Human Reproduction vol.12 no.4 pp.647–649, 1997

OUTSTANDING CONTRIBUTION

Reversal of tubal sterilization using laparoscopically placed titanium staples: preliminary experience

Laurel Stadtmauer and Mark V.Sauer[1]

Department of Obstetrics and Gynecology, Division of Reproductive Endocrinology, Columbia-Presbyterian Medical Center, Columbia University College of Physicians and Surgeons, 622 West 168th Street, New York, NY 10032, USA

[1]To whom correspondence should be addressed

We tested the feasibility of performing outpatient laparoscopic surgery to reverse tubal sterilization using titanium staples to reapproximate the oviducts. A total of 14 women underwent the procedure which involved excision of the tubal eschar, stenting of the severed remnants, and circumferential stapling of the muscularis and serosa. Reapproximation was possible in all cases, with a measured tubal length post-anastomosis of 4.5 ± 0.5 cm (range 3.0–7.0 cm). The length of operating time was 2.8 ± 0.2 h (range 2.2–3.8 h), and all patients were discharged the same day. There were no operative complications, and no readmissions were necessary. Within 6 months of surgery there were six pregnancies including one spontaneous abortion and five ongoing pregnancies. Of those not conceiving within 8 months, seven (100%) demonstrated tubal patency on a follow-up hysterosalpingogram. We conclude the laparoscopic approach to tubal sterilization reversal is a viable alternative to open abdominal microsurgical approaches. Although preliminary, laparoscopic surgery promises to be cost effective, as it can be performed on an outpatient basis, may reduce operative time and minimizes the recuperative period of patients.

Key words: laparoscopy/sterilization reversal/tubal sterilization

Introduction

There is increasing demand for tubal sterilization reversals. This is largely due to the large number of tubal ligations performed on women of young age, who often divorce and remarry, and later wish for a second family with their new partner. Traditionally, sterilization reversal was performed through an open abdominal incision. Best results were obtained using an operating microscope to reapproximate the tubal remnants. Using such techniques a successful pregnancy should occur in the majority of patients within a year of surgery (Sauer *et al.*, 1987).

In the United States the ability to provide surgical services for sterilization reversal has mainly been dictated by financial remuneration. In the private sector, occasional coverage is available through insurance reimbursement. However, this is not often a covered benefit, and patients must pay $5000–$15 000 per procedure to cover the costs of hospitalization and surgical fees. In the public sector, cutbacks in governmental expenditures have recently precluded this service. Unfortunately, women in the poorer segments of the population are the most likely to request this procedure, since many undergo tubal sterilization at a very young age.

Appreciative of the necessity to limit hospital spending and provide surgical services on an outpatient basis, we began to offer laparoscopic reconstructive surgery to allow patients in the indigent population the opportunity to reverse their previous tubal sterilizations. We believe this method offers an alternative to conventional surgery, yet greatly reduces the need for hospitalization and dramatically cuts the cost of the procedure.

Materials and methods

From May 1995 laparoscopically performed reversal of sterilization was offered to patients of the Harlem Hospital Reproductive Endocrinology and Infertility Clinic. Patients who attend this clinic are largely indigent and on public aid. They have no means of obtaining private insurance coverage, and are restricted in their ability to pay for expensive medical services. Outpatient surgery was billed through the hospital at a cost of $1000–$2000, or collected through Medicaid reimbursement. A preoperative evaluation of couples included documentation of ovulation, semen analyses, hysterosalpingography, and infectious disease status [serum human immunodeficiency virus (HIV), venereal disease reference laboratory (VDRL), hepatitis screen].

The patients (n = 14) were <45 years of age (mean 34.0 ± 1.1 years; range 27–44). All were parous (mean 3.3 ± 0.5; 1–7 children). The mean time since their sterilization was 5.9 ± 0.5 years (range 1–9 years). Previous surgery included a modified Pomeroy (n = 11) or laparoscopic tubal cautery (n = 3). In all cases the reason for requesting a reversal of sterilization related to a new partner and a desire to have a second family with the new spouse.

Inclusion criteria were liberally applied, and surgery was performed on patients with a visibly intact fimbriated end of normal appearance and at least 1 cm of patent tubal segment on both the proximal and distal side of the anastomosis. Anastomosis was possible in all women but not all Fallopian tubes, with 19 tubes reapproximated in an isthmic-ampullary manner and six as ampullary-ampullary anastomosis. In three instances no attempt at anastomosis was made due to extensive tubal damage.

At the time of informed consent, all individuals were counselled with respect to results for this procedure using conventional surgery and outcomes following assisted reproduction through in-vitro fertilization. However, in all cases the financial burden posed by these approaches precluded them from consideration.

