Chapter 27
Tubal Sterilization

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DEFINITIONS

Bipolar coagulation—Method of tubal occlusion usually performed via laparoscopy that causes electrocoagulation of the tube when current is applied by grasping forceps; one jaw of the forceps is an active electrode, and the other is a return electrode. There is less chance for unintended thermal injuries than with unipolar coagulation, and the chance of unintended thermal injury by capacitive coupling is virtually eliminated. However, less widespread thermal destruction of the tube increases the chance for sterilization failure relative to unipolar coagulation unless the surgeon uses techniques that maximize the likelihood of adequate tubal coagulation.

Capacitive coupling—Unintended consequence of laparoscopic use of unipolar coagulation, which under certain conditions can result in a charge being transferred to the operative laparoscope or conductive laparoscopic sheath. Subsequent occult transference of this charge to intestines can lead to thermal injury and subsequent perforation with infectious morbidity or mortality.

Cumulative failure rates—Contrary to previous beliefs, tubal sterilization failures are not isolated to a narrow window of time after the procedure but rather increase cumulatively with each passing year following sterilization. Younger women, who are more fecund at sterilization and for years after, have higher failure rates initially and over time.

Gas embolism—Potential complication of laparoscopic abdominal insufflation with the Veress needle, associated with “vapor lock” of the right ventricle, which occludes blood flow and results in cardiovascular collapse. A “cogwheel” murmur can sometimes be heard.

Hysteroscopic sterilization—Surgical approach in which an endoscope is introduced transcervically into the uterine cavity for the purpose of placing the Essure microinsert into the fallopian tubes across the uterotubal junction. It has the advantage of requiring no abdominal incision and only minimal analgesia. It can be performed in an outpatient or office surgery setting.

Irving method—Method of partial salpingectomy that buries the end of the proximal tubal stump in the myometrium of the uterus, in an attempt to reduce the rate of tuboperitoneal fistula.

Luteal phase pregnancy—Refers to pregnancies that occurred before sterilization but were detected after sterilization. Such pregnancies may be erroneously attributed to sterilization “failure.”

Open laparoscopy—Laparoscopic procedure begun without prior insufflation by directly visualizing, elevating, and incising the layers of the abdominal wall near the umbilicus. Has the benefit of reducing vascular injuries and, potentially, bowel injuries associated with blind direct Veress needle and trocar insertion.

Parkland method—Method of partial salpingectomy that involves ligation of the tube in two places, followed by excision of the intervening segment of tube. Achieves immediate separation of severed tubal ends.

Pomeroy method—Method of partial salpingectomy that involves ligation, followed by excision, of a loop of tube. No attempt to bury the severed ends of the tube.

Poststerilization regret—Regret after the decision to undergo surgical sterilization can be related to several factors, including preexisting patient characteristics, subsequent changes in the patient's situation or attitudes, and dissatisfaction resulting from adverse side effects caused or perceived to be caused by the procedure. Studies have identified young age at tubal sterilization as a risk factor for later regret.

Posttubal ligation syndrome—Refers to the historic perception that menstrual disturbances could result from tubal sterilization. This term is outdated, as substantial evidence against such a syndrome now exists. Women who undergo sterilization are no more likely than are their nonsterilized counterparts to experience a syndrome of menstrual abnormalities.

Silicone rubber banding—Method of tubal occlusion usually performed via laparoscopy in which a silicone rubber band is applied to the isthmic portion of the tube. The technique is most effective when the tube has normal anatomy and the operator is experienced with the technique of application. The possibility of tubal transection, and resultant hemorrhage, appears to be highest with this technique.

Sterilization timing—Sterilization can be performed in relation to pregnancy (following vaginal delivery, cesarean section, or abortion) or remote from pregnancy (interval sterilization).

Tubal clips—Method of tubal occlusion usually performed via laparoscopy in which a Filshie or Hulka clip is applied to the isthmic portion of the tube. The technique is most effective when the tube has normal anatomy and the operator is experienced with the technique of application. These methods inflict the narrowest zone of tubal damage (3 to 5 mm), affording a greater chance of sterilization reversal when compared with other methods.

Tuboperitoneal fistula—Poststerilization communication of the proximal tubal stump with the peritoneal cavity, which can result in sterilization failure, including ectopic gestation. Theoretically, may be reduced by leaving a proximal tubal stump of 2 cm and by minimizing ligature-induced necrosis at the site of tubal interruption.

Uchida method—Method of partial salpingectomy that buries the end of the proximal tubal stump within the leaves of the mesosalpinx in an attempt to reduce the rate of tuboperitoneal fistula.

Unipolar coagulation—Method of tubal occlusion usually performed via laparoscopy that causes electrocoagulation of the tube when current is applied by grasping forceps; both jaws of the forceps serve as an active electrode. The high effectiveness rates observed with this method are a property of the wide zone of thermal destruction of the tube that results, but this same property increases the potential for morbidity from unintended thermal injuries. The surgeon must be vigilant regarding possibility of capacitive coupling.

In proposing the concept of tubal sterilization in 1842, James Blundell suggested the following:

> … the operator … ought to remove a portion, say one line, of the Fallopian tube, right and left, so as to intercept its caliber— the larger blood vessels being avoided. Mere divisions of the tube might be sufficient to produce sterility, but the further removal of a portion of the tube appears to be surer practice. I recommend this precaution, therefore, as an improvement of the operation.

Samuel Smith Lungren of Toledo, Ohio, is credited with having performed the first tubal sterilization in 1880, after having performed a cesarean section for a woman whose previous child was also born by cesarean section because of a contracted pelvis. During the second cesarean section, Lungren intended to remove

the woman's ovaries to prevent future pregnancy, but instead decided that "the risk would be lessened and the same result would be accomplished by tying both Fallopian tubes with strong silk ligatures a one inch from the uterus." At the time of Lungren's successful tubal sterilization, laparotomy was a life-threatening procedure; thus, the performance of tubal sterilization at the time of cesarean section to prevent future pregnancy was potentially lifesaving. In 1919, Madlener reported on 85 tubal sterilizations performed at the time of laparotomy for other reasons, including cesarean section; 3 of the 85 women died postoperatively from infection. Because of the extreme risks, performing a laparotomy for the sole purpose of tubal sterilization remained an unpopular idea until the mid-20th century. Indeed, when three deaths occurred from 1936 to 1950 among 1,022 women who had postpartum Pomeroy sterilization, investigators Prystowsky and Eastman concluded that the risk for sterilization was comparable to that for multiparity and that "sterilization because of great multiparity alone cannot be justified on medical grounds."

In addition to concerns about safety, the early history of tubal sterilization included debate about the appropriateness of tubal sterilization for fertility control. At the 21st Annual Meeting of the American Gynecological Society in 1886, participants debated a woman's right to undergo surgical sterilization. During this debate, Edward P. Davis said, "I hold it [sterilization] to be the right of a woman who is in a condition to which natural delivery is impossible…." H. J. Garrigues objected by saying,

> We must leave that to Nature or to God. … I do not think that the woman has a right of that kind. … The mere fact that she does not want to have more children should not decide the question. (Speert)

The availability and acceptability of tubal sterilization as a method of fertility control remained limited until the mid-20th century, and, accordingly, tubal sterilization remained uncommon in the United States and around the world until the 1960s. In the 1970s, the worldwide popularity of tubal sterilization increased dramatically. Between 1970 and 1980, the estimated number of tubal sterilizations increased markedly in Europe, China, India, other parts of Asia, and Latin America. In the United States, the number of tubal sterilizations increased nearly fourfold—from approximately 200,000 in 1970 to approximately 700,000 in 1977. Among the factors affecting this increase were the availability and acceptability of two new surgical approaches—minilaparotomy and laparoscopy. In contrast to laparotomy for sterilization, these approaches were safer, allowed for surgery without hospitalization, reduced recovery time, and gave a better cosmetic result. Minilaparotomy has been used in many developing countries, and laparoscopy has been used in many developed countries, including in the United States.

Minilaparotomy for interval sterilization (i.e., sterilization at a time unrelated to pregnancy) requires a 2.5- to 3.0-cm suprapubic incision. The technique was first described by Uchida and colleagues in Japan in 1961. It was used in the early 1970s in Thailand by Vitoon and associates and then rapidly gained acceptance worldwide. Laparoscopy for tubal sterilization was first proposed by Anderson in 1937 and later described by Power and Barnes in 1941. The use of laparoscopy in Europe was encouraged by the work of Palmer (France), Steptoe (Britain), and Frangenheim (Germany), and use of the technique rapidly gained popularity in the 1970s, particularly in Europe and the United States.

In the United States, the increased use of tubal sterilization in the 1970s occurred concurrently with the widespread availability and acceptability of laparoscopy. In 1970, less than 1% of sterilizations were performed with a laparoscope, but by 1975, more than one third of the 550,000 women who had tubal sterilization had the procedure performed laparoscopically. This transition was associated with a marked reduction in length of hospital stay for tubal sterilization— from 6.5 nights in 1970 to 4 nights in the years 1975 to 1978. By 1987, one third of tubal sterilizations in the United States required no overnight hospital stay, and 79% of these were performed by way of laparoscopy. In 2002, the FDA approved a new even less

invasive hysteroscopic approach for sterilization (Essure) that can be performed successfully in the office setting.

Sterilization is now the method of contraception most commonly used in the world. In 2009, about 251 million couples used sterilization (of themselves or their spouses) for contraception; 223 million were women using tubal sterilization and 28 million were men using vasectomy. Most of these sterilizations were performed in the developing world—229 million versus 22 million in the developed world.

In the United States, sterilization is also the most commonly used method of contraception. According to data from the National Center for Health Statistics, among women aged 15 to 44 in 2006-2010, about 14 million (22.7%) reported using either tubal sterilization (about 10 million) or vasectomy (about 4 million) for contraception. Among currently married women using contraception in 2006-2010, 47.3% were using either tubal sterilization (30.2%) or vasectomy (17.1%) for contraception. These percentages were very similar to those for 1995 (31.2% and 17.3%, respectively).

In 2006, of an estimated 643,000 tubal sterilizations, 351,000 (55%) were inpatient procedures and 292,000 (45%) were performed in an ambulatory setting. Nearly all of the former were postpartum procedures (either after vaginal delivery or concurrent with cesarean section). An increasing proportion of ambulatory procedures is being performed by hysteroscopy using the Essure device, but it is too early to determine the impact of such procedures on sterilization trends.

TIMING OF STERILIZATION

Tubal sterilization can be performed at the time of cesarean section, shortly after delivery or induced abortion, or at a time unrelated to pregnancy. About one half of tubal sterilizations in the United States are performed at a time unrelated to pregnancy. The timing of tubal sterilization can influence the choice of anesthetic, surgical approach, and method of tubal occlusion. For example, most sterilizations performed concurrently with cesarean section require no separate anesthesia and involve partial salpingectomy as the method of tubal occlusion. Most tubal sterilizations performed after vaginal delivery are done by minilaparotomy with subumbilical incisions and partial salpingectomy. Tubal sterilization not associated with birth usually is performed by laparoscopy (with use of coagulation, silicone rubber band application, or clip application), hysteroscopy (with use of Essure device), or minilaparotomy (with use of partial salpingectomy).

PREOPERATIVE EVALUATION

The candidate for sterilization should be extensively counseled. The intended permanence of the procedure, alternatives to sterilization, and risks of surgery should be discussed.

For couples desiring sterilization, no such discussion is complete without consideration of vasectomy as an alternative. Women also should be made aware that sterilization failure can occur and that the relative likelihood of ectopic pregnancy is increased when sterilization failure does occur.

The workup of women who are to undergo tubal sterilization includes a history and physical examination and a laboratory evaluation, as indicated. Consideration should be given to whether the woman might be pregnant at the time of sterilization, and pregnancy testing should be ordered as necessary.

A careful gynecologic history and examination also are necessary before sterilization. Women with gynecologic disease or symptoms may require additional diagnostic or therapeutic measures. Some ultimately may be better served by other surgical procedures, either instead of or in addition to sterilization. For example, some women with enlarged and symptomatic uterine leiomyomata, women with severe dysmenorrhea, and those with symptomatic pelvic relaxation may benefit more from hysterectomy than from tubal sterilization. Others, such as

women with abnormal cervical cytology, need careful evaluation before a decision can be made about preventing or treating invasive cervical cancer.

ANESTHESIA

Complications of general anesthesia are the leading cause of death attributed to sterilization in the United States. The risks inherent in general anesthesia are exacerbated by its use postpartum and during laparoscopy. The special requirements of general anesthesia for laparoscopy have been well described.

Except for the use of conduction anesthesia postpartum, general anesthesia is the technique most often used for female sterilization by laparoscopy and minilaparotomy in the United States. A 1988 survey of members of the American Association of Gynecologic Laparoscopists revealed that the number of providers of tubal sterilization who used local anesthesia for laparoscopic sterilization had increased from 4% (in the 1982 survey) to 8%. Worldwide, more than 75% of tubal sterilization procedures are performed under local anesthesia. A discussion of the technology and regimen for administering general or conduction anesthesia is beyond the scope of this chapter. Instead, we focus on local anesthesia because of its increasing use in outpatient settings for many types of surgery.

Sterilization by laparoscopy, hysteroscopy, or minilaparotomy can be performed safely under local anesthesia, and hysteroscopic sterilization with the Essure device can be performed with minimal analgesia alone. The patient avoids the risks associated with general anesthesia, spends less time sedated or anesthetized, and has a more rapid recovery. Nausea and vomiting are less likely to occur, and the patient is awake to report symptoms that can indicate the occurrence of a complication. Furthermore, the overall expense often is reduced compared with procedures done under general anesthesia.

In the United States, the overall morbidity rate for female sterilization is so low that it is difficult to obtain a sample large enough to demonstrate a comparative safety advantage for local versus general anesthesia. One US study randomly assigned 100 women to either local or general anesthesia for laparoscopic sterilization. Serious or life-threatening events did not occur in either group. However, women who had general anesthesia were more likely to have intraoperative hypotension, hypertension, or tachycardia, which suggests that these women were hemodynamically less stable and may have been at increased risk for cardiovascular complications. In another study, 125 women were randomly allocated to the use of local or general anesthesia for laparoscopic sterilization. Women who had general anesthesia were more likely to develop hypotension; hypertension was more common in the local anesthesia group. No women in either group had tachycardia.

