Falloposcopic tuboplasty as an option for tubal infertility: an alternative to in vitro fertilization

This is a case series to evaluate the efficacy of falloposcopic tuboplasty (FT), a surgical technique of recanalization of occluded fallopian tube. Of 153 patients with tubal infertility for more than 2 years who underwent FT, 28.9% (44 patients) conceived, and 27.3%, 75.0%, and 88.8% conceived in 1 month, 6 months, and 12 months after FT, respectively. (Fertil Steril® 2011;95:441–3. ©2011 by American Society for Reproductive Medicine.)

Key Words: Falloposcopic tuboplasty, tubal occlusion, natural conception

Fallopian tube disease is responsible for 20%–30% of female infertility worldwide, the second most common cause of infertility after unexplained infertility, and finding a solution has preoccupied gynecologists for many years (1). Surgical attempts to recanalize occluded fallopian tubes have been made, but the results varied according to the technique as well as the surgeon (1). The reports of these early attempts were frustrating and almost led to abandonment of this approach.

Since the introduction of IVF in the 1980s, the worldwide trends in therapeutic choices for tubal infertility have shifted from surgical recanalization of fallopian tubes toward IVF, and fewer attempts were made at surgical recanalization. However, there is a substantial population of tubal infertile patients who wish to recover tubal patency for subsequent natural conception. In the 1990s, the concept of tubal cannulation emerged again as an alternative to treat patients with cornual obstruction. For this purpose, the technique of falloposcopic tuboplasty (FT) has been established as a tool to reopen occluded fallopian tubes (2, 3).

This is a case series of 160 tubal infertile patients who underwent FT from January 1, 2005, to February 28, 2010, at our institution. Written informed consent was obtained from each patient before FT was performed. Tubal occlusion was diagnosed by either hysterosalpingography (HSG) or hydrotubation with diluted indigo carmine solution during laparoscopic surgery. The FT was indicated when the occlusion was in the proximal portion of the tube. Patients with midsegment occlusion and distal tubal obstruction were excluded from indication. In total 153 patients were included in our analysis. As transient tubal occlusion may be induced by uterine and tubal contraction due to pain, tubal occlusion was confirmed by either HSG at two occasions or one HSG and one intraoperative hydrotubation.

The patients' ages ranged from 22–49 years with a mean of 34.6 years. The occlusion was unilateral in 51 cases (33.3%), and bilateral in the remaining 102 cases (66.7%, 2.0 times the rate of unilateral occlusion). The mean operative time was 17 minutes (range, 14 ± 28 minutes). Patients were discharged 3–5 hours after the surgery depending on their recovery from the anesthesia. Tubal recanalization was defined as successful only when the inner sheath was extended to its full length (11 cm), with a clear image of the tubal intralumen bilaterally; when the ipsilateral tube remained occluded, the case was considered to be a failure. Pregnancy was attempted either by natural intercourse or by IUI any time after the surgery.

All procedures were done using an FT catheter system (Imagyn Medical, Inc., Irvine, CA), which is distributed by Terumo Corporation (Tokyo, Japan), as described elsewhere (2). The FT catheter system consists of three units: a charge coupled device video camera and light source, a falloposcope, and a linear eversion (LE) catheter. The LE catheter consists of an outer catheter sheath and an inner body attached to a tubular pressurized polyethylene balloon, which can be unrolled from within a plastic polymer cannula after the falloposcope is preloaded into its lumen. The process of tubal dilatation and images of tubal intralumen is shown in Figure 1. The balloon inside the LE catheter is pressurized by an inflation device filled with normal saline. The high-resolution falloposcope, achieving a 5,000-pixel image bundle, passes through the central channel of the LE catheter, and is connected to the charge coupled device video camera. As the balloon unrolls, it carries the falloposcope into and along the tubal lumen to a maximum length of 11 cm. When the balloon encounters an obstruction, it is felt as resistance against the forward advancement of the balloon. When this occurs, the inflation pressure is gradually increased to break down the adhesion. Tubal perforation by the tip of catheter may occur when one pushes the catheter forward too hard. In this series, the perforation occurred in two patients (1.3%). However, this perforated hole is very small, therefore it will close spontaneously without any particular follow-up as the outer diameter of the falloposcope is very small (0.6 mm). Once perforation occurs, we consider it as treatment failure and advise patients to undergo IVF.