Table I. Outcomes of laparoscopically placed titanium staples to reverse tubal sterilization

No. patients	14
No. tubes anastomosis performed upon	19
Tubal length post-anastomosis (cm)	4.5 ± 0.5 (3–7)
Operating room time (hours)	2.8 ± 0.2 (2.2–3.8)
Recovery time prior to discharge (hours)	5.0 ± 0.5 (3.0–6.0)
Time to pregnancy (months)	4.3 ± 0.8 (2–8)
Ongoing or delivered pregnancies	5/14
Spontaneous abortions	1/14
Ectopic pregnancies	0
Tubal patency by HSG at 6 months	7/7 women studied (11/14 tubes)

Results are mean ± SD, with range in brackets.
HSG = hysterosalpingogram.

Operative procedure

Patients were given general anaesthesia and placed in the Trendelenburg position. A 10 mm laparoscope was used and initial inspection of the pelvis required complete visualization of the tubal length. Accessory ports were placed in each of the two lower abdominal quadrants, one 10 mm, the other 5 mm. An intrauterine cannula was inserted and methylene blue dye injected to delineate tubal patency. When encountered, pelvic adhesions were lysed, and then the tubal eschar was excised using laparoscopic scissors. Monopolar cautery using a microneedle tip bovie controlled bleeding points. The distal tube was cannulated using a 3-Fr ureteral catheter introduced through the fimbriated end and gently threaded to the point of obstruction. Here scissors were used to open both occluded ends and allow passage of the catheter into the proximal portion. The mesosalpinx was then reappromimated using endosutures (2–0), or titanium staples followed by the anastomosis of the tubes by EAS titanium staples (Ethicon Endosurgical, Cincinnati, OH, USA). A circumferential line of staples (3–4) was placed to align the seromuscular layer of the proximal and distal segments, over the top of the previously placed stent. The stent was extremely valuable for lining up the lumens. In cases in which the isthmic lumen was too small to navigate ($n = 2$), the stent was placed hysteroscopically. Following anastomosis, the lower pelvis was lavaged with lactated Ringer's solution containing 5000 U heparin, and methylene blue dye was injected to confirm tubal patency. Patients were seen 2 weeks postoperatively and again after 3 months to monitor progress. Those not pregnant by 6 months underwent a repeat hysterosalpingogram to evaluate tubal patency.

Results

Table I lists the outcomes following the operative procedures. Surgery was successful in re-establishing patency of at least one tube in all patients. The average length of surgery was 2.8 ± 0.2 h (range 2.2–3.8 h) with a postoperative recovery time of 5.0 ± 0.5 h (range 3.0–6.0 h). All patients went home on oral analgesics within 6 h of surgery, and none required readmission or additional pain control measures. There were no operative complications.

Within 6 months, six pregnancies occurred in 5/14 (36%) patients. Of these pregnancies, five are ongoing and one patient who spontaneously aborted went on to have a subsequent pregnancy. There have been no ectopic pregnancies. The oldest pregnant patient is 36 years old (range 27–36). In the nine non-pregnant patients, seven have undergone hystero-salpingogram, with patency of at least one tube noted in all seven women. With respect to the surgical anastomosis of these women, 11/14 (71%) tubes studied demonstrated patency at 6 months.

Discussion

There are reports of outpatient approaches to tubal reconstruction combining laparoscopy and minilaparotomy (Silva *et al.*, 1991; Daniell and McTavish, 1995). The intrauterine pregnancy rates in these studies were between 40% and 60%, a figure slightly lower than those traditionally published by authors experienced with open abdominal microsurgical techniques (Gomel, 1978; Rock *et al.*, 1987; Dubuisson *et al.*, 1995a; Seiler, 1983). The first reported case of a tubal sterilization reversal performed entirely laparoscopically occurred in 1989 at which time a single tube was reapproximated using a intraluminal guidewire and biological glue (Sebon *et al.*, 1989). However, the patient did not become pregnant. Other reports which combined glueing and suturing techniques or one-stitch suture techniques have demonstrated pregnancies, however at rates much lower than reported using conventional surgical methods (Rucker *et al.*, 1988; Dubuisson and Swolin, 1995b). Reports of anastomosis of tubes reapproximated by endoscopic suturing have also shown reduced pregnancy rates (Reich *et al.*, 1993; Tsin and Mahmood, 1993; Istre *et al.*, 1993; Katz and Donesky, 1994). However, recently a report demonstrating pregnancy rates between 70–80% has renewed interest in this approach (Koh, unpublished data).

Our pregnancy rates are lower than conventional surgical approaches, but are preliminary in nature. A longer follow up interval is necessary to evaluate fully the clinical efficacy of this trial. However, long-term surveillance in an indigent population such as Harlem, New York, is nearly impossible. We are pleased with the rate demonstrated to date given the patients operated upon, with six greater than 35 years of age, three with only one Fallopian tube and four with accompanying pelvic adhesions. In addition, none of our patients had previously placed Yoon Rings or clips, methods known to be associated with the best prognosis for tubal reversal procedures (Rock *et al.*, 1987). Our rates are comparable to success seen after 1–2 cycles of in-vitro fertilization (SART, 1995). Again, although a non-surgical approach using assisted reproduction may be optimal, none of our patients can afford this type of care.