Operating under local anesthesia incurs several possible disadvantages. The patient's anxiety may be increased; therefore, the surgeon must use a decisive and gentle surgical technique while talking with the patient. The patient may feel discomfort; thus, the physician must have a thorough understanding of the use of sedative and analgesic drugs. Although obesity can complicate the use of local anesthesia, several studies indicate that local anesthesia can be used successfully for obese women. Women with a history of multiple abdominal or pelvic surgical procedures or peritonitis may need additional anesthesia if the procedure is difficult or prolonged. Additional anesthesia also may be required during minilaparotomy if the abdominal incision needs to be extended. The hysteroscopic approach may be ideal for both obese women and those with multiple previous abdominal procedures as it avoids the necessity to access the tubes through the abdominal wall.

One US-based retrospective study reviewed 2,827 outpatient laparoscopic sterilizations performed under local anesthesia and mild sedation from 1980 to 1988. The mean operating time was 10.0 (±5.1) minutes, and the mean anesthesia time was 23.3 (±6.9) minutes. The hospital cost to the patient was reduced 65% to 85%. Another US study reported on 358 minilaparotomies for interval sterilization performed under local anesthesia. The average operating time was 21 minutes, and no complications were reported. In both series, the local anesthetic was 0.5% bupivacaine hydrochloride used alone or in combination with lidocaine. In one series,

midazolam hydrochloride and fentanyl citrate were used for mild intravenous sedation; in the other series, meperidine hydrochloride and diazepam were used.

For local infiltration and paracervical block, agents of intermediate intrinsic potency (defined as the minimum concentration required to produce a block within 5 to 10 minutes), such as lidocaine or mepivacaine, have been found suitable. Both are amides with good stability and low toxicity. Onset of analgesic effects is rapid, even when a low concentration of medication is used, and the duration of the effect is sufficient for the procedure but not prolonged (about 1.5 hours when the medication is given in plain solution). Bupivacaine, a more potent and a longer-acting amide, is frequently used in the United States. However, the short duration of action provided by lidocaine or mepivacaine is preferred by some because it allows for awareness of any abnormal degree of persistent pain and early diagnosis of complications, such as hematoma formation.

SURGICAL APPROACH

Minilaparotomy

The minilaparotomy approach to tubal occlusion can be used in the interval or postpartum period. Although interval sterilization by minilaparotomy is the sterilization procedure most frequently performed in many countries, it is not a common procedure in the United States. Minilaparotomy in the United States often is used preferentially among women considered to be at increased risk for laparoscopy.

Interval minilaparotomy is performed with the use of a 2- to 3-cm midline vertical or transverse suprapubic incision. In patients with an enlarged uterus resulting from uterine leiomyomata or other benign conditions, the minilaparotomy incision should be made at the level of the uterine fundus to ensure access to the fallopian tubes. A uterine manipulator is placed through the cervix just before surgery and is used to bring the uterus toward the incision. Placement of a paracervical block before insertion of the uterine manipulator reduces

discomfort for patients having surgery under local anesthesia. The abdomen is then entered with the approach that is used for laparotomy; small handheld retractors and the Trendelenburg position are used to enhance exposure. Once the uterus is identified, a tubal hook or a finger is placed posteriorly at the top of the fundus and moved along the uterus. The fallopian tube is identified first by the fimbriated end, and then the midportion of the fallopian tube is grasped with a small Babcock clamp and elevated through the abdominal incision. Tubal occlusion most often is performed by use of the modified Pomeroy or Parkland technique. However, clips or rings can be applied through the minilaparotomy incision with modified instruments originally developed for use through the operating laparoscope.

Postpartum minilaparotomy is performed in a manner similar to that of interval minilaparotomy. It is ideally performed before the onset of postpartum uterine involution while the uterine fundus is high in the abdomen (within 48 hours of delivery). A 2- to 3-cm subumbilical vertical or semicircular incision is made in the midline where the abdominal wall is thin. Because of the proximity of the enlarged uterus to the incision, access to the fallopian tubes is easier than it is with an interval approach. A uterine manipulator is unnecessary when minilaparotomy is performed in the postpartum period.

Laparoscopy

> The magic is in the magician, not in the wand. … Entering the abdomen is the most dangerous part of the laparoscopic procedure. (Hulka and Reich)

The laparoscopic instrumentation, including laparoscope, light cables and light source, insufflator and tubing, and video camera and television, if used, should be set up and tested for proper functioning before any incisions

are made. If a Veress needle is to be used, it is good practice to attach it to the insufflation tubing and test that gas flows freely through it. High line pressures (3 mm Hg or higher) during low-flow insufflation (1 L/min) through a Veress needle that has yet to be inserted into the abdominal cavity suggest that the needle has some occlusion. Checking for occlusion before inserting the needle can avoid the multiple attempts at needle placement that might occur in the belief that incorrect placement, rather than needle occlusion, is the cause of resistance to flow. It is convenient, while waiting for surgery, to have the end of the laparoscope bathing in warm sterile fluid to prevent it from fogging when it is inserted into the abdominal cavity.

A no. 11 scalpel blade is used to make a single vertical incision in the lower rim of the umbilicus. This must be done carefully because the aorta can lie just a few centimeters beneath the abdominal wall, particularly in a thin patient. The abdominal wall is lifted away from the aorta by pinching the skin beneath the umbilicus between thumb and index finger. The umbilicus is elevated with one hand or towel clips while the surgeon's other hand makes the controlled incision.

The Veress needle is disconnected from the insufflation tubing before insertion. The stopcock on the needle then is placed in the open position, and the spring action of the needle is tested for smooth operation. Elevating the abdominal wall and using the Veress needle with the stopcock open allows air to rush into the previously gas-free abdominal cavity when the end of the needle penetrates the peritoneal layer. The inrushing air, if heard, is one of the first indicators that successful abdominal entry has occurred. Outflow of blood likewise can serve as an immediate indicator of vessel injury. Allowing air to rush in also can cause the bowel to fall away from the abdominal wall.

The terminal aorta is palpated, even in a moderately obese patient, through the abdominal wall in the midline, just above or at the umbilicus. The pulsations of the aorta are lost in the midline just beneath the umbilicus, corresponding to the sacral hollow. The aorta bifurcates at the level of L4, which corresponds to the summits of the iliac crests. This is a more reliable landmark for bifurcation of the aorta than the umbilicus. The Veress needle is placed through the umbilical incision and is directed at an angle toward the sacral hollow or uterine fundus (to avoid the aorta) and in the midline (to avoid the iliac vessels). Elevating the abdominal wall during this placement increases the distance between the Veress needle and major vessels. While placing the Veress needle, the surgeon should hold the needle like a dart, being careful not to impede the action of the spring mechanism. Resistance at the tip of the needle causes the blunt cannula inside the needle to be pushed back, and the spring mechanism at the hub of the needle extends. When resistance at the tip of the advancing needle is lost, as occurs with successful penetration of the peritoneal cavity, the blunt cannula inside the needle advances back out to the tip, and the spring mechanism at the hub of the needle snaps back in. Observing the spring mechanism for this snap can serve as a sign to test for successful placement. Often, there are two snaps —the first when the fascia is penetrated and the second with peritoneal penetration. Continuing to advance the needle tip much beyond the point of penetration of the parietal peritoneum risks placing the needle tip between loops of bowel or under the omental apron, both of which can cause resistance to flow and can result in reinsertion of the needle. Continued advancement of the Veress needle also risks vascular injury. The needle tip should not be moved laterally once the tip is inserted in the abdomen; any simple vascular or intestinal puncture could be transformed into a major laceration if the needle tip is moved from side to side. Once abdominal penetration is made with the Veress needle, the needle should be stabilized carefully until the safety checks have been completed. The needle should not be moved, and a laparotomy should be performed immediately if major vascular injury is suspected.

The distance between skin and fascia can increase with increasing patient obesity. A given angle of entry of the Veress needle that successfully penetrates the peritoneal cavity in a thin patient might fall far short of the peritoneum in an obese patient. To bring the peritoneal cavity within the physical length of the Veress needle, it is often necessary to pursue entry with a trajectory closer to the vertical. However, this also directs the Veress

needle toward the aorta and therefore should be attempted only by experienced surgeons, and with extreme care. Alternatively, open laparoscopy can be performed.

Several safety checks for correct intraabdominal placement can be performed while the Veress needle is held steady. The instillation of 5 to 10 mL of sterile saline through the needle, followed immediately by aspiration, can be helpful. The fluid should meet little resistance, and, more important, scant fluid should return on reaspiration. Reaspiration of fluid suggests that the needle tip is in a small enclosed space that does not allow immediate dispersion of the instilled fluid. Reaspiration of feculent fluid or bloody fluid suggests bowel or vascular penetration, respectively. Simple penetration of the bowel with a Veress needle does not mandate immediate exploratory laparotomy. Depending on the setting and the skill level of the surgeon, reinsertion of the needle or open laparoscopy, followed by laparoscopic visualization of the intestine, can be pursued.

A second safety check consists of attaching a filled 10-mL syringe to the hub of the Veress needle and then removing

the plunger. Elevation of the abdominal wall at this point should cause an increased negative intraperitoneal pressure, which allows the fluid in the syringe to drain passively into the abdominal cavity through an open stopcock. Alternatively, a drop of saline (drip test) can be placed on the hub of the Veress needle, and, with the stopcock open, elevation of the abdominal wall should result in the drop flowing downward freely.

Once these safety checks are performed, insufflation is begun at 1 L/min or less. Initial insufflation pressures often are 5 mm Hg or less in thin patients and, even with correct needle placement, can be 10 mm Hg or more in obese patients. An intraabdominal pressure greater than 15 mm Hg during insufflation generally is avoided to prevent respiratory compromise and decreased venous return secondary to vena caval compression. Abdominal distention increases the distance between the abdominal wall and major pelvic vessels, and this increases the safety buffer when the trocar is inserted. However, the abdomen should not be distended so taut that it is difficult to manually elevate it for trocar insertion.

During insufflation, a shift from dullness to tympany with percussion over the liver is indicative of pneumoperitoneum formation. It also is prudent for the surgeon to pay attention to the electrocardiogram rhythm during insufflation, because the sudden appearance of premature ventricular contractions can be an indicator of intravascular insufflation. Sudden vascular collapse during insufflation can be caused by a gas embolism into the right side of the heart and, at times, this life-threatening event can be signaled by a new “cogwheel” or “mill wheel” murmur. Rapidly tilting the patient into Trendelenburg position and onto her left side and advancing a Swan-Ganz catheter into the right heart for aspiration can be lifesaving.

Once insufflation is complete, the Veress needle is removed, and the umbilical incision is widened to accommodate the trocar and sleeve. An incision that is too large can result in leakage of gas around the sleeve. An incision that is too small can restrict access. The trocar should be checked before insertion to ensure that it is sharp; a dull trocar potentially is dangerous because it requires increased force for abdominal entry.

The trocar is grasped as shown in **Figure 27.1**. If the surgeon’s hand is large enough, the middle finger can serve as a stopper, preventing the forward momentum following fascial puncture from carrying the trocar deep into the pelvis. The precautions for insertion of the Veress needle pertain even more to insertion of the trocar; the abdominal wall is elevated, the trocar is directed toward the hollow of the sacrum or the uterine fundus, and a midline trajectory is followed. Slow, steady pressure with a sharp trocar will permit immediate recognition when the gas-filled cavity is penetrated.

Open laparoscopy is performed without previous creation of a pneumoperitoneum. The skin beneath the umbilicus is incised sufficiently with a scalpel in either a vertical or transverse direction to adequately visualize the underlying fascia. Small S retractors are most helpful in visualization—especially in obese patients. The skin

is released, and the fascia is grasped and elevated. The fascia is then incised in the midline, and the opening is stretched with a hemostat or incised to a length just sufficient to visualize the underlying peritoneum, which in turn is elevated and incised. Keeping the incision in the central portion of the umbilicus where the peritoneum and fascia are fused is the easiest method for entry in obese patients. Each angle of the fascial incision is sutured with a no. 0 absorbable stitch but not tied. The Hasson blunt cannula and sleeve are then placed through the opening of the peritoneum. The blunt cannula then is removed, and the abdomen is insufflated through the port found on the sleeve.

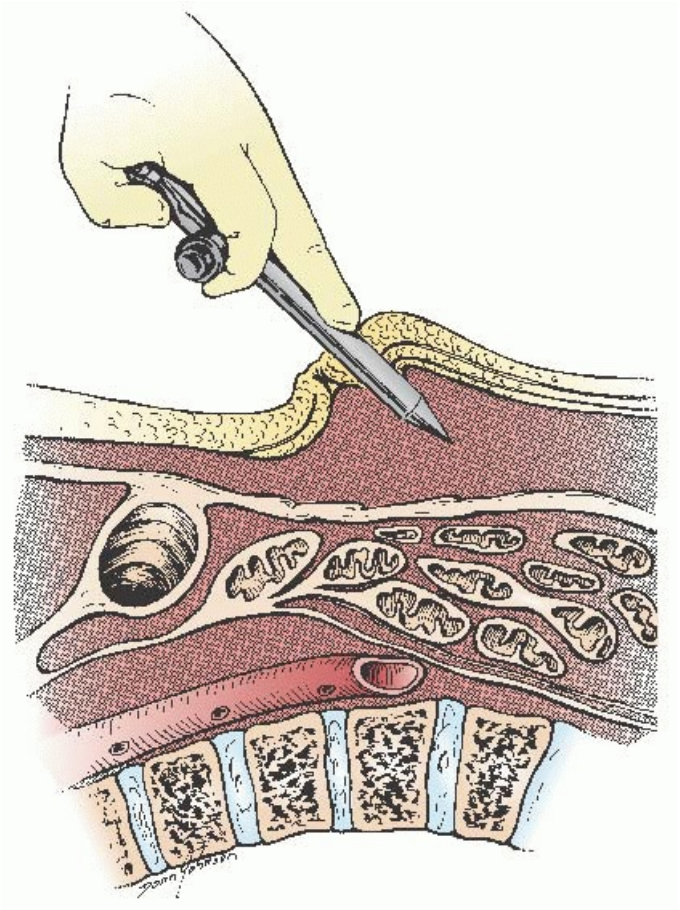

FIGURE 27.1 Trocar entry. When inserting the trocar through the abdominal wall, the trocar is “palmed” in the surgeon’s dominant hand, with the extended middle finger serving as a stopper to prevent deep abdominal penetration. If the surgeon’s hand is too small to accomplish this, open laparoscopy should be considered.