Yudai Tanaka, M.D., Ph.D.
Hiroto Tajima, M.D., Ph.D.
Department of Obstetrics and Gynecology, Yazaki Hospital, Kanagawa, Japan

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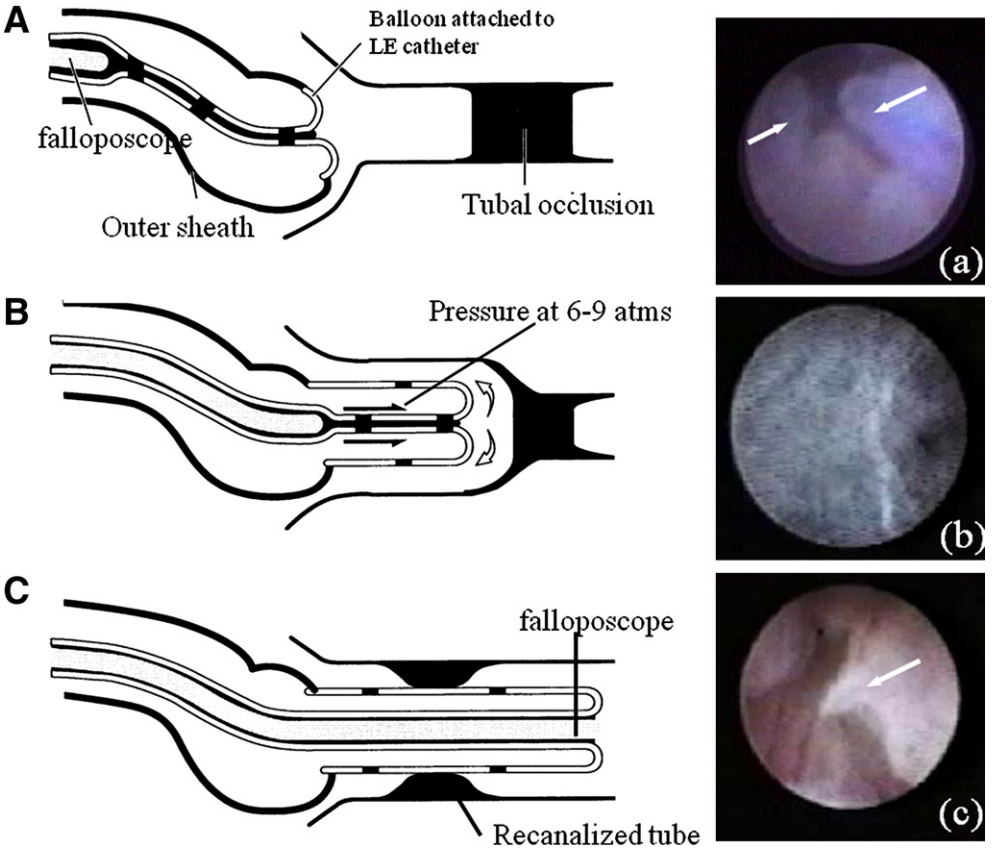
Reprint requests: Yudai Tanaka, M.D., Ph.D., 1-1-16 Kamitsuchidana-Naka Ayase, Kanagawa 252-1113, Japan (FAX: 81-466-41-0332; E-mail: yudai_hello@yahoo.co.jp).

FIGURE 1

Schema of the linear eversion (LE) catheter and release of tubal occlusion and images of the intralumen of fallopian tube. (**A**) The LE catheter is progressed into the tubal lumen. (**B**) The outer sheath is then extended to break down the occlusion with the balloon pressurized at 6–9 atm. The falloposcope stays within the outer sheath so that it will not be damaged. (**C**) The occlusion is released. The falloposcope is extended to the surface of the balloon so that the intralumen can be observed. In normal fallopian tubes, the intralumen is filled with a gyrus-like mucosa (*arrows*), which can be clearly seen when it moves during irrigation with normal saline (**a**). In the occluded portion, the mucosa is completely absent and the surface is flat (**b**). When the occluded portion was successfully recanalized by the falloposcopic tuboplasty catheter, the gyrus-like mucosa can usually be recovered (*arrow*), depending on the degree of adhesion (**c**).



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The successful recanalization rate was 94.8% (145/153), and the pregnancy rate (PR) was 28.9% (44/153). Of those who conceived, 8 patients (18.2%) had miscarriages and 3 (6.8%) had ectopic pregnancies (EP). Of the 44 patients who conceived, 12 (27.3%) conceived in 1 month after FT; 75.0% and 88.8% of the patients conceived in 6 and 12 months after FT, respectively.

Accidental breakage of the LE catheter and falloposcope occurred in 15 cases (9.8%) and 3 cases (2.0%), respectively. Although there was no harm to the patients in any of these instances, another LE catheter or falloposcope was required to complete the procedure. There was no statistical difference in recanalization rate between cases in which instruments breakage occurred and did not occur.

In early 1990s, falloposcopy was first developed for the purpose of direct visualization of the entire length of the fallopian tube lumen (2–4). As falloposcopy techniques were refined, FT was established not only as a diagnostic tool but also as a way to treat occluded fallopian tubes (3). The United States Food and Drug Administration approved the FT catheter system in 1997. Although the mechanism of the FT catheter system is complicated, it takes only 10 cases or so to master the technique as long as appropriate instruction is given by an experienced trainer.

However, as the use of IVF spread worldwide in the 1990s, the recovery of tubal patency attracted less interest from gynecologists, putting FT as rather remote technique. In fact, a search of PubMed using the keyword "falloposcopic tuboplasty" failed to find any articles published in the 2000s, and only four articles in the 1990s. According to TERUMO Corporation, the unique manufacturer of falloposcopy in the world, it is only Japan where they supply the LE catheter. Even in Japan, there are less than 10 facilities where FT is capable of being performed regularly at present.

The FT can be an option to women with tubal infertility who do not wish to undergo IVF. In the present study we have shown that FT is an effective and useful treatment for tubal infertility, yielding a PR equivalent to IVF. The International Committee for Monitoring Assisted Reproductive Technology reported that PR of

IVF/ intracytoplasmic sperm injection (ICSI) of 53 countries in 2002 ranges from 16%–37% (5).

The cumulative number of successful pregnancies showed a characteristic tendency. Of the 44 women who become pregnant, 12 patients (27.3%) conceived within 1 month and 88% of the pregnancies occurred within the first year after FT. This suggests that the recanalized tubes do not remain patent permanently, and reocclusion may occur in a year. Similarly, the PR after HSG increases, but only temporarily (6). Based on our data we advise patients that the golden time for natural conception after FT is about 1 year.

Three pregnancies (6.8%) resulted in EP. This higher rate should be considered as a late complication. All three patients had a history of previous EP, and two patients were positive for Chlamydia antibodies. These results suggest that there are cases in which ability of transportation of embryo from tube to uterine cavity remains impaired even after recanalization of fallopian tube. If the occulted tubes had not been reopened, these patients possibly would not have developed EP. Thus, we always emphasis the possible increased risk of EP, especially if a patient has a history of EP, when informed consent is obtained before FT.

In conclusion, FT can be an excellent alternative to IVF for tubal infertility, with a PR of 28.9%, which is comparable to that of IVF. The procedure is not difficult to master and is less invasive than other surgical techniques for recanalization. However, the risk for EP may slightly be increased after FT. Reocclusion may occur within 1 year. Nonetheless, we propose that FT is an attractive therapeutic option for patients suffering from tubal infertility and hope that FT will gain more popularity in the field of reproductive medicine.

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