Laparoscopic sterilization falope ring technique update: A 10-year study of 2,831 cases

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This report covers the author's experience with 2,831 cases of laparoscopic sterilization in which a silicone rubber band applicator was employed. The study was performed at an outpatient surgery facility in Saint Louis, Missouri. All of the surgical procedures were performed by the author, and this appears to be one of the largest individual studies in the literature at the present time. The method of surgery as well as the patient population are described, and the results, including significant complications, are analyzed. The pregnancy rate was 1.4 per thousand cases. A significant number (22.7 percent) of the patients had undergone at least one prior pelvic or abdominal operation. A large number of patients had concomitant surgery performed at the time of sterilization. No major pelvic injuries occurred in the series. Most common complications were transection of an oviduct (39 cases), uterine perforation (29 cases), difficulty in achieving pneumoperitoneum (18 cases), and bleeding mesosalpinx (13 cases). The average surgical time was 14.8 minutes; anesthesia time was 31.5 minutes, and recovery room time was 78.6 minutes. Based on this long-term study, the falope ring operative technique is a safe and effective procedure for ambulatory surgical sterilization and appears to have significant advantages over other operative techniques.

laparoscopic sterilization approach—the silicone rubber band technique. My study of this procedure began in 1975, and a preliminary report² on 131 cases was published in 1977. The present report of 10 years' experience with 2,831 patients confirms the simplicity, safety, and effectiveness of the technique. All of the procedures were performed on an outpatient basis in a free-standing outpatient surgery center.³ The study is one of the largest individual studies in the American literature.

Materials and methods

Laparoscopic silicone applicator

Instruments used in this series of 2,831 cases primarily were single- or double-puncture laparoscopes manufactured by Kli (now Cabot) Laboratories. The single puncture was used in 2,524 cases, the double puncture in 179 cases. A single-puncture instrument made by Storz was used in 15 cases. Forty-five cases were combined with rings and coagulation, 53 cases by bipolar coagulation, and 3 cases by unipolar coagulation. Minilaparotomy was performed in 2 cases; in 10 cases, diagnostic laparoscopy was performed because sterilization could not be accomplished.

The two-cylinder laparoscopic silicone ring applicator employs a standard laparoscopy lens system and fiberoptic light source. A grasping forceps for lifting a segment of the fallopian tube is within the inner cylinder. The outer surface of the inner cylinder is fitted with a silastic ring. (The newer equipment allows two rings to be placed at one time, so that the ligation can be accomplished without reloading the applicator.) The ring is displaced onto the inner cylinder by means of a loading cone. The ring is made of a combination of silicone and rubber that allows specific elastic power and 90 to 100 percent memory. It is 2.2-mm. thick, with an inner diameter of 1 mm. and an outer diameter of

In 1974, Yoon and associates¹ reported on a new

3.6 mm.; when placed on the surface of the inner cylinder, it is stretched to 6 mm.

The inner cylinder of the device slides to and fro, and the grasping forceps are exposed as the handle is moved forward. In moving the handle backward after grasping a segment of fallopian tube, the tube is drawn into the inner cylinder. Simultaneously, the silicone ring is forced onto the fallopian tube.

Study group and procedures

A total of 2,831 patients were included in the study. Of these, 1,716 patients were referred by the Family Planning Council of Saint Louis, Missouri, through its various family planning agencies, and 1,115 patients were from my private practice, which involved welfare recipients as well as middle-class women. The patients all desired permanent sterilization. All procedures were performed at a free-standing surgical center named Surgicare, Inc., (now Community Surgical Center, Inc.).

The study was begun in March 1975 and includes all cases performed through 1984. Age, marital status, and parity were not primary criteria in the study. All women who requested permanent sterilization and were older than legal age were considered for the procedure. Exception was made in 15 cases (0.5 percent); these patients exhibited severe mental retardation and were carefully evaluated and had consultations recommending the procedure.

In 1975, I used both ring and cautery techniques in my practice, but by 1976, it was my intent to use the silastic ring for all patients.

Presurgical and laparoscopic procedures

Age distribution of the patients is noted in Table 1. The youngest patient was 13 years and the oldest 49 years; average age was 30.2 years. Marital status distribution is presented in Table 2. The average weight was 143.8 pounds, with a range of 80 to 340 pounds; 224 patients (7.9 percent) weighed in excess of 200 pounds. Based on 2,741 patients, the average number of living children was 2.6 (90 patients not recorded).

Previous major abdominal or pelvic surgery had been performed for 642 patients (22.7 percent). Table 3 lists the number and Table 4 the type of major operations. Most of these patients had undergone cesarean section, appendectomy, cholecystectomy, or pelvic laparotomy. Four patients had five previous major operations. Table 5 shows the distribution of cesarean sections, with 209 patients having undergone at least one prior C-section.

Preoperative evaluation and physical examination were performed for each patient, and the necessary consent forms were reviewed fully in

TABLE 1. AGE DISTRIBUTION OF 2,831 FALLOPE RING STERILIZATION PATIENTS.