METHOD OF TUBAL OCCLUSION

All tubal sterilization methods rely on correct identification of the fallopian tube for success. With any of the transabdominal methods, the tube should be followed out to its fimbriated end to confirm that the correct structure has been identified.

Theoretically, the risk of tuboperitoneal fistula formation can be reduced by preserving a proximal tubal segment 1 to 2 cm in length. It is possible that the proximal tubal stump serves as a distensible reservoir for the small amount of uterine fluid that is normally forced through the interstitial portion of the tube by uterine contractions. This distensibility capacitance of the proximal stump might serve to dissipate the fluid pressure emanating from the uterus. Otherwise, this direct fluid pressure on the cut end of the tube might prevent complete closure of the tubal lumen during the healing process.

Irving Procedure

In 1924, and later in 1950, Irving reported on his method of achieving tubal sterilization. He attempted to reduce

the risk of tuboperitoneal fistulae by extensively dissecting the ligated ends of the tubes and burying the proximal tubal segment. Although the extra dissection in this technique likely enhances effectiveness, it also carries the potential for greater blood loss, as well as increases the difficulty of performing the technique through a minilaparotomy incision. The procedure also takes slightly longer to perform than simpler methods.

The Irving technique is accomplished by first using a hemostat or scissors to create a window in the mesosalpinx just beneath

the tube, about 4 cm from the uterotubal junction (**Fig. 27.2A**). Then, the tube is twice ligated (no. 1 chromic) and divided between the ties at this location. The free ends of the proximal stump ligature are held long. A 1-cm incision is made in the serosa of the posterior uterine wall near the uterotubal junction. A hemostat, or similar pointed instrument, is then used to bluntly deepen the incision, creating a pocket in the uterine musculature about 1 to 2 cm deep (**Fig. 27.2B**). The two free ends of the proximal stump ligature, previously held long, are then individually threaded onto a curved needle and brought deep into the myometrial tunnel and out through the uterine serosa (**Fig. 27.2C**). Traction on the sutures then draws the ligated proximal stump deep into the myometrial tunnel, and tying the free sutures fixes the tube in this buried location (**Fig. 27.2D**). Often, this can be accomplished without incising the mesosalpinx, but if extra mobilization of the proximal stump is needed, or if the proximal stump mesosalpinx appears in danger of being torn when traction is applied, then the mesosalpinx under the proximal tubal segment can be incised partly back toward the uterus. The serosal opening of the myometrial tunnel is then plicated closed around the tube with the use of a fine absorbable suture, but great care should be exercised to avoid compromising the tube as it enters the tunnel. Strangulation or damage to the tube with this stitch could cause necrosis and fistula formation in the extramyometrial portion of the proximal tube. No treatment of the distal tubal stump is necessary, but some surgeons choose to bury that segment in the mesosalpinx.

Modified Pomeroy Procedure

Bishop and Nelms, colleagues of Pomeroy, reported on the Pomeroy technique for tubal occlusion in 1930. They were careful to point out the importance of using absorbable suture as opposed to permanent suture.

In this method, the tube is grasped in its midportion, usually with a small atraumatic clamp such as the Babcock, and a loop of tube is elevated (**Fig. 27.3A**). The base of the loop is ligated with no. 1 plain catgut, leaving a 2-cm proximal stump of isthmus, and the sutures are held long. A 2- to 3-cm portion of tube in the ligated loop is transected and removed with scissors (**Fig. 27.3B**). Bishop and Nelms, in the original report on this method, pointed out that ligation was performed with a double strand of absorbable chromic catgut suture to allow the cut tubal ends to quickly separate after surgery. It was their belief that this would allow the ends to naturally fibrose and peritonealize without fistulization or communication. This also is the rationale for the common modification of the Pomeroy technique, in which the original chromic suture is replaced by plain catgut because of the more rapid degradation of the latter. Surgeons have a tendency to strenuously tighten the catgut ligature around the tube (as though the tighter the ligature, the better the occlusion), but this appears to go against the very principles of the procedure. This tightening can result in greater strangulation and necrosis of the adjoining tubal segments, potentially increasing the risk of fistula formation

and failure. Taking time to identify the muscular tube, which is often seen pouting from each of the severed limbs of the ligated tube, is a good habit to develop, as is checking the tubal stumps for hemostasis. Resection of a limited amount of tube, restricted to the isthmic section, is ideal should unexpected future reanastomosis be requested. Making the knuckle of tube in the loop too small, however, can result in only a shave excision of the side of the tube, with incomplete transection of the lumen. To avoid incomplete resection, the mesosalpinx within the ligated loop should be perforated with scissors before the tubal limb on each side of this window is

individually cut. It is important not to cut the loop so close to the suture that only short distal segments of tube remain beyond the tie. These short limbs can easily slip out of the ligature and cause delayed bleeding.

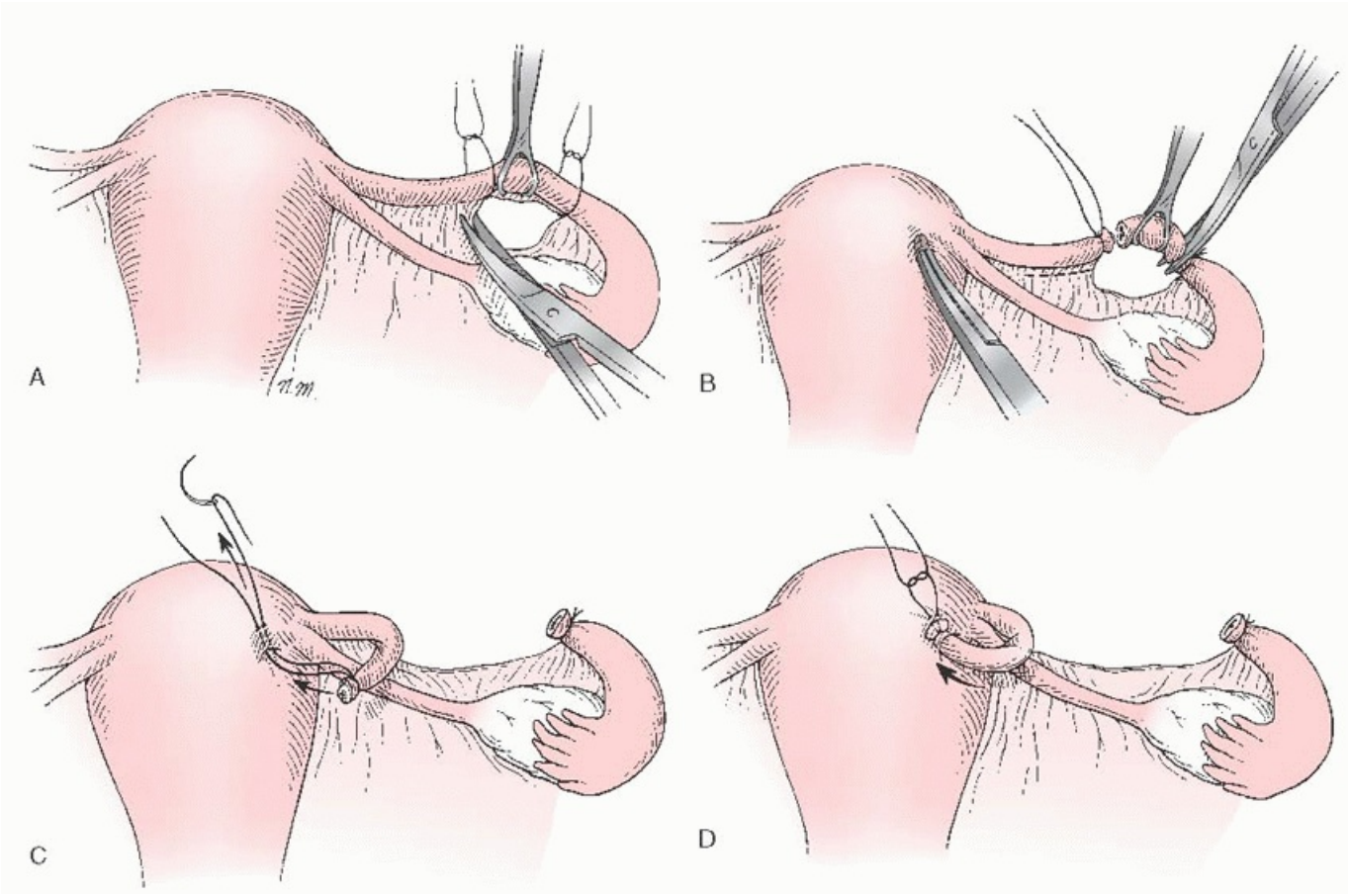

FIGURE 27.2 Irving method. **A:** A fenestration is made beneath the tube about 4 cm from the uterotubal junction using scissors or a hemostat. **B:** The tube is then twice ligated and a portion resected. A deep pocket is created in the myometrium on the posterior uterus. The *dashed line* shows the line of incision if added mobilization of the proximal tube is necessary to bury the end of the tube in the myometrium. **C:** The tagged ends of the tube are sutured deep into the myometrial tunnel and out through the uterine serosa. **D:** Tying these sutures secures the cut end of the proximal tube deep in the myometrial pocket.

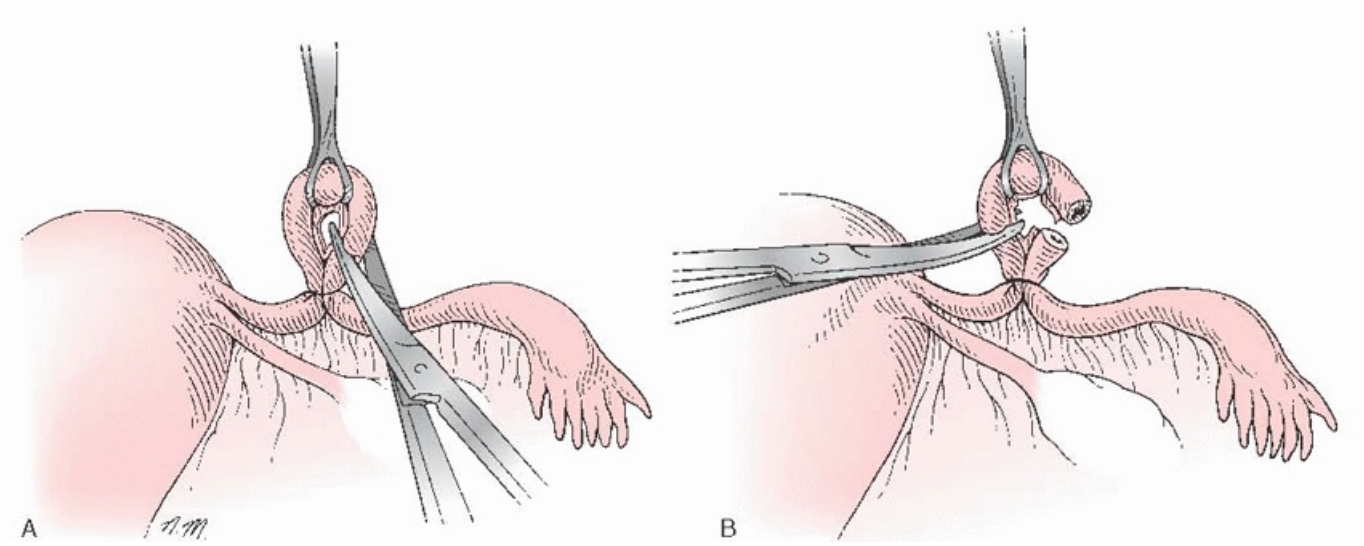

FIGURE 27.3 Pomeroy method. **A:** A loop of the isthmic portion of the tube is elevated and ligated at its base with one or two ties of no. 1 plain catgut suture. If performed through a minilaparotomy incision, these ties should be held long to prevent premature retraction of the tubal stumps into the abdomen when the loop of tube is

transected. **B:** A fenestration is bluntly created through the mesentery within the tubal loop, and each limb of the tube on either side of this fenestration is individually cut. The cut ends of the tube are inspected for hemostasis and allowed to retract into the abdomen.

The Pomeroy method minimizes bleeding by compressing and sealing the vascular mesosalpinx before tubal transection. It is not unusual when performing tubal sterilization at the time of cesarean section to find the mesosalpinx greatly engorged with distended veins. Elevation of the uterus through the abdominal incision often facilitates tubal occlusion by allowing the vessels to drain and decompress. It is important when replacing the uterus into the peritoneal cavity to lead with one adnexa at a time while protecting the tubal ligation site on that side. Otherwise, when the uterus is replaced, a tight fit can cause the adnexa to be squeezed against the incision, with resultant avulsion of the ligature and postoperative bleeding. When a Pomeroy ligation is performed through a minilaparotomy incision, the ligation sutures are held while the tube is cut. This prevents retraction of the cut tubal stumps into the peritoneal cavity before they can be adequately examined and before hemostasis can be ensured. After examination is complete, the sutures are cut, and the tubal stumps are allowed to retract into the abdomen.

It is also possible to perform a modified Pomeroy tubal ligation as a laparoscopic interval procedure. In this technique, a laparoscope with an operating channel is placed through the umbilical port, and a 5-mm midline suprapubic cannula is introduced under direct vision. A plain gut Roeder loop (endoscopic slip knot) is introduced through the 5-mm port. A grasper is introduced through the operative channel of the laparoscope, advanced through the suture loop, and the appropriate portion of tube is grasped and retracted back through the loop. The slip knot of the loop is then tightened, ligating a knuckle of the tube. Scissors are then introduced through the operative scope, and the suture is cut. With the use of a grasper through the 5-mm port, the loop of tube is held on tension while the scissors are used through the operative channel to transect the tube above the ligature. When the procedure is complete and the tubal segment has been resected, the grasper is used through the operative channel to hold the specimen while the operative scope and grasper are removed together through the umbilical sleeve. In contrast to most other methods of laparoscopic sterilization, this technique has the advantage of producing a surgical specimen for evaluation.

