostika GmbH, Oberursel, Germany). According to the manufacturer’s documentation, titers of more than 1:320 are considered positive for a history of chlamydial infection [18].

Statistical Analysis

Statistical analysis was performed using SPSS for Windows statistical software (version 11.0; SPSS, Inc., Chicago, IL). Data were analyzed using the *t* test or *χ*-square analysis, as appropriate. All statistical tests were 2-tailed, and *p* < .05 was considered statistically significant.

Results

Mean (SD; 95% CI) age of patients who underwent falloposcopic tuboplasty was 34.5 (3.5; 34–35), years and of those who chose IVF was 39.5 (2.4; 38.5–40.3) years. There was no statistical difference between the ages of the 2 groups. IVF pregnancies are not included in the statistics. The occlusion was unilateral in 100 patients (32.9%), and bilateral in the remaining 204 (67.1%), twice the rate of unilateral occlusion. In 31 patients (11.3%), the occlusion was detected during laparoscopic surgery. In these patients, HSG was scheduled at different menstrual cycles to confirm the occlusion. Falloposcopic tuboplasty was performed after confirmation of the diagnosis. Eighty patients (26.3%) were positive for serum antibodies to *C. trachomatis*. Mean operative time was 15 (4.03; 11–19) minutes. In 6 patients, laparoscopy was performed concomitant with falloposcopic tuboplasty. The indications for laparoscopy were ovarian cystectomy in 4 patients (3 because of endometrioma, and 1 because of teratoma) and myomectomy in 2 patients.

Typical images of the fallopian tube intralumen at various points are shown in Fig. 4. In normal fallopian tubes, the intralumen is filled with a mucosa containing folds (Fig. 5, A and B), which can clearly be observed to move during irrigation with normal saline solution. In the abnormal intralumen, the mucosa is completely absent, and the surface is flat (Fig. 5, C and D).
Clinical outcomes are given in Table 1. The success rate for recanalization was 81.6% (248 of 304 patients). During the observation period, 91 patients (29.9%) conceived spontaneously, and 21 (23.1%) of these 91 patients conceived in the month after falloposcopic tuboplasty. Of 91 patients who achieved pregnancy, 69 (75.8%) conceived via timed intercourse, and 22 (24.2%) via intrauterine insemination. No patients received controlled ovarian hyperstimulation in either the timed intercourse group or the intrauterine insemination group. The cumulative probability of conception was 50.6%, 73.6%, and 82.4%, respectively, at 3, 6, and 9 months of follow-up (Fig. 6). Eighteen patients (19.8%) had miscarriages, and 4 (4.4%) had ectopic pregnancies. Complications related to the procedure were observed in 24 patients (7.9%). One patient (0.3%) who developed an infection at 3 days after the operation was readmitted and received intravenous antibiotic therapy for 2 days until the fever subsided. This patient conceived naturally 2 months after falloposcopic tuboplasty. Accidental breakage of the linear eversion catheter occurred in 15 procedures (4.9%), and of the falloposcope in 4 procedures (1.3%). In these cases, another linear eversion catheter or falloposcope was used to complete the procedure. The tube was perforated in 4 patients (1.3%); however, no specific treatment was required.

To identify factors that may have contributed to the patients’ ability to become pregnant, characteristics were compared between patients who did and did not become pregnant (Table 2). Among the characteristics studied, mean age and the presence of unilateral occlusion were significantly different. The odds ratio (OR) of pregnancies between unilateral and bilateral occlusion was 2.02 (95% confidence interval [CI], 1.21–3.36). There was no difference in the history of chlamydial infection or any breakage of instruments between the 2 groups.