Perhaps with longer follow up and more surgical experience, success rates using this approach will approximate rates seen following conventional therapy. However, with these preliminary findings we believe titanium stapling devices offer a viable option to relatively easy laparoscopic surgery and allow sterilization reversals to be performed on an outpatient basis. The limitations of this technique are largely related to cases where segments are far apart and lumen discrepancies exist. In patients with short isthmic segments, hysteroscopic cannulation is very beneficial. Titanium clips have been shown successfully to reconstruct rat uterine horns (Zhu *et al.*, 1994) and are less inflammatory than sutures (Weis-Fogh *et al.*, 1993). They certainly are easier to place than 7–0 or 8–0 sutures when operating endoscopically.

We conclude that a laparoscopic approach to reversing tubal sterilization is possible and may be simplified using titanium

staples to reapproximate tubal segments. This technique simplifies the operation and allows it to be reasonably performed by most physicians familiar with basic skills in endoscopic surgery. Converting to an outpatient operation should allow more women access to care, and dramatically reduce cost. Even preliminary rates of success appear to be reasonably comparable to rates from limited numbers of attempts at in-vitro fertilization, a procedure few in indigent areas can afford.

References

The American Society of Reproductive Medicine and the Society for Assisted Reproductive Technology in the United States and Canada (1995) 1992 results generated from the Society for Reproductive Medicine/ Society of Assisted Reproductive Technology Registry. *Fertil. Steril.*, **64**, 13–21.

Daniell, J.F. and McTavish, G. (1995) Combined laparoscopy and minilaparotomy for outpatient reversal of tubal sterilization. *So. Med. J.*, **88**, 914–916.

Dubuisson, J.B., Chaperon, C. *et al.* (1995a) Sterilization reversal: fertility results. *Hum. Reprod.*, **10**, 1145–1151.

Dubuisson, J.B. and Swolin, K. (1995b) Laparoscopic tubal anastomosis: the one stitch technique: preliminary results. *Hum. Reprod.*, **10**, 2044–2046.

Gomel, V. (1978) Tubal reanastomosis by microsurgery. *Fertil. Steril.*, **28**, 59–65.

Istre, O., Olsboe, F. and Trolle, B. (1993) Laparoscopic tubal anastomosis: reversal of sterilization. *Acta Obstet. Gynecol. Scand.*, **72,** 680–681.

Katz, E. and Donesky, B.W. (1994) Laparoscopic tubal anastomosis. A pilot study. *J. Reprod. Med.*, **39(7),** 497–498.

Reich, H., McGlynn, F., Parente, C. *et al*. (1993) Laparoscopic tubal anastomosis. *J. Am. Assoc. Gynecol. Laparosc.*, **1**, 16–19.

Rock, J.A., Guzick, D.S. *et al.* (1987) Tubal anastomosis, pregnancy success following reversal of fallope ring or monopolar cautery sterilization. *Fertil. Steril.*, **48**, 13–17.

Rucker, K., Baumann, R. *et al.* (1988) Tubal anastomosis using tissue adhesive. *Hum. Reprod.*, **3**, 185–186.

Sauer, M.V., Zeffer, K. *et al.* (1987) Sterilization reversal performed by fellows in training. What success rates can we reasonably expect? *Microsurg*., **8**, 125–127.

Sebon, E., Delajolinieres, J.B. *et al.* (1989) Tubal sterilization through exclusive laparoscopy. *Hum. Reprod.*, **4**, 158–159.

Seiler, J.C. (1983) Factors influencing the outcome of microsurgical tubal ligation reversals. *Am. J. Obstet. Gynecol.*, **146**, 292–298.

Silva, P.D., Schaper, A.M., Meisch, J.K. *et al.* (1991) Outpatient microsurgical reversal of tubal sterilization by a combined approach of laparoscopy and minilaparotomy. *Fertil. Steril.*, **55**, 696–699.

Tsin, D.A. and Mahmood, D. (1993) Laparoscopic and hysteroscopic approach for tubal anastomosis. *J. Laparoend. Surg.*, **3**, 63–66.

Weis-Fogh, U.S., Petersen, H. *et al.* (1993) Histomorphological evaluation of wound healing of rat oviduct after microsurgical reanastomosis with the use of autologous fibrin adhesive or polyglycolic acid suture. *Eur. Surg. Res*., **25,** 278–286.

Zhu, Y.H., Kirsch, W.M., Tredway, D. *et al.* (1994) Nonpenetrating, arcuate-legged clip reconstruction of the rat uterine horn. *J. Am. Assoc. Gynecol. Laparosc.*, **1**, 395–400.

Received on August 9, 1996; accepted on January 29, 1997