Uchida Method

Originally reported on in 1961, and reported on in revised form in 1975, the Uchida method, like the Irving procedure before it, recognized the role of fistula formation in tubal sterilization failures and included steps to prevent this complication.

This method begins by having the surgeon grasp the tube in its midportion, about 6 to 7 cm from the uterotubal junction. A 1:1,000 epinephrine in saline solution is injected subserosally, creating a bleb over the tube that is then incised (**Fig. 27.4A**). The muscular tube, which often can be seen springing up through the serosal incision, then is divided between two hemostats. The serosa over the proximal tubal segment is dissected bluntly toward the uterus, exposing about 5 cm of the proximal tubal segment (**Fig. 27.4B**). The tube then is ligated with no. 0 chromic suture near the uterotubal junction, and this 5-cm segment of exposed tube is resected. The shortened proximal stump is allowed to retract into the mesosalpinx (**Fig. 27.4C**). The serosa around the opening in the mesosalpinx is sutured in a purse-string fashion with a fine absorbable

stitch. Simultaneous ligation of the distal tube and gathering of the mesosalpinx around the distal stump are accomplished when the purse-string suture is tied (**Fig. 27.4D**). This step also fixes the distal stump in a position open to the peritoneal cavity while burying the proximal stump within the leaves of the mesosalpinx.

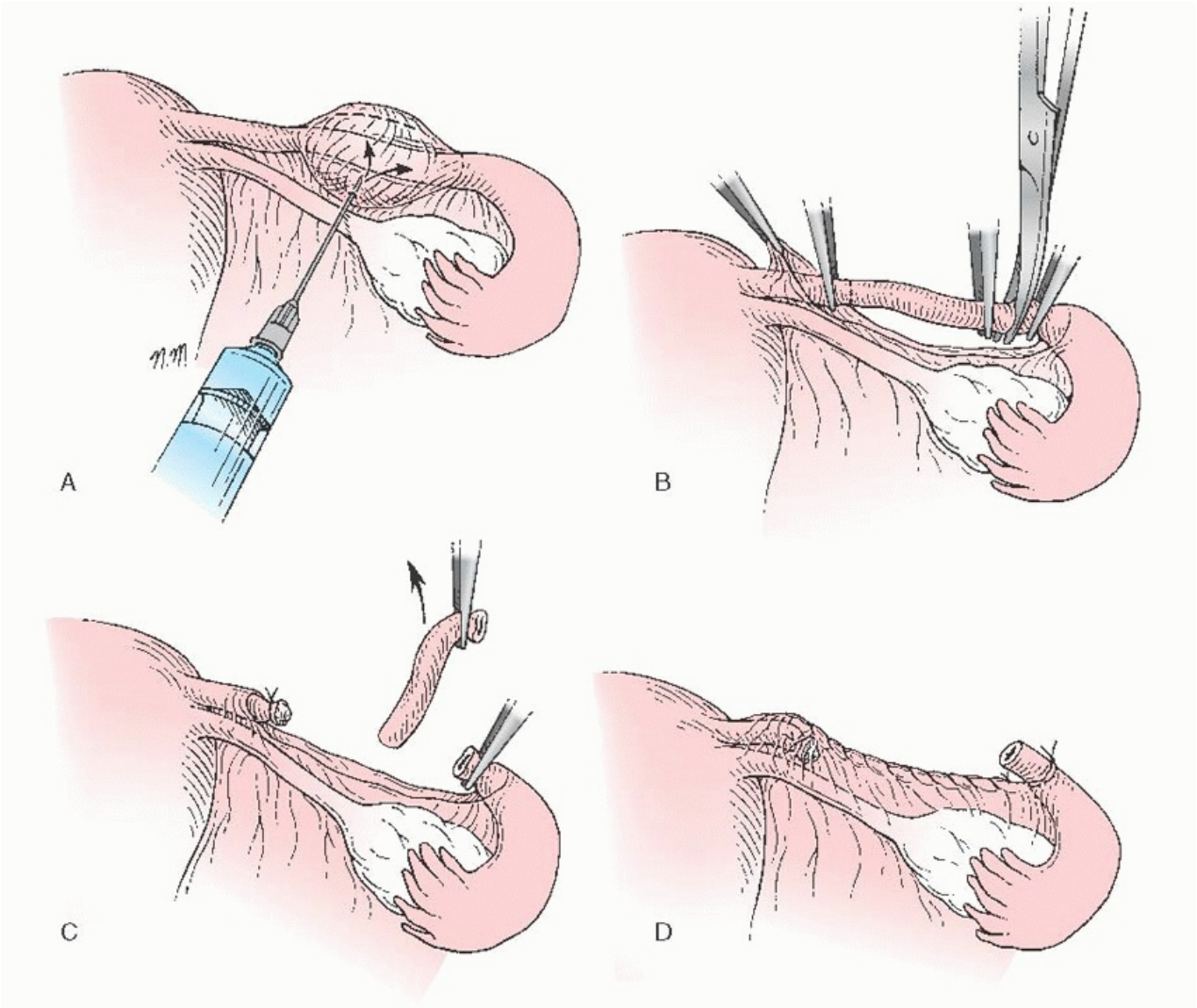

FIGURE 27.4 Uchida method. **A:** An injection of vasoconstricting solution is given beneath the serosa of the tube about 6 cm from the uterotubal junction. The serosa is then incised (*dashed line*). **B:** The antimesenteric edge of the mesosalpinx is pulled back toward the uterus, exposing about 5 cm of the tube. **C:** The tube is ligated proximally and cut, and the tied stump is allowed to retract into the mesosalpinx. The hemostat on the distal stump remains attached to facilitate exteriorization of this portion of the tube. **D:** The mesosalpinx is closed. A purse-string stitch of the mesosalpinx around the exteriorized tubal stump secures it in a position open to the abdomen, whereas the ligated proximal stump is buried within the mesosalpinx. Once the purse-string suture is tied, the hemostat can be removed.

Uchida added fimbriectomy to the procedure in 1975 to enhance effectiveness. Some surgeons omit this step, and in addition excise only 1 to 2 cm of tube (rather than the recommended 5 cm) to permit future tubal anastomosis.

Parkland Method

In this method, made popular during the 1960s at Parkland Memorial Hospital, the tube is grasped in its midportion with a Babcock clamp, and a hemostat or scissors is used to create a window in an avascular area of the mesosalpinx just beneath the isthmic portion of the tube (**Fig. 27.5A**). The window is stretched to about 2.5 cm in length by opening the hemostat. Two ligatures of no. 0 chromic material are passed through the window, and the tube is ligated proximally and distally, leaving a 2-cm proximal stump of isthmic tube (**Fig. 27.5B**). The intervening segment of tube between the ties then is resected (**Fig. 27.5C**). In contrast to the Pomeroy method,

in which the resected portions of the tubes are ligated together and later separate when the suture weakens, immediate separation of the tubal ends is accomplished with the Parkland method. Care should be taken to avoid undue traction on the ligatures while resecting the tubal segments, because this could result in tearing of the mesosalpinx and excessive bleeding.

Unipolar Coagulation

Unipolar coagulation was the first method of laparoscopic tubal occlusion to achieve widespread use. However, reports of electrical complications, particularly thermal bowel injury, resulted in a significant decline in this method's popularity as soon as alternative methods of laparoscopic tubal occlusion became available in the mid-1970s. In unipolar coagulation, a specially designed insulated grasping forceps is introduced through the operating channel of the laparoscope or independently through a 5-mm second-puncture port. As a safety precaution, attachment of the

electric cable to the grasping forceps should be delayed until the surgeon is ready to coagulate the fallopian tube.

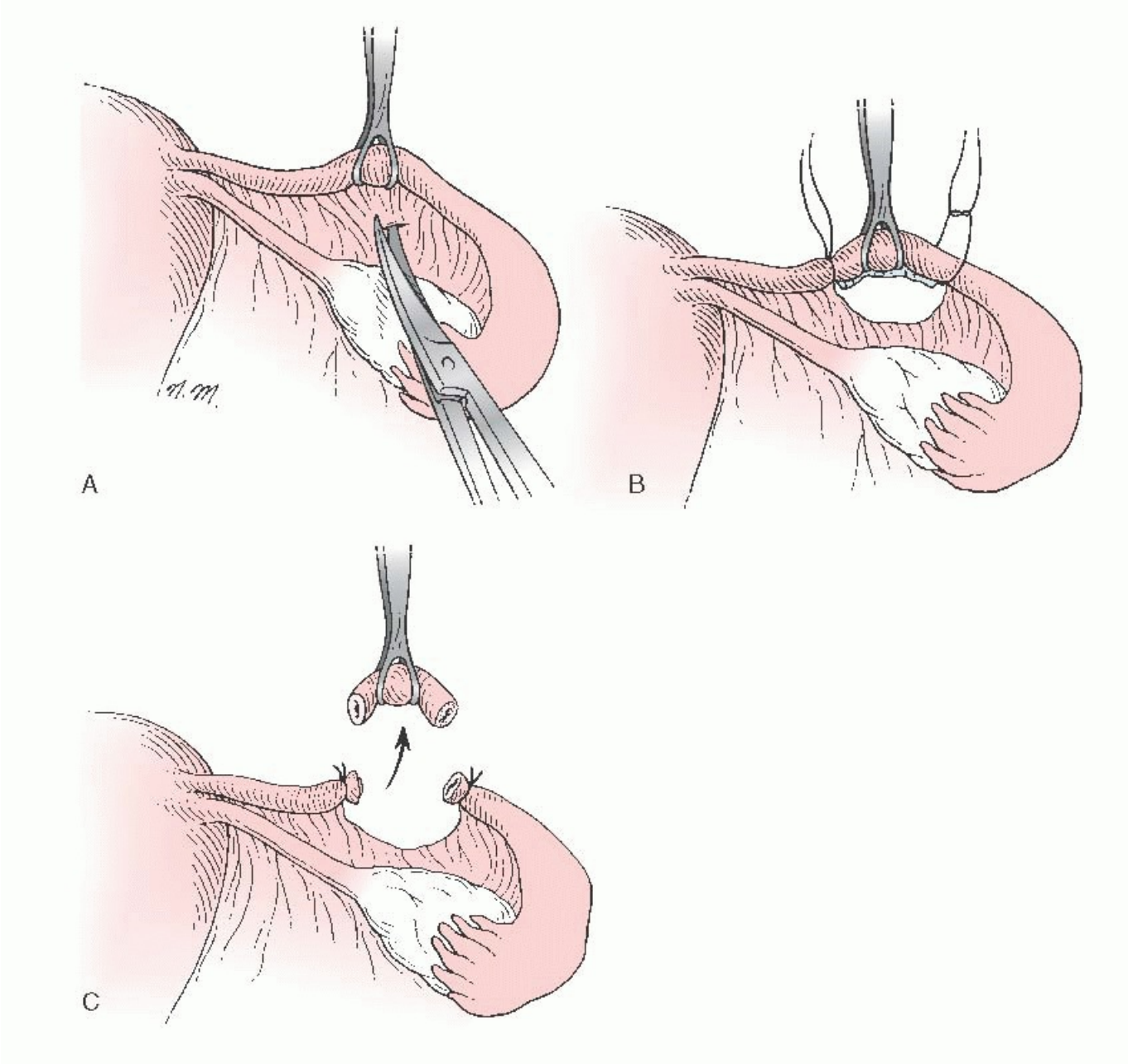

FIGURE 27.5 Parkland method. **A:** A 2- to 3-cm fenestration is made beneath the isthmic portion of tube either

with scissors or bluntly with a hemostat. **B:** Ligation of the tube. Pulling up on the suture during ligation or during transection of the tube can shear the tube off the underlying mesentery, resulting in troublesome bleeding. **C:** Portion of tube removed.

With unipolar coagulation, as much as 3 to 5 cm of tube can be destroyed with a single burn, with occult damage occurring beyond the visual zone of desiccation. For this reason, the isthmic-ampullary portion of the tube should be carefully identified and grasped about 5 cm from the uterus to preserve some length of proximal tube. The jaws of the grasping forceps should completely encircle the fallopian tube and include a portion of the mesosalpinx as well. The tube should be elevated away from adjacent structures, such as bowel and bladder, before current is applied for about 5 seconds. If a second burn is required, it should be applied to the proximal rather than the distal portion of the tube. The current should be turned off before the tube is released and the grasping forceps are retracted into the laparoscope. Both jaws of the grasping forceps serve as active electrodes and will cause electrosurgical injury to any structure they touch while current is applied.

The thermal injuries to abdominal viscera that are seen with unipolar coagulation are, in some cases, likely attributable to the phenomenon of capacitive coupling. The current flowing down the unipolar probe creates an electromagnetic field that can transfer an electric charge to any conductor surrounding the probe. The greater the voltage being used with the probe, the greater this capacitive effect. In the case of laparoscopic unipolar coagulation for sterilization, the conductor surrounding the insulated unipolar probe is the operative laparoscope itself. As long as the operative laparoscope is safely grounded (usually by contact with a metal trocar sleeve that, in turn, is in contact with the abdominal wall over a large surface area), then the capacitive charge on the laparoscope can be harmlessly dissipated. If, however, the laparoscope is prevented from safely grounding into the abdominal wall by a nonconducting trocar sleeve or by a nonconducting barrier around the trocar sleeve (e.g., a plastic collar with threads), then the capacitive charge that builds up on the scope discharges when and wherever any portion of that instrument touches the patient's tissues. Depending on the surface area of contact, the discharging current from the scope into the patient's tissues has either a high current density (small contact surface) or a low current density (large contact surface), resulting in either a large thermal effect or a minimal thermal effect, respectively. In the case of contact with bowel, this thermal effect easily can result in delayed necrosis and peritonitis. If the unipolar probe is brought into the abdomen by way of a second puncture trocar sheath, then it is the sheath itself that is capacitively charged (if it is made of a conducting material). If the charge on the conducting trocar sleeve is prevented from grounding through the abdominal wall (as could occur if a plastic collar with threads is being used around the trocar sleeve), then any bowel or other grounded tissue touching the trocar sleeve again has capacitive current flowing into it. The use of unmodulated cutting current minimizes the voltage required to create the desired tissue effect. Coagulation or modulated current relies on short bursts of much higher

voltage and should be avoided in order to reduce the risk of capacitive coupling and unseen or unrecognized injury.

If thermal injury to the intestine is noticed during the laparoscopic procedure, then it is important to recognize that the injury can extend well beyond the visibly damaged area. Small burns of the bowel serosa may not require repair, but close observation for 5 to 7 days is recommended so the patient can be monitored for delayed peritonitis. A laparotomy is required if peritonitis occurs. A large area of superficial thermal bowel injury, or one that is thought to extend beyond the serosa, requires resection of that portion of intestine with a 5-cm margin on either side of the lesion. Oversewing the damaged area can result in stitches being placed in bowel that appears healthy visually but in reality is destined to necrose from occult thermal or electrical injury.

Bipolar Coagulation

The use of bipolar coagulation for tubal sterilization was reported by Rioux and Cloutier in 1974. With bipolar coagulation, current flows from one jaw of the grasper to the other, requiring only the intervening tissue of the patient within the jaws of the instrument to complete the circuit. This eliminates the need for a distant return electrode. Compared with unipolar coagulation, which uses the patient's body to complete the circuit, bipolar coagulation applies current in a more discrete manner (a 1.5- to 3-cm zone of thermal injury) and with a potentially increased element of safety. Capacitive coupling does not occur with bipolar forceps because the field effects from the equal but opposite currents that flow in both directions along the shaft of the instrument cancel out one another.

Once the fallopian tube is carefully identified, it is grasped in the distal isthmic section with the bipolar forceps in such a way that the tube is completely encircled, including a portion of the mesosalpinx (**Fig. 27.6**). The tube then is elevated away from any adjacent structures, and current is applied. Two additional contiguous areas similarly are coagulated to ensure at least a 3-cm area of desiccation. As with unipolar coagulation, an effort should be made to leave the proximal 2 cm of tube undisturbed to reduce the risk of tuboperitoneal fistula formation.

The visual end points of tubal blanching and swelling noted with bipolar coagulation cannot be used to ensure destruction of the endosalpinx. Desiccation of the outer one third of the fallopian tube can occur without desiccation of the inner one third. The use of an optical flowmeter has been recommended to evaluate cessation of current flow through the tube as an end point. Presumably, when complete desiccation occurs, there will be no further electrolytes in solution to carry current through the dehydrated tissue. Soderstrom and coworkers have demonstrated that complete desiccation of the fallopian tube with bipolar systems is more likely when a cutting waveform, as opposed to a coagulation or blended waveform, is used and when the power output is at least 25 W against a 100-V load.

Silicone Rubber Bands

Complications associated with the use of unipolar coagulation led to the pursuit of safer, nonthermal methods that could be applied laparoscopically. The first of these methods to gain popularity was the silicone rubber band, developed by Yoon and coworkers in the early 1970s.

The band is introduced with a specially designed endoscopic applicator that can be delivered through either the operating channel of a laparoscope or a separate second puncture port. The band is first stretched over the distal end of the applicator barrel (immediately before use to avoid extended deformation of the band). A transcervical uterine manipulator can be used to help achieve proper exposure. After the device is introduced into the abdominal cavity, grasping tongs are extended from within the applicator barrel. One of the tongs is used to gently hook and elevate the isthmic portion of the tube about 3 cm from the uterus. The tongs then are retracted into the applicator, which closes both arms of the tongs around the grasped tube while pulling the loop of tube up into the barrel (**Fig. 27.7**). The surgeon must take care in ensuring that the tube is completely encircled by the tongs as they are retracted into the applicator. Failure to do this can result in a band that is only tangentially applied to the tube (failing to occlude its lumen) or applied only to the mesosalpinx.

It is important to avoid excessive traction on the tube during retraction of the tongs. The surgeon should slowly advance the entire applicator toward the tube while gradually retracting

the tongs and tube up into the applicator. Failure to do this can result in mesosalpingeal hemorrhage and tubal laceration. Once the loop is fully retracted into the device, the band is slid off the applicator barrel and onto the base of the loop.

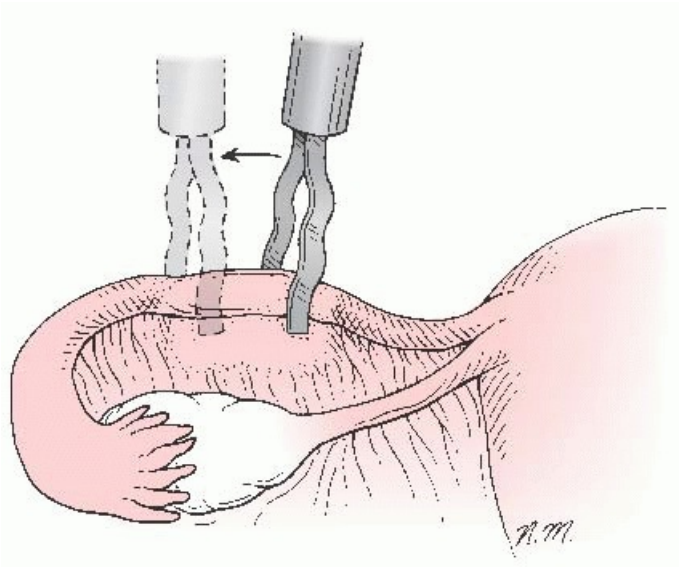

FIGURE 27.6 Bipolar method. A 3-cm minimum zone of isthmic tube is desiccated with bipolar forceps. The paddles of the forceps extend across the tube onto the mesosalpinx.

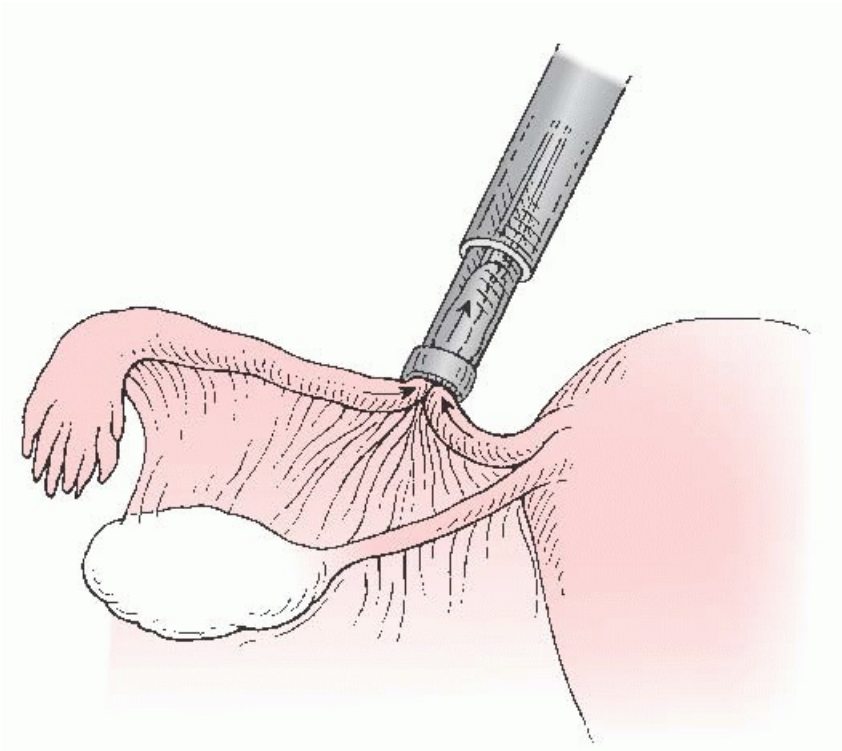

FIGURE 27.7 Silicone band method. The isthmic portion of the tube is retracted into the applicator barrel using grasping tongs, which should completely surround the tube. The applicator barrel is advanced toward the tube during this retraction process to avoid excessive traction on the tube and its mesentery.

Approximately 1.5 to 2 cm of tube is contained in the constricted loop. After devascularization, this portion of tube becomes anoxic and resorbs over time. Eventually, the band no longer encircles any tube; later it is often found in the mesosalpinx. Apart from the 2-cm loop of encircled tube, very little destruction is caused by the band, and 2 mm lateral to the area of constriction of the tube is relatively undisturbed.

It is difficult to apply a band to edematous or thickened fallopian tubes successfully. Tubal adhesions can reduce the mobility of the tube and preclude pulling an adequate loop of tube into the applicator. Additional rings can be applied to the cut edges if transection of the mesosalpinx or tube with accompanying hemorrhage occurs. Bipolar or unipolar coagulation can be used if this is unsuccessful.

Spring Clip

The use of a spring clip for tubal sterilization was reported by Hulka and colleagues in 1973. The introducer for the clip can be delivered into the abdomen through the operative channel of the laparoscope or a second puncture cannula (**Fig. 27.8**). Because the clip must be applied exactly perpendicular to the long axis of the fallopian tube, it is helpful at times to use the two-puncture method—placing the tube on stretch by use of a transcervical uterine manipulator and a grasping forceps inserted through the operating channel of the laparoscope and introducing the applicator through the second puncture port.

The clip is held in a cradle by the applicator and can be closed and opened on the tube multiple times until an acceptable application is achieved. At this point, further pressure on the thumb device of the applicator drives the spring mechanism over the jaws of the clip, locking it closed. If improper application is determined at this point, the clip cannot be removed, and another clip has to be placed. To be effective, the clip must be applied to the isthmic portion of the tube, approximately 2 cm from the uterus and exactly at right angles to the long axis of the tube. It must be applied fully advanced over the tube, with the hinge of the clip pressing against the tube and with the tips of the jaws of the clip extending beyond the tube onto the mesosalpinx, creating a characteristic fold in the mesosalpinx when the clip is closed. The tube is not elevated when applying the clip, in contrast to the techniques used in coagulation and band application.

The clip, like the silicone rubber band, is most likely to be successful when applied to a normal tube. Tubal distortion, thickening, and adhesions make correct application difficult and often impossible.

A considerable advantage to the clip method of sterilization is that only 3 mm of tube is compressed by the clip, and minimal collateral damage occurs in the adjacent tissue. As a result, anastomosis procedures after clip sterilization often are highly successful.

Filshie Clip

The Filshie clip was first introduced in Europe in 1975, and the hinged Mark VI model was approved for use in the United States by the U.S. Food and Drug Administration (FDA) in 1996. The device has titanium jaws lined with silicone rubber and is used with specially designed applicators that are available in both single- and double-puncture versions for use with laparoscopy or minilaparotomy. The Filshie clip has a hinge on one end and a small curve on the other and is designed to be placed on the isthmic portion of the fallopian tube approximately 1 to 2 cm from the cornua (**Fig. 27.9**).

To be effective, the jaws of this clip, as with the spring clip, must include the entire circumference of the tube. Only one properly applied clip needs to be applied to each fallopian tube. Once the tube is occluded, both the tube and the silicone

rubber lining of the clip are compressed. Over time, approximately 3 to 5 mm of the compressed tissue undergoes avascular necrosis, and the compressed silicone rubber expands. Eventually, plical attenuation and fibrosis of the adjacent tubal segments occurs, and the clips are peritonealized.

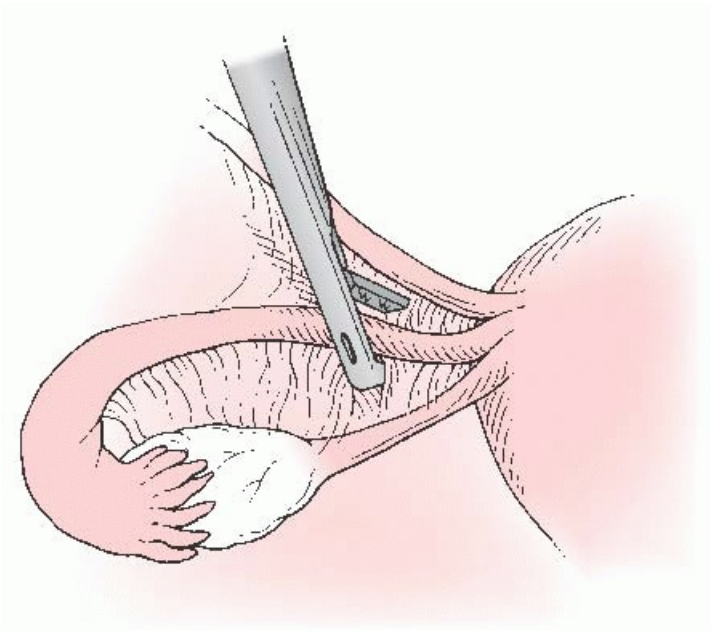

FIGURE 27.8 Spring clip method. The clip is applied to the midisthmus (approximately 2 cm from the cornua) at a 90-degree angle to the long axis of the tube. The hinge of the clip should be pressed against the tube, and the tips of the clip should extend onto the mesosalpinx.