Age group (years)	No. of patients	Percent of patients
<21	15	0.5
21-25	559	19.8
26-30	832	29.4
31-35	728	25.7
36-40	471	16.6
41-45	187	6.6
>45	39	1.4

TABLE 2. MARITAL STATUS DISTRIBUTION OF 2,831 FALLOPE RING STERILIZATION PATIENTS.

Marital status	No. of patients	Percent of patients
Single	468	16.5
Married	1,265	44.7
Separated	362	12.8
Divorced	683	24.1
Widowed	53	1.9

TABLE 3. PREVIOUS MAJOR ABDOMINAL OR PELVIC OPERATIONS IN SERIES OF 2,831 PATIENTS.

No. of procedures per patient	No. of patients	Total no. of procedures
1	483	483
2	113	226
3	38	114
4	4	16
5	4	20
Total	642	859

accordance with the standards set by the Department of Health, Education, and Welfare (DHEW). Counseling often was done in group sessions; it was found that this method stimulated more questions than when the patients were counseled individually. Each patient also was given an opportunity to have her questions answered privately during her physician examination. The procedure usually was scheduled in accordance with DHEW's waiting period, and the patient was instructed to fast after 12:00 a.m. on the day of surgery.

Hemoglobin and hematocrit levels were determined and urinalysis and a pregnancy test were performed on the day of surgery. An evaluation was made by an anesthesiologist prior to the administration of general anesthesia. No preoperative medications were employed. Chest roentgenography was performed at the discretion of the anesthesiologist.

The patient was taken to the operating suite and placed in a modified lithotomy position. The abdomen, perineum, and vagina were prepared with a povidone-iodine preparation, and appropriate drapes were applied. A bimanual pelvic examina-

TABLE 4. DISTRIBUTION OF PREVIOUS MAJOR ABDOMINAL OR PELVIC SURGERY BY TYPE.

Type of procedure	No. of procedures
Cesarean section	322
Appendectomy	176
Cholecystectomy	152
Pelvic laparotomy	128
Umbilical herniorrhaphy	29
Gastric resection or bypass	13
Inguinal herniorrhaphy	11
Splenectomy	8
Stab or gunshot wound of abdomen	3
Bowel resection	2
Bladder suspension	2
Hiatal herniorrhaphy	2
Volvulus	1
Colostomy	1
Abdominal fistula	1
Liver resection	1
Tubal ligation	1
Diaphragmatic abscess	1
Miscellaneous (thyroidectomy and open-heart surgery)	5
Total	859

TABLE 5. PREVIOUS CESAREAN SECTIONS IN SERIES OF 2,831 PATIENTS.

No. of procedures per patient	No. of patients	Total no. of procedures
1	122	122
2	66	132
3	17	51
4	3	12
5	1	5
Total	209	322

tion was performed. A weighted speculum was introduced, and the cervix was grasped with a tenaculum and brought downward and forward. For purposes of manipulation during the procedure, a blunt uterine sound was placed in the uterus. A Verres needle was introduced into the infraumbilical fold, and, utilizing 2 liters or less of carbon dioxide, a pneumoperitoneum was created. The needle was removed, a small incision was made in the infraumbilical fold, and a trocar and cannula were introduced. The trocar was then removed, with the trocar sleeve left in place.

Next, the laparoscope and silicone rubber band applicator were inserted through the trocar sleeve, and the pelvic cavity with its contents were visualized. A spinal needle was inserted suprapubically, and approximately 2 ml. of 1 percent Xylocaine solution was infused on the surface of each oviduct. After the oviducts were fully identified from the cornu to the fimbria, the grasping forceps were used to pick up the fallopian tube approximately 1 to 2 inches from the cornu, at a point of greatest mobility. The oviduct was drawn into the inner cylinder of the ring applicator device.

TABLE 6. CONCOMITANT SURGERY PERFORMED AT TIME OF STERILIZATION.

Procedure	No. of cases
Dilatation and curettage	599
Cryocautery of cervix	236
Lysis of adhesion	103
Removal of intrauterine contraceptive device	80
Electrocautery of cervix	54
Salpingochromoscopy	11
Myomectomy	10
Aspiration of ovarian cyst	5
Cervical polypectomy	4
Cervical biopsy	4
Removal of nevi	4
Coagulation of uterine perforation site	4
Biopsy of vagina	3
Cautery of condylomata	3
Umbilical herniorrhaphy	2
Aspiration of peritoneal fluid	2
Excision of labial cyst	2
Cervical cold knife coagulation	2
Marsupialization of Bartholin's gland cyst	2
Posterior colporrhaphy	1
Breast biopsy	1
Coagulation of endometrial implants	1
Excision of Gartner's duct cyst	1
Excision of hymenal tags	1
Partial vulvectomy	1
Excision of abdominal lesions	1
Excision of vaginal septum	1
Excision of Bartholin's cyst	1
Coagulation of mesosalpinx bleeder	1
Removal of perforated intrauterine contraceptive device	1
Excision of vulva lesion	1
Vacuum suction curettage	1

One silicone rubber band was applied to the grasping segment of the fallopian tube by moving the outer cylinder forward. After application of the silicone ring, the grasping forceps were moved forward out of the inner cylinder to release the segment of the fallopian tube that had been occluded by the band. Similarly, the opposite tube was grasped and a silicone ring was applied. Injection of indigo carmine dye to test patency was not performed. Following removal of the laparoscope, the pneumoperitoneum was relieved. In most instances, the puncture site was sutured with no. 4.0 chromic catgut using either a standard or subcuticular technique, or atraumatic allis forceps were used to accomplish skin closure.

A surgical center nurse phoned each patient at home on the day after surgery and recorded her responses on her medical chart.

Concomitant procedures

Table 6 illustrates the concomitant surgical procedures performed at the time of sterilization. Dilatation and curettage, cryocautery of cervix, lysis of adhesions, removal of intrauterine contraceptive

devices, and electrocautery of the cervix accounted for these majority of procedures.

Anesthesia

General anesthesia was used in all but 8 cases. The choice of anesthetic agent was left to the anesthesiologist. Not all patients had endotracheal intubation. In almost all cases, 1 percent Xylocaine was infused on the surface of the oviducts, because early study had shown that it helped to reduce postoperative nausea and vomiting. It may also have helped to reduce postoperative pain, which seems to be significant when silastic rings are employed. The most significant recovery room prob-

lem was vomiting, which occurred in 429 cases. Postoperatively, patients were given oral medications containing codeine or a similar substance for pain control.

Procedural times

The average operating room time for all cases, including those involving concomitant procedures, was 14.8 minutes. The average anesthesia duration was 30.5 minutes, and the recovery room time was 78.6 minutes.

Results

Complications

No major injuries to the pelvis occurred in this series. Table 7 illustrates the type of complications encountered at the time of surgery.

The most common complication was transection of the oviduct, which occurred as the oviduct was drawn into the cylinder by the grasping forceps because the tube was too thick to be introduced into the laparoscope. With experience, this complication can sometimes be overcome by "milking" the tube (grasping it and slowly drawing it into the operative channel and releasing it). This maneuver is performed several times until the tube can be drawn into the laparoscope and the ring applied. In each case of transection, a "click" sound was heard. When this occurred, an attempt was made to ligate

TABLE 7. OPERATIVE COMPLICATIONS ENCOUNTERED DURING SURGERY.

Complications	No. of cases
Transection of oviduct	39
Uterine perforation	29
Difficulty of achieving pneumoperitoneum	18
Bleeding mesosalpinx	13
Inability to ligate	9
Trocar injury to uterus	8
Mechanical problems with instrument	6
Ring placed on ovarian or round ligament	5
Superficial laceration of bowel	3
Conversion to minilaparotomy	2
Ectopic pregnancy	1
Protrusion of bowel through incision	1
Tenaculum tear of cervix	1
Total	135

TABLE 8. CASES REQUIRING HOSPITAL ADMISSION.

No.	Reason for hospitalization	Comments
1	Previously undiagnosed ectopic pregnancy	Transfer
2	Cornual pregnancy, which ruptured 3 days after ligation	Negative pregnancy test
3	Umbilical hematoma	Patient dismissed within 24 hours
4	Undiagnosed hemoperitoneum, probable tubal abortion	Patient hospitalized 48 hours (transfer)
5	Urinary tract infection	Patient dismissed within 24 hours
6	Severe scoliosis	Minilaparotomy performed (1) Patient hospitalized 72 hours (transfer)

TABLE 9. PREGNANCIES THAT OCCURRED IN 2,831 CASES OF STERILIZATION.

No.	Date of surgery	Year of pregnancy	Outcome	Re-evaluation comments
1	11/8/76	1978	Spontaneous abortion	Two rings originally placed on right tube. No dye spilled at repeat laparoscopy, but right tube was coagulated.
2	11/7/77	1979	Voluntary termination of pregnancy	Dye passed on right side, and right tube was coagulated.
3	10/14/80	1981	Voluntary termination of pregnancy	No dye was passed, but bilateral coagulation was performed.
4	8/2/83	1984	Carried to term	Postpartum ligation was performed.

the oviduct on each side of the transection with a silicone band, or the procedure was converted to a cautery technique.

Hospital admissions

As noted in Table 8, there were 6 hospital admissions for any cause in the entire series. In 1 case, a cornual pregnancy that ruptured 3 days later was not recognized at the time of surgery.

Pregnancies

The 4 known pregnancies that occurred are described in Table 9. The pregnancy rate was 1.4 per thousand.

Comment

As is evident in the present series, the silicone rubber band applicator for laparoscopic sterilization is a safe and effective way to achieve outpatient sterilization. Also, tubal reconstruction may be possible in those rare instances when such reanastomosis may be desirable.⁴ Because thermoenery is not required, there are no bowel burns, and the procedure should be considered by physicians who already are utilizing laparoscopic ster-

ilization techniques that utilize thermocautery.

Appreciation is expressed to Mrs. Linda Vetter for her statistical analysis.

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1. Data on file, Fisons Corporation. From perennial allergic rhinitis trial by Wittig H.J., with Cohan R.H., Bloom F.L., Rhoades R.B., et al.

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