The treatment flow of all 345 patients after the diagnosis of proximal tubal occlusion is shown in Fig. 7. All 56 patients (18.4%) in whom the tubes failed to be recanalized underwent IVF. Of those, 27 patients (48.2%) conceived via IVF. Of 157 patients in whom tubes were recanalized but who had not conceived after falloposcopic tubuloplasty, 66 patients (42.0%) abandoned natural conception and proceeded to IVF. Of these 66 patients, 35 patients (53.0%) conceived via IVF. Of 6 patients (3.8%) who underwent repeated falloposcopic tubuloplasty, none conceived naturally, and all proceeded to IVF. At present, 85 patients are still trying for natural conception.

Discussion

Falloposcopic tuboplasty is an effective technique for recanalizing fallopian tubes. It offers hope of natural pregnancy for women with a diagnosis of proximal tubal occlusions. Herein, we demonstrated that falloposcopic tuboplasty is an effective treatment for tubal infertility, yielding a pregnancy rate comparable to that with IVF. According to a 2002 report from the International Committee for Monitoring Assisted
Reproductive Technology on 601 243 cycles of IVF in 53 countries, delivery rates per transfer for conventional IVF, intracytoplasmic sperm injection, and frozen embryos were 22.4%, 21.2%, and 15.3%, respectively [19], compared with 28.3% in the present study. Although the mechanism of the catheter system seems complicated, no special technique is required to complete the procedure. Unlike laparoscopic or other endoscopic surgical procedures, approximately only 10 cases are required to master falloposcopic tuboplasty if appropriate instruction is given by an experienced trainer. However, although the potential value of falloposcopic tuboplasty for treating tubal infertility was emphasized repeatedly in the 1990s, it has not yet achieved widespread use or entered routine clinical practice [13]. Little evidence pertaining to the clinical efficacy of falloposcopic tuboplasty is available. A search of PubMed (www.ncbi.nlm.nih.gov/pubmed) using the keyword “Falloposcopic tuboplasty” revealed only 4 articles published in the 1990s and none in the 2000s. According to Terumo Corp (Tokyo, Japan), at present the sole distributor of falloposcopic tuboplasty catheter systems, they supply them only to Japan. Even in Japan, fewer than 10 facilities are currently capable of regularly performing falloposcopic tuboplasty [2].

<table>
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<tr>
<td>Clinical outcome in 304 patients who underwent falloposcopic tuboplasty</td>
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<tr>
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</tr>
<tr>
<td>Variable</td>
</tr>
<tr>
<td>Recanalization</td>
</tr>
<tr>
<td>Pregnancy</td>
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<tr>
<td>Miscarriage</td>
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<tr>
<td>Ectopic pregnancy</td>
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<tr>
<td>Complications</td>
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<tr>
<td>Breakage of linear eversion catheter</td>
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<td>Breakage of falloposcope</td>
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<td>Postsurgical infection</td>
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Fig. 5
Images of normal and abnormal tube intralumen. (A) and (B) Normal intralumen. The intralumen is filled with a gyruslike mucosa (arrows). The mucosa is easily distinguished during the operation because it moves during irrigation using normal saline solution. (C) and (D), Abnormal intralumen. Note that the mucosa is completely absent and the surface is flat.
In the last 2 or 3 decades, IVF has become the first option worldwide for achieving pregnancy in women with tubal infertility. More than half of patients who visit our clinic hoping for natural conception via tubal recanalization have been told by other clinicians that IVF is the only way to become pregnant; however, they persevered because they continued to hope for natural conception. The present study indicates that falloposcopic tuboplasty can be an alternative therapeutic choice to IVF for tubal infertility. Compared with the entire IVF procedure, conception after falloposcopic tuboplasty offers many advantages: there is no need for multiple hormone injections for ovarian hyperstimulation or \textit{in vitro} handling of oocytes and embryos, and less chance of multiple gestations. In this study, 91 patients (29.9\%) conceived naturally after falloposcopic tuboplasty. Thus, not choosing IVF yielded successful results in these 91 patients.

The cumulative number of successful pregnancies demonstrated a characteristic tendency: Almost one-fourth of the patients (n = 21) conceived within a month after falloposcopic tuboplasty, and 88\% of pregnancies occurred within the first year. Confino et al\cite{20} and Gleicher et al\cite{21} reported that pregnancy after transcervical balloon tuboplasty, Fig. 6

Table 2

<table>
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<tr>
<th>Variable</th>
<th>Pregnant</th>
<th>Not pregnant</th>
<th>P value</th>
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<tr>
<td>Total patients</td>
<td>91</td>
<td>213</td>
<td></td>
</tr>
<tr>
<td>Age, mean (SD), yr</td>
<td>32.9 (4.3)</td>
<td>35.3 (4.2)</td>
<td>.001\textsuperscript{a}</td>
</tr>
<tr>
<td>Chlamydial infection, No. of patients</td>
<td>22 (27.5)</td>
<td>58</td>
<td>.58\textsuperscript{b}</td>
</tr>
<tr>
<td>Unilateral occlusion</td>
<td>41</td>
<td>59</td>
<td>.02\textsuperscript{b}</td>
</tr>
<tr>
<td>Intraoperative breakage of instruments</td>
<td>5</td>
<td>14</td>
<td>.84\textsuperscript{c}</td>
</tr>
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NS = not significant.
\textsuperscript{a} Student t test.
\textsuperscript{b} \chi\textsuperscript{2} analysis.

Fig. 7

Treatment flow and outcome in 345 patients with a diagnosis of proximal tubal occlusion. \textsuperscript{*}Total pregnancy rate was calculated with division by 304 (number of patients who underwent falloposcopic tuboplasty), not 248 (patients in whom recanalization was successful). FT = falloposcopic tuboplasty; IVF = \textit{in vitro} fertilization.
the other catheter technique used to treat tubal occlusion, also occurred mostly within 6 months of the procedure. Similarly, the pregnancy rate increased after HSG, but only temporarily [21,22]. We suspect that recanalized tubes do not remain patent permanently and eventually become reoccluded, although there are no data to support this hypothesis. However, based on our data, we advise patients that natural conception after fallopian tubeoplasty is likely to occur only in the first postoperative year and that they should proceed to IVF after this period.

Although it was not a significant difference, the mean age of patients who chose IVF was 4.9 years higher than that of those who chose fallopian tuboplasty. This indicates that patient age at diagnosis of tubal occlusion may be an important factor for patients to make the decision as to whether IVF or fallopian tubeoplasty is the most appropriate option. The younger the patient, the longer she can try for natural conception after fallopian tubeoplasty. How long a patient should try for natural conception will depend on the patient’s age and requirements. If the patient wishes to persist in attempting natural conception for a prolonged period, repeated HSG or fallopian tubeoplasty should be recommended to rule out reocclusion.

The present study included patients with both unilateral and bilateral proximal tubal occlusions. Even when the occlusion was unilateral, we always also tried tuboplasty in the contralateral patent tube because we expected the dilating effect of catheterization to act like the flushing effect of HSG [22–25]. The pregnancy rate in women with unilateral occlusion was almost twice as high as that for women with bilateral occlusion (OR, 2.02; 95% CI, 1.21–3.36). This result indicates that dilation of the normal tube may be more effective than recanalization of the occluded tube. Accordingly, we believe it is possible that the indications for fallopian tubeoplasty can be extended beyond proximal tubal occlusion to unexplained infertility. Questions may be raised that patients with unilateral occlusion conceived simply because ovulation occurred in the ovary on the side in which the fallopian tube had been patent. However, every patient involved in the study had been infertile for at least 2 years. Thus, we interpret that dilation of the nonoccluded tube, not only the occluded tube, certainly contributed to the increased pregnancy rate.

Tubal perforation by the tip of the catheter may occur when the catheter is pushed forward too hard. However, this perforated hole is small and will close spontaneously without any particular follow-up because the outer diameter of the linear eversion catheter is less than 1.0 mm [2]. Once perforation occurs, the operation should be ended because the catheter tends to advance into the perforation rather than along the tubal lumen. These cases were considered recanalization failures, and patients were advised to proceed to IVF instead.

Pregnancy was attempted via either timed intercourse or intrauterine insemination. Of 91 patients, 22 (24.2%) conceived via intrauterine insemination. It may be questioned whether intrauterine insemination itself may have been responsible for subsequent pregnancy after the surgery. However, of 21 patients in the intrauterine insemination group, 8 (38.1%) had already undergone intrauterine insemination elsewhere before they underwent fallopian tubeoplasty. A meta-analysis that compared intrauterine insemination with timed intercourse showed that while intrauterine insemination with ovarian hyperstimulation is associated with a significantly higher pregnancy rate than is timed intercourse with ovarian hyperstimulation (OR, 1.68; 95% CI, 1.13–2.50), no randomized controlled trials were found that compared intrauterine insemination and timed intercourse with the natural cycle [26]. No patients in this study received ovarian hyperstimulation. Given this information, we believe that the effect of intrauterine insemination on the pregnancy rate after fallopionic tubeoplasty is not significant.

The incidence of ectopic pregnancy has been increasing since the late 20th century; in the United States, almost 2% of all pregnancies are ectopic [27]. In the present study, 4 pregnancies (5.1%) were ectopic. Three of the 4 patients (75%) had a history of previous ectopic pregnancy, and 2 patients (50%) tested positive for serum antibodies to C. trachomatis. This indicates that reopening of the fallopian tube does not necessarily mean recovery of the ability to transport an embryo from the tube to the uterine cavity. The incidence of ectopic pregnancy may be increased after a previous ectopic pregnancy, which should be emphasized when informed consent is obtained before surgery, especially if the patient has a history of ectopic pregnancy.

Technical problems have limited the usefulness of fallopian tubeoplasty to the extent that the method has not yet been adopted for routine practice [14,28]. We encountered accidental breakage of the linear eversion catheter in 15 procedures (4.9%), and of the falloposcope in 4 procedures (1.3%). No harm occurred to the patients in any of these cases, and there was no statistical difference in the recanalization rate between the procedures in which instrument breakage did or did not occur (data not shown). However, another linear eversion catheter or falloposcope was required to complete these procedure. A linear eversion catheter is designed to be disposable, and a falloposcope has a life span of about 10 uses. The fragility of the equipment in the fallopian tuboplasty catheter system is an annoyance, and may be one of the obstacles to fallopian tubeoplasty gaining popularity.

In 1988, Thurmond et al [29] described tubal catheterization via selective HSG. They used a 3F to 9F Teflon catheter and dilated the occluded portion of the fallopian tube. They reported that the pregnancy rate after selective HSG was 28% (10 of 36), which is similar to our observation. Similar reports had been published in the late 1980s [30,31]. Accordingly, it may be opined that selective HSG should be sufficient and considered first and that fallopionic tubeoplasty is unnecessary to reopen fallopian tubes. However, a big advantage is that the tube intralumen can be directly observed at fallopian tubeoplasty. We
believe that morphologic changes in the tubal mucosa are as important as tube patency; in some patients, the tubal mucosa is sparse and the lumen is completely flat. We doubt that even after recanalization, lack of tubal mucosa is a poor prognostic factor. A prospective survey of the relationship between the architecture of the tubal lumen and pregnancy outcome has been conducted in our facility, and we hope to report the results in the near future.

Conclusion

Fallopian tuboplasty is effective treatment for tubal infertility patients who still wish for natural pregnancy. The cumulative pregnancy rate after fallopionic tuboplasty is 29.9%. The procedure is not difficult to master, is less invasive than other tubal surgeries, and complications are rare. We propose that fallopian tuboplasty can be an alternative therapeutic option for treatment of tubal infertility.

References