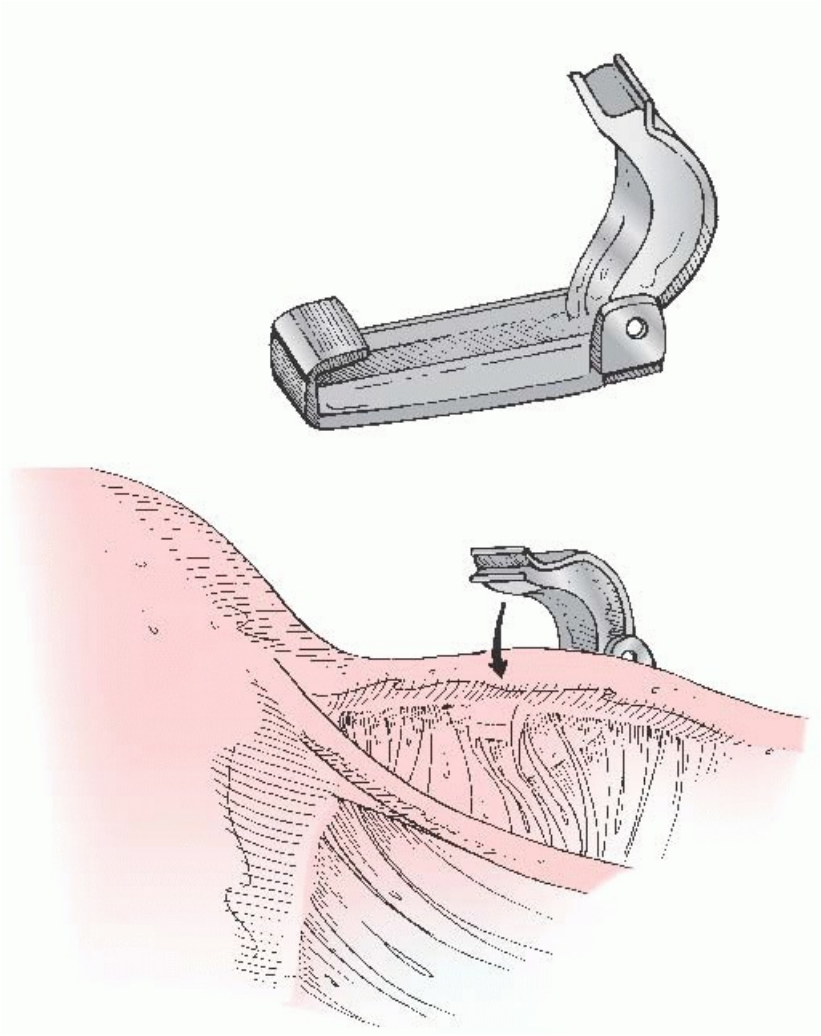

FIGURE 27.9 Filshie clip method. The clip is applied to the midisthmus (approximately 1 to 2 cm from the cornua) with the lower jaw of the clip being visible in the mesosalpinx to assure that the entire circumference of the tube is included.

The clip is placed into the applicator, and the applicator and clip then are introduced through the cannula with the jaws of the clip in a partially closed position so that the instrument with the clip in place can be used to manipulate the fallopian tube into proper position. The clip may close prematurely if too much pressure is placed on the handle of the applicator. The lower jaw of the clip, with its small curve at the tip, should be seen through the mesosalpinx to assure that the clip includes the entire circumference of the isthmic portion of the tube before the clip is applied. Because of the clip's hinge and the silicone lining of the jaws, the tubes can be manipulated and released several times for better positioning of the clip. Gentle pressure is placed on the applicator handle once desired placement is obtained, which causes the upper jaw of the clip to flatten and lock under the curved tip of the lower jaw. The clip should be closed slowly to avoid transection of the fallopian tube, which is more likely with edematous tubes. A clip can be placed on each transected end if transection occurs. Many surgeons recommend the use of a double-puncture technique to assure proper placement.

Essure

The Essure microinsert was approved by the FDA for use as an interval tubal sterilization device in 2002. In 2007, the FDA approved the ESS 305 model, which was developed to improve bilateral placement rates. The device is inserted transcervically via hysteroscopy and thus avoids both entry into the abdominal cavity and the need for general or regional anesthesia. It is available as part of a disposable system that includes the microinsert, a delivery system, and a split introducer. The microinsert is comprised of a stainless steel inner coil, a nickel titanium alloy outer coil, and a layer of polyethylene terephthalate (PET) fibers around the inner coil. The microinsert is 4 cm in length and 0.8 mm in diameter before release from the insertion catheter; following release, it expands to 1.5 to 2.0 mm in diameter as the coils open up to anchor into the fallopian tube across the uterotubal junction (**Fig. 27.10**).

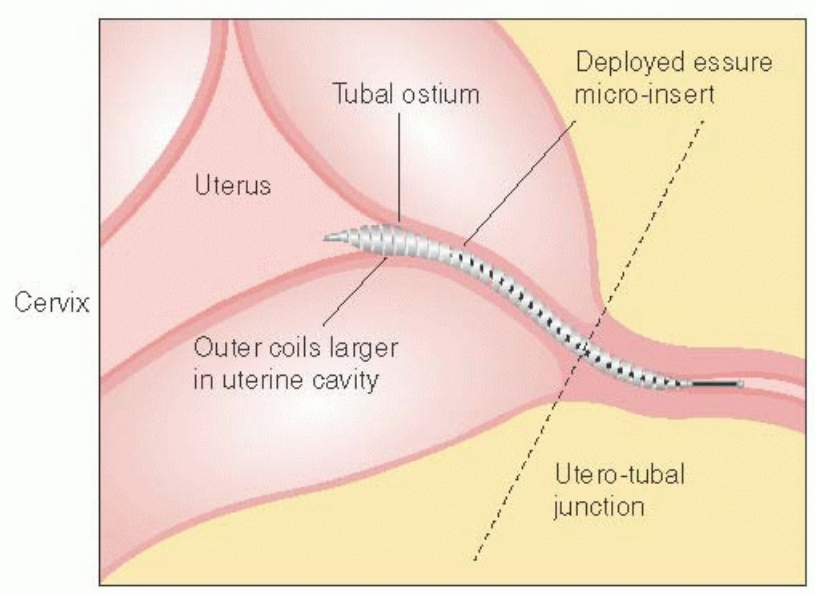

FIGURE 27.10 Essure method. The Essure microinsert is designed to be placed in the fallopian tube across the uterotubal junction where the tube exits the uterine wall but with 5 to 10 mm (the equivalent of three to eight coils) still trailing into the uterus.

The Essure microinsert can be placed in an outpatient or office surgery setting with oral analgesia alone or using a paracervical block with or without intravenous sedation. Using a sterile standard 5-mm hysteroscope with a minimum 5-French operating channel and a 12- to 30-degree angled lens, the uterine cavity is distended adequately with 2 to 3 L of warmed physiologic saline to allow accurate identification of both tubal ostia. The procedure should be terminated if both tubal ostia are not visible, accessible, and considered likely to be patent. The manufacturer's package insert recommends that the risk of hypervolemia be reduced by immediately

terminating the procedure if the fluid deficit of the physiologic saline distention medium exceeds 1,500 mL and by limiting the time of the hysteroscopic procedure to a maximum of 20 minutes.

The Essure microinsert is designed to be placed in the fallopian tube across the uterotubal junction where the tube exits the uterine wall but with 5 to 10 mm (the equivalent of three to eight coils) still trailing into the uterus. This is achieved by inserting the delivery catheter with the microinsert into the proximal tubal lumen to the level indicated by the black position marker on the catheter. When the device is correctly placed, the delivery catheter is withdrawn, and the delivery wire is separated from the microinsert. The trailing end of the coils aids in anchoring the device to decrease the risk of expulsion. The device is also anchored as it expands in the tube at placement, but occlusion is not considered adequate without tissue ingrowth from the tubal wall into the coils that occurs as a result of an inflammatory and fibrotic response to the PET fibers in the inner coil. A hysterosalpingogram (HSG) must be performed 3 months postinsertion to assure complete bilateral tubal occlusion. Transvaginal ultrasonography has also been used for microinsert localization but is not approved by the FDA as an alternative to HSG for this purpose. Alternate contraception should be used until occlusion is documented.

In early studies, 14% of microinsert attempts failed with the first attempt on one or both sides, using the original braided catheter. Although the rate of failed attempts was reduced as training improved, the insertion failure rate remained considerable at 10%. In a postapproval trial by Levie et al. of the ESS 305 model reported in 2011, the successful bilateral placement rate was 97.2%, but these encouraging findings require confirmation in the general population.

The Essure microinsert is indicated, as for other methods of sterilization, only for women who are certain about their desire to terminate future fertility. The effects of the microinserts on a desired subsequent pregnancy are unknown, but they are not removable once the fibrotic ingrowth is complete, and several coils may potentially project into the uterine cavity, making in vitro fertilization potentially less feasible than following sterilization by laparoscopy or minilaparotomy.

STEPS IN THE PROCEDURE

General Considerations

- Patient counseled on alternative options, permanence, risks, and failure rate of intended procedure
- Pregnancy test obtained preoperatively as indicated
- Procedure performed in follicular phase of cycle
- Sterilization procedures are performed on the area of tube, appropriate for the specific procedure approximately 2 cm from cornu

Minilaparotomy (Postpartum) Sterilization Pomeroy Technique

- Incision at umbilicus, with patient in Trendelenburg position
- Sweep tube up to incision using finger behind adnexa, Babcock clamp, and table tilt
- Elevate 2- to 3-cm knuckle of mid-isthmic portion of tube with Babcock clamp
- Ligate a 2- to 3-cm knuckle of tube with no. 1 plain catgut suture
- Bluntly create window in mesosalpinx of looped tube
- Excise the knuckle of the tube, cutting the tube to one side of window and then the other

Laparoscopic (Interval) Methods
Bipolar Coagulation

- Three contiguous burns (approximately 3 cm length) of fallopian tube using bipolar forceps, beginning 2 cm from cornu and progressing distally
- Bipolar at least 25 watts cutting current, and forceps grasp entire width of tube to include portion of underlying mesosalpinx
- Ammeter demonstrating cessation of current flow can help determine end point of desiccation

Clips

- Hulka or Filshie clips applied with device at right angle to the isthmic portion of tube, approximately 2 cm from cornu
- Clips should traverse entire width of tube and extend onto a portion of the mesosalpinx

Ring (Bands)

- One tong of the applicator gently hooks and elevates tube, approximately 3 cm from the cornu
- Ensure tongs completely encircle the tube as they are retracted into the applicator
- To avoid excessive traction that can sever tube, applicator should be advanced toward tube as tongs are retracted

Hysteroscopic Method

- Essure
- Gently introduce an operative hysteroscope through the cervix
- With adequate uterine distention using warmed normal saline, visualize both fallopian tube orifices
- Place the delivery catheter through the operating port of the scope and into the tubal orifice up to the level of the black marker
- Deploy the microinsert and separate it from the delivery catheter
- Remove the first catheter and repeat the procedure on the opposite side
- Visualize both tubal ostia and record the number of trailing coils visible on each side

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Women with a known hypersensitivity to nickel should not have the Essure devices inserted because the outer coil is made of nickel-titanium alloy.

IMMEDIATE COMPLICATIONS

Mortality

In an international study of 41,834 sterilizations performed from 1971 to 1979 in 28 countries, the estimated case fatality rate was 13.4 per 100,000 interval tubal sterilization procedures, 53.3 per 100,000 postabortion sterilization procedures, and 43.4 per 100,000 sterilizations after vaginal delivery. At least some of the differences in case fatality rates between interval tubal sterilization and sterilization associated with pregnancy were likely attributable to complications of pregnancy termination or delivery rather than tubal sterilization per se.

The potential health impact of tubal sterilization in countries that have a high rate of maternal mortality can be

assessed by analyzing sterilization-attributable deaths in Bangladesh. In the first of two epidemiologic investigations, 28 deaths were attributed to tubal sterilization in two geographic areas; the case fatality rate was 19 deaths per 100,000 tubal sterilizations. In the second investigation, 19 deaths were identified nationwide, for a case fatality rate of 12.4 deaths per 100,000 procedures. Anesthesia overdosage, tetanus, and hemorrhage were the leading causes of death in both investigations. On the basis of an estimated maternal mortality rate of 570 per 100,000 live births, more than 1,000 maternal deaths for each 100,000 tubal sterilizations performed would have been averted during the reproductive years of the cohort.

In the United States, deaths attributable to tubal sterilization are rare. Based on an assessment of tubal sterilizations performed in US hospitals in 1979 and 1980, the estimated case fatality rate for tubal sterilization is 1 to 2 per 100,000 procedures. Complications of general anesthesia are the leading cause of sterilization-attributable death. In a survey of deaths attributable to tubal sterilization in the United States from 1977 to 1981, 29 deaths were identified: Eleven followed complications of general anesthesia, seven were caused by sepsis, four were caused by hemorrhage, three were caused by myocardial infarction, and four were related to other causes.

At least some of these deaths are preventable. Safer use of general anesthesia or use of local anesthesia, particularly for interval laparoscopic and minilaparotomy procedures, should reduce the risk of death from anesthesia. Of the seven identified deaths caused by sepsis from 1977 to 1981, three were associated with the use of unipolar electrocoagulation. Safer use of unipolar coagulation or alternative methods of tubal occlusion reduces the risk of thermal bowel injury. Three of the four deaths attributable to hemorrhage occurred after major vessel laceration during abdominal entry for laparoscopy. Safer insertion of the Veress needle and trocar or use of alternative techniques, such as open laparoscopy or minilaparotomy, should reduce the risk of such major vessel injuries.

Morbidity

Morbidity attributable to tubal sterilization is uncommon but not rare. The risks for and types of morbidity vary somewhat by surgical approach and method of tubal occlusion. Direct comparisons of minilaparotomy and laparoscopy for tubal sterilization are limited, but studies suggest several differences. In a nonrandomized study in 23 countries, 7,053 women who had silicone rubber band application by way of laparoscopy were compared with 3,033 women who had silicone rubber band application by minilaparotomy and 5,081 women who

had modified Pomeroy ligation by minilaparotomy. The surgical complication rates were 2.04%, 1.45%, and 0.79% for the three groups, respectively. In a smaller but randomized study in eight centers, 791 women who had modified Pomeroy occlusion by minilaparotomy were compared with 819 women who had occlusion from electrocoagulation (technique not specified) by way of laparoscopy. Major complications occurred in 1.5% of the women in the minilaparotomy group and 0.9% of the women in the laparoscopy group. Minor complications, which are more common, occurred in 11.6% of women in the former group and 6.0% in the latter group.

In a US multicenter, collaborative study, major complications were more common among women who had minilaparotomy (3.5%) than among those who had interval laparoscopic sterilization (1.6%). However, women in the study were not randomly assigned to groups, and the sterilization procedures were performed in institutions where most interval tubal sterilizations were done by way of laparoscopy. Thus, minilaparotomy sterilizations may have been performed selectively for women at increased risk for complications.

Although the overall complication rates are similar for minilaparotomy and laparoscopy, the types of complications appear to vary. Complications of minilaparotomy usually are not serious and typically include minor wound infection, longer operating time, slightly longer postoperative convalescence, and greater postoperative pain. Laparoscopic complications are more likely to include rare but life-threatening hemorrhage and viscus

perforations during abdominal entry and thermal bowel injury during electrocoagulation. A study of 100,000 laparoscopies in France suggests that major vessel laceration occurs in three of 10,000 procedures. In a study conducted in the United Kingdom, major vessel laceration occurred in nine of 10,000 laparoscopies.

Some of the most serious complications of both interval minilaparotomy and laparoscopy occur during abdominal entry. Bladder laceration during suprapubic minilaparotomy can occur, but usually, it is recognized during surgery and is repaired easily. Major vessel and bowel laceration during needle or trocar insertion for laparoscopy are more difficult to recognize or repair, and delayed treatment of these injuries can be fatal. Meticulousness is required to reduce the risks of abdominal entry. Comparative studies of open versus conventional laparoscopy are limited and have insufficient power to assess the risk of life-threatening complications, but use of open laparoscopy should markedly reduce the risk of major vessel laceration and should reduce, to a lesser extent, the risk of bowel laceration. The use of open laparoscopy can be particularly advantageous for women known or strongly suspected to have multiple abdominal or pelvic adhesions. However, even open laparoscopy can result in bowel injury if the bowel is adherent to the anterior abdominal wall.

The method of tubal occlusion chosen influences the risk for and type of complications during laparoscopy. Thermal bowel injury is more common with unipolar than bipolar coagulation, but it can occur during the latter if the bowel is grasped and coagulated. Transection of the fallopian tube can occur with any technique, particularly when an attempt is made to mobilize the fallopian tube in the presence of thick peritubal adhesions. Tubal transection is most likely to occur when silicone rubber bands are used, but any resultant bleeding usually can be managed by the application of a second ring or by the use of coagulation.

Complications associated with insertion of the Essure device are generally related to the risks inherent in hysteroscopy, including hypervolemia, uterine perforation, and vasovagal syncope. Tubal spasm may occur precluding delivery of the microinserts beyond the tubal orifice. Patience while reducing intrauterine pressure and gentle pressure with the delivery catheter tip at the tubal orifice will usually result in relaxation of the spasm and successful microinsert placement. Intravascular delivery of local anesthetic solutions can occur. This may create the potential for seizures and cardiopulmonary arrest. Care should be taken when performing paracervical block anesthesia to infiltrate tissues superficially. Tubal perforation may also occur with placement of the microinserts across the uterotubal junction. This is typically unrecognized until the 3-month HSG confirmation test demonstrates poor positioning of the devices. Very rarely, patients may develop unrelenting crampy pain after insertion, which may necessitate removal of the devices if relief cannot be obtained with 7 to 10 days of medical management.

DELAYED COMPLICATIONS

Pregnancy

Tubal sterilization is highly effective in preventing pregnancy. A frequently cited failure rate is four pregnancies per 1,000 sterilization procedures. However, a range of failure rates is more likely to portray the risk of pregnancy after sterilization. The determinants of that range are likely to include the method of tubal occlusion, surgical technique, and the age of the woman at sterilization. In the US Collaborative Review of Sterilization, a multicenter, prospective, cohort study, 10,685 women undergoing tubal sterilization in medical centers in nine US cities from 1978 to 1987 were followed for up to 14 years. A total of 143 sterilization failures were identified with the 10-year cumulative probability of failure ranging from 7.5 per 1,000 procedures (for unipolar coagulating procedures and postpartum partial salpingectomy procedures) to 36.5 per 1,000 (for spring clip application procedures). The failure rates for most methods of tubal occlusion were higher for women aged 18 to 27 years at sterilization (as high as 54.3 and 52.1 per 1,000 bipolar coagulation and spring clip applications, respectively) than for women aged 34 to 44 years at sterilization (as low as 1.8 and 3.8 per 1,000 unipolar coagulation and postpartum partial salpingectomy procedures, respectively).

This large US multicenter study and two smaller studies in Thailand and Belgium have dispelled the widely held belief that nearly all pregnancies after sterilization occur in the first year or two after the procedure. In the Thai study, 418 women were followed for 6 to 10 years after sterilization, and only one of four pregnancies identified occurred within 2 years of the procedure. In the Belgian study, of 17 pregnancies after 1,437 sterilizations by bipolar coagulation, none occurred within 12 months of electrocoagulation, and eight occurred more than 24 months after the procedure. In the US study, the 10-year cumulative probability of pregnancy after bipolar coagulation (24.8 per 1,000 procedures) was approximately 10 times the probability (2.3 per 1,000) at 1 year. Further, pregnancies occurred in the 10th year after all four methods of laparoscopic sterilization studied (bipolar and unipolar coagulation, silicone rubber band application, and spring clip application).

The fact that the risk of pregnancy after sterilization only can be determined after long-term follow-up creates a dilemma in interpreting published failure rates. For example, the failure rates in the US Collaborative Review of Sterilization for six methods of tubal occlusion were based on procedures performed in the late 1970s and 1980s when laparoscopic sterilization was fairly new. Whether failure rates for procedures performed in the past reflect the risk for current procedures

is unclear. In an analysis of bipolar coagulation procedures in the US Collaborative Review of Sterilization, the 5-year cumulative probability of pregnancy for women sterilized in 1978 to 1982 (19.5 per 1,000 procedures) was significantly greater than that for women sterilized in 1985 to 1987 (6.3 per 1,000 procedures). Further, most of the procedures evaluated in that study were performed in teaching institutions; it is unclear whether procedures performed in teaching institutions can be generalized outside such settings.

Luteal phase pregnancy, or pregnancy diagnosed after sterilization but conceived before sterilization, is estimated to occur in 2 to 3 per 1,000 sterilization procedures. The most effective strategy for reducing the risk for luteal phase pregnancy is to time the sterilization procedure to occur during the follicular phase of the menstrual cycle. Reliance on dilatation and curettage at the time of sterilization is substantially less effective. The likelihood of luteal phase pregnancy occurring also depends on the method of contraception used before tubal sterilization. Women who use steroid hormonal contraceptives or intrauterine devices are at substantially lower risk for luteal phase pregnancy than are women who use barrier methods or no method of contraception. Testing for pregnancy by using an enzyme-linked immunosorbent assay pregnancy test as indicated before sterilization also reduces the risk for luteal phase pregnancy.

The likelihood of ectopic pregnancy occurring is increased when pregnancy occurs after sterilization. In the US Collaborative Review of Sterilization, the highest proportion of ectopic pregnancies among all pregnancies after sterilization was among women who underwent bipolar coagulation (65%), followed by interval partial salpingectomy (43%), silicone rubber band application (29%), postpartum partial salpingectomy (20%), unipolar coagulation (17%), and spring clip application (15%). The proportion of pregnancies that were ectopic increased over time; for all methods combined, the proportion of ectopic pregnancies was three times greater in the 4th through 10th years after sterilization (61%) than in the first 3 years (20%). All pregnancies that occurred in the 10th year after unipolar and bipolar coagulation, silicone rubber band application, and spring clip application were ectopic. All but one (an ovarian pregnancy after bipolar coagulation) of the 47 ectopic pregnancies identified in the study were tubal pregnancies. The index of suspicion for ectopic pregnancy should be high when pregnancy is suspected after tubal sterilization. Pregnancy should be confirmed by use of a highly sensitive pregnancy test as soon as feasible.

A woman’s individual risk for ectopic pregnancy can be considered in both absolute and relative terms. Her absolute risk is determined by the likelihood that the sterilization procedure can fail to prevent pregnancy and the likelihood that a resulting pregnancy will be ectopic. This risk is also relative to the risk for ectopic pregnancy that a woman had before tubal sterilization. Depending on the method of contraception used before sterilization,

some women may be at greater risk for ectopic pregnancy after tubal sterilization. In a report from a case-control study in Seattle, both postpartum sterilization and interval sterilization were associated with a lower risk of ectopic pregnancy than was use of no contraception. However, women who had interval tubal sterilization had a higher risk of ectopic pregnancy than did women who were using oral contraceptives or barrier methods of contraception. In contrast, the risk for ectopic pregnancy was similar between women who had postpartum tubal sterilization and those who used oral contraceptives or barrier contraception.

Careful attention to surgical technique is required to maximize sterilization effectiveness. To reduce the risk of pregnancy after bipolar coagulation, Soderstrom and colleagues identified determinants of complete electrocoagulation. In the US Collaborative Review of Sterilization, women undergoing bipolar coagulation later in the study who had three or more sites of coagulation had a 5-year cumulative probability of failure of 3.2 per 1,000 procedures. This is similar to the 5-year probability for unipolar coagulation (2.3 per 1,000) and substantially lower than that for women undergoing bipolar coagulation with fewer than three sites of coagulation (12.9 per 1,000). Stovall and coworkers reported on the use of silicone rubber bands and spring clips in a residency training program; all of 20 sterilization failures were associated with improper application of the occlusive device on gross and microscopic evaluation after subsequent bilateral salpingectomy. In the US Collaborative Review of Sterilization, the risks of pregnancy were significantly increased among women who had a silicone rubber band applied solely to the distal one third of at least one fallopian tube and among women who had a spring clip applied to a site other than the proximal one third of at least one tube.

The likelihood of sterilization failure depends not only on the sterilization technique but also on patient and physician factors. For example, proper application of silicone rubber bands and spring clips generally is difficult in the presence of thickened tubes or dense pelvic adhesions; under such circumstances, alternative techniques usually are preferred. As noted, failure rates generally are higher for women sterilized at younger ages, not only because they are more fecund at the time of sterilization than older women but also because they have a longer period after sterilization during which it would be feasible for pregnancy to occur. The latter consideration, which is an issue because it is now clear that pregnancy can occur for many years after sterilization, also applies to any temporary method of contraception that a woman chooses to use. For example, based on data from the US Collaborative Review of Sterilization, a woman sterilized at 28 to 33 years old has a 10-year chance of pregnancy of less than 1% to approximately 3%, depending on the method of tubal occlusion. The comparable risk for 10 years of use of the Copper T 380 intrauterine device is approximately 2%, but the typical failure rate for oral contraceptive use is approximately 6% to 8% in just the first 12 months of use. Data regarding the long-term failure rates of the Filshie clip and the Essure microinsert are less complete than those for the other commonly used techniques. However, based on data to date, both appear highly effective with proper placement.

In a 2012 systematic review that included 22 studies, 102 pregnancies were identified after Essure placement, but most of these pregnancies occurred when FDA's instructions for use were not followed. Especially noteworthy findings were not placing the microinserts during days 7 to 14 of the menstrual cycle, not having an imaging study at 3 months postinsertion to document successful placement, and not using effective contraception until tubal occlusion had been documented. Only 15 pregnancies occurred among women who had imaging confirmation of correct placement or tubal occlusion, highlighting not only the very low risk of pregnancy after successful bilateral tubal occlusion but also the importance of adequate follow-up imaging. Given the fundamentally different mechanism of tubal obstruction (fibrotic endosalpingeal ingrowth) with the hysteroscopic technique, the risk of ectopic pregnancy in sterilization failures may be quite different than with the laparoscopic or minilaparotomy approaches. Long-term careful follow-up studies will be needed to establish the long-term failure and ectopic risks with Essure.

Menstrual Changes

After nearly a half century of debate, questions regarding the existence of a posttubal ligation syndrome of menstrual abnormalities appear to be largely resolved. Questions arose initially when Williams and colleagues reported in 1951 that sterilized women had a higher-than-expected occurrence of menorrhagia and metrorrhagia. Studies in the 1970s appeared to support the existence of a poststerilization syndrome, but most of those studies had major methodologic shortcomings, including failure to account for factors other than sterilization per se that might have influenced poststerilization menstrual changes. One such factor was the use of oral contraceptives; in the United States, as many as 30% of women may use oral contraceptives immediately before tubal sterilization, and many of these women have menstrual changes after sterilization attributable solely to cessation of oral contraceptive use. Although one well-controlled study by Shain et al. in the 1980s identified poststerilization menstrual changes, nearly all other studies reported in the 1980s that controlled for factors such as cessation of oral contraceptive use found little or no evidence of a poststerilization syndrome at 1 to 2 years after sterilization.

Until the 1990s, questions remained about whether menstrual changes attributable to sterilization may occur several years after the procedure. Two US multicenter, prospective, cohort studies argue strongly against such an occurrence. In the first, reported in 1993, 500 women were evaluated at 6 to 10 months and 3 to 4.5 years after sterilization. When women who were taking oral contraceptives were excluded, no significant differences in seven menstrual parameters were found between sterilized women and two groups of nonsterilized women.

In the second, reported in 2000, 9,514 sterilized women enrolled in the US Collaborative Review of Sterilization were compared with 573 women whose husbands underwent vasectomy. All women were asked the same questions about six menstrual parameters before tubal sterilization or the husband's vasectomy and again at annual follow-up interviews for up to 5 years. The sterilized women were no more likely than the nonsterilized women to report changes in intermenstrual bleeding or cycle length. The sterilized women were more likely than the nonsterilized women to have decreases in the number of days of bleeding and the amount of bleeding and menstrual pain; they were also more likely to have an increase in cycle irregularity. When the risk of menstrual abnormalities was evaluated by method of tubal occlusion, there were no significant differences between the women sterilized by any of six methods and the women whose husbands underwent vasectomy in amount or duration of menstrual bleeding, intermenstrual bleeding, or menstrual pain. Women undergoing one of three methods of sterilization (silicone rubber band application, interval partial salpingectomy, and thermocoagulation) were more likely than nonsterilized women to have an increase in cycle irregularity, whereas women undergoing either of two other methods (unipolar and bipolar coagulation) were more likely to have decreases in cycle irregularity. This latter observation suggests strongly that the differences between sterilized and nonsterilized women in the likelihood of cycle irregularity and other menstrual features were attributable to chance or unmeasured differences between the study groups. Finally, sterilized women were compared with nonsterilized women for risk of a syndrome consisting of persistent increases in amount of bleeding, days of bleeding, or intermenstrual bleeding; no significant differences were identified.

Although sterilization procedures have been hypothesized to adversely affect ovarian function, laboratory studies have identified no consistent abnormalities that reflect ovarian dysfunction. Further, the biologic plausibility of such an occurrence is uncertain. The tubal branch of the uterine artery, which often is occluded during sterilization, connects with the ovarian branch of the uterine artery; thus, interrupting the tubal branch could affect the blood supply to the ovary. However, blood also is supplied to the ovary by the ovarian artery, which branches directly off the aorta and is remote from the site of tubal occlusion. The possibility has been raised that tubal occlusion could damage the ovary by acutely increasing pressure in the uteroovarian arterial loop. However, as noted, neither laboratory nor epidemiologic studies find changes consistent with acute injury to the ovary, and there is now strong evidence against the occurrence of sterilization-attributable menstrual abnormalities within 5 years of the procedure.

Some women who have no menstrual abnormalities before sterilization have them later, and for other women, menstrual abnormalities before sterilization resolve. To consider the former group as having a syndrome is inappropriate unless the latter group is considered to have an opposing syndrome. Although menstrual abnormalities are common among sterilized women, they also are common among nonsterilized women of similar ages. The balance of the evidence to date suggests strongly that sterilized women are no more likely than comparable nonsterilized women to have menstrual abnormalities.

Hysterectomy

Tubal sterilization and hysterectomy are common procedures in the United States, and any relation between the two has important consequences. Tubal sterilization could increase the risk for hysterectomy by increasing either the reality or the perception that a poststerilization syndrome occurs. As noted, the evidence against such a syndrome is now strong; thus, it should not be an indication for hysterectomy. Alternatively, the fact that a woman has had tubal sterilization could affect decision making about further surgery. At least three studies suggest that this effect can occur. Cohen studied 4,374 women 25 to 44 years old who had tubal sterilization in 1974 while enrolled in a universal health insurance plan in Canada. Women 25 to 29 years old at the time of sterilization were 1.6 times more likely than nonsterilized women to have a hysterectomy at a later time. However, women 30 years or older at the time of sterilization were no more likely than nonsterilized women to have a hysterectomy subsequently. Goldhaber and colleagues, who studied 39,502 women sterilized during 1971 to 1984, found that women sterilized at 20 to 24 years old were 2.4 times more likely than nonsterilized women to have a hysterectomy subsequently. For other sterilized women, the risk for hysterectomy steadily decreased with increasing age; women sterilized at 40 to 49 years old had no increased risk. Stergachis and associates studied 7,414 women sterilized during 1968 to 1983 and found that women sterilized at 20 to 29 years old were 3.4 times more likely than nonsterilized women to subsequently have a hysterectomy. Women sterilized at 30 years old or older had no increased risk for hysterectomy.

The fact that the increased risk for hysterectomy was concentrated among women sterilized at a young age in the noted studies suggests that any increased risk for hysterectomy after tubal sterilization is not biologic in etiology but attributable to other factors, such as removal of fertility preservation as a factor in decision making. In the US Collaborative Review of Sterilization, women sterilized at 34 years old and younger were four to five times more likely to undergo hysterectomy than women the same age whose husbands underwent vasectomy. However, women sterilized at 35 years old and older were also four to five times more likely to undergo hysterectomy than women

whose husbands underwent vasectomy, suggesting that fertility preservation does not explain all differences in decision making between sterilized and nonsterilized women.

In the US Collaborative Review of Sterilization, the cumulative probability of undergoing hysterectomy within 14 years after sterilization was 17%. Although women with gynecologic disorders at the time of sterilization were at greater risk of hysterectomy, most women who reported gynecologic disorders at sterilization did not undergo hysterectomy within the followup period. For example, women who reported having a history of endometriosis at sterilization were more likely to undergo hysterectomy than women without a history of endometriosis; the probability of women reporting endometriosis undergoing hysterectomy within 14 years was 35% versus 15% for women without endometriosis. Similarly, women who reported having a history of uterine leiomyomata at sterilization were more likely to undergo hysterectomy than women without a history of leiomyomata; the 14-year cumulative probability of hysterectomy among women reporting leiomyomata was 27% versus 14% for women without leiomyomata.

Regret

The decision to undergo sterilization is serious to both men and women because the intent is to permanently terminate fertility. Although microsurgical methods of reversal are available, these methods require special skill, the procedures are complicated and lengthy, the costs are high, and none of the methods guarantees success.

Findings from studies of poststerilization regret provide useful information for presterilization counseling. Sterilization regret is a complex condition that is often causally linked to unpredictable life events. The risk factors for regret described here should not be used as reasons for restricting access to sterilization. Instead, they should be used to identify persons who may need extensive counseling. Presterilization counseling has been shown to correlate with poststerilization satisfaction.

Poststerilization regret can arise from several factors, including preexisting patient characteristics, subsequent changes in the patient's social situation or attitudes, and dissatisfaction resulting from adverse side effects caused or perceived to be caused by the procedure. Estimates of the prevalence of sterilization regret vary widely by measure of indication of regret and geographic region. During the last two decades, US-based studies have reported rates of poststerilization regret ranging from 0.9% to 26.0%. The wide range reflects, in part, differences in study design and questions asked of respondents. In general, the likelihood of a woman expressing regret after sterilization appears to increase over time. In the US Collaborative Review of Sterilization, the cumulative probability of regret increased from 4% at 3 years after sterilization to 8% at 7 years and 13% at 14 years. The 5-year cumulative probability of regret after tubal sterilization (7%) was similar to that for women whose husbands underwent vasectomy (6%).

In the 1982 National Survey of Family Growth, approximately 10% of women who had been sterilized reported that they would have the sterilization reversed if it were safe to do so. In the US Collaborative Review of Sterilization, 14% of sterilized women reported that they had sought information about tubal reanastomosis at least once within 14 years of sterilization; only 1% actually obtained a reversal.

At least five studies have identified young age at sterilization as the strongest predictor of later regret of sterilization. In the US Collaborative Review of Sterilization, young age at sterilization also was a strong predictor of regret, regardless of parity or marital status. After adjusting for other risk factors, women 30 years of age or younger at sterilization were about twice as likely as older women to express regret within 14 years of sterilization. Similarly, the cumulative probability of expressing regret within 14 years was 20% for women 30 years old or younger versus 6% for women older than 30 years at sterilization. Likewise, the 14-year cumulative probability of requesting information about reversal was 40% among women sterilized at 18 to 24 years of age, and, after adjustment for other risk factors, women 18 to 24 years old were almost four times as likely as women 30 years old or older to request information about reversal. Although low parity has been identified as a risk factor for regret in some studies, it was not an independent risk factor in other studies after control for factors such as young age at the time of sterilization. The US Collaborative Review of Sterilization also found that women identifying substantial conflict with their husbands or partners before sterilization were more than three times as likely to regret their decision and more than five times as likely to request sterilization reversal.

Timing of the procedure in relation to pregnancy has been reported as a risk factor for regret. Several studies found that women who had tubal sterilization concurrent with cesarean section or following vaginal delivery or abortion were more likely to regret sterilization, but studies have been inconsistent in this regard. In the US Collaborative Review of Sterilization, the 14-year cumulative probability of regret was nearly identical for women whose sterilizations were concurrent with cesarean section (16%), after vaginal delivery (18%), and within 1 year of pregnancy (18%). The probability of regret decreased with time since the birth of the youngest child; women with 8 or more years since the birth of the youngest child had a probability of only 5%, a rate similar to that for women with no previous births (6%).

In summary, indicators of regret can vary significantly by cultural and individual circumstances. Most studies

have found that age younger than 30 years is an independent risk factor for regret. The presterilization counseling for women in this age group should place special emphasis on the risk for regret. Other risk factors, such as time in relation to an obstetric event, ambivalence, or unstable life circumstances, should be assessed with each patient on an individual basis.

Sexual Function

In the US Collaborative Review of Sterilization, approximately 80% of women undergoing interval sterilization reported no consistent change in either sexual interest or pleasure in the first 2 years after the procedure. Of women reporting a consistent change, women were 10 and 15 times more likely to report positive changes in sexual interest or pleasure than negative ones.

Cancer

Although there is no evidence that tubal sterilization increases the risk for cancer at any site, studies are inconsistent regarding a possible reduction in risk of breast cancer after sterilization. One large prospective study by the American Cancer Society found that tubal sterilization reduced the risk of breast cancer mortality but only among women sterilized before 1975. It is unclear whether women who were sterilized had rates of screening mammography similar to those of nonsterilized women; thus, women who underwent tubal sterilization may have had greater access to screening services. A retrospective cohort study using data from the Ontario Cancer Registry found a reduced risk of breast cancer incidence among sterilized women, but that study was unable to control for potentially confounding variables. Two population-based case-control studies supported by NIH that did control for

confounding found no effect of sterilization on breast cancer risk. Thus, at this point, it is unclear whether there is any biologic relationship between tubal sterilization and reduction in risk of subsequent breast cancer.

Several studies have identified a reduced risk of ovarian cancer after tubal sterilization. Hankinson and colleagues reported on the first large prospective cohort study of this relation; the risk of ovarian cancer for women who had tubal sterilization was one third that of nonsterilized women. In a pooled analysis of case-control studies, Whittemore and coworkers found a reduced risk of ovarian cancer after tubal sterilization. Whether the observed reduction in risk of ovarian cancer is a real protective effect or is attributable to some other factor remains unclear. However, there is reason for optimism that reduction in risk of ovarian cancer may be an important noncontraceptive health benefit of tubal sterilization.

VASECTOMY AS A SURGICAL ALTERNATIVE

Some couples who have chosen surgical sterilization for permanent contraception have difficulty in deciding whether vasectomy or tubal sterilization is most appropriate. Although numerous individual- or couple-related concerns can influence the decision, many couples include considerations about safety and effectiveness in their decision making. To assist such couples, we provide a brief overview of the health effects of vasectomy.

In regard to immediate surgical complications, vasectomy is a remarkably safe procedure. Serious morbidity and death are extremely rare. Fairly minor complications, such as scrotal swelling, ecchymosis, and pain, occur in up to 50% of men who have a vasectomy, but these symptoms usually resolve spontaneously within 1 to 2 weeks. Vasectomy generally has been performed through two incisions in the scrotum, one overlying each vas. Hematoma formation occurs in approximately 2% of such procedures; infections occur in less than 2%. In 1985, a new vasectomy technique was introduced, referred to as no-scalpel vasectomy. It reduced the alreadylow rate of minor complications. In most reports, pregnancy rates after vasectomy are less than 1%. Unlike tubal sterilization, vasectomy is not immediately effective. Three months are required to flush the vasa of viable sperm. This should be confirmed by a postvasectomy semen analysis at 3 months or more after the procedure.

In 1978, questions about the long-term health effects of vasectomy were raised when an increased risk for atherosclerosis was found among monkeys that had had a vasectomy. At least nine subsequent epidemiologic studies in men found no such increased risk, and later findings in monkeys did not support an increased risk. Thus, vasectomy does not affect the risk for subsequent cardiovascular disease. These studies also provided strong evidence that vasectomy does not increase overall mortality. More recently, questions were raised about the risk of prostate cancer after vasectomy. A 1998 metaanalysis of 14 observational studies concluded that the evidence for an association between vasectomy and prostate cancer was of low quality because of biases that overestimate the effect of vasectomy and that any association is likely not a causal one. Subsequently, a large population-based study in New Zealand found no relation between vasectomy and risk of prostate cancer. Thus, the evidence to date argues strongly against any causal relationship.

Questions remain regarding a potential syndrome of postvasectomy pain. The purported syndrome has been varyingly defined as chronic testicular, epididymal, or scrotal pain, and the proposed causes include epididymal congestion, nerve entrapment, and sperm granulomas. Although a few small, uncontrolled surveys found rates of such pain as high as 2% to 15%, the largest and best study found the incidence of epididymitis-orchitis more than 12 months after vasectomy to be 24.7 per 10,000 person-years versus 13.6 per 10,000 person-years among men who did not undergo vasectomy. Although uncertainties remain, it is likely that a small percentage of men will indeed experience chronic pain after vasectomy. It appears, based on limited information, that many such men will respond to conservative measures and that surgical management, including vasectomy reversal, may help others.

BEST SURGICAL PRACTICES

- Preprocedure assessment and counseling are essential elements in a successful sterilization procedure. Counseling regarding failure rates, risks, and risk factors for later regret should be performed. Preprocedure cytologic screening and day-of-surgery pregnancy testing are encouraged if indicated.
- General anesthesia is the leading cause of death from tubal sterilizations in the United States. Although tubal sterilizations can usually be performed safely under local anesthesia, general anesthesia is used more often in the United States. One of the reasons that vasectomy is safer than tubal sterilization is that general anesthesia is rarely required.
- A major portion of morbidity and mortality associated with laparoscopic methods of sterilization is related to entry into the abdominal cavity. Open laparoscopy can reduce the incidence of major vascular injury at entry. In closed laparoscopy technique, meticulous attention to details of entry can help reduce injury. Hysteroscopic sterilization eliminates both the need for general anesthesia and the risk of abdominal entry.
- With all the techniques of tubal sterilization, success is dependent on correct identification of the tube; hasty tubal identification, without taking the time to follow the tubes out to their fimbriated ends (if not distorted by adhesions), can result in procedural failure.
- Nearly all the techniques of tubal sterilization involve the isthmic portion of the fallopian tube, which is the narrowest and most uniform caliber portion of the extramural tube. However, it is suggested that 2 cm of the isthmic portion of the tube be left at the cornu, proximal to the site of tubal interruption, to theoretically reduce the incidence of tuboperitoneal fistula. Aggressive overtightening of ligatures, just as avoided in surgical technique elsewhere in the body, should likewise be avoided at the time of tubal interruption, as strangulation and necrosis of the tube can lead to fistulization and failure rather than success. Ligatures applied during partial salpingectomy methods of sterilization (e.g., Pomeroy, Parkland) at the time of cesarean delivery are at risk of dislodgement by shearing forces when the uterus is restituted into the abdominal cavity at the end of the procedure. Care should be exerted to protect the ligated areas as one and then the other adnexum is replaced into the abdomen.

- Laparoscopic unipolar coagulation of the fallopian tube is one of the most successful methods of sterilization, likely attributed to the approximately 5-cm zone of thermal destruction that results. However, the risk for thermal injuries is also highest with this method, unless the safe application of unipolar energy at laparoscopy and the concept of capacitive coupling are understood by the surgeon. Greater tubal destruction and sterilization success with this method go hand in hand with least likelihood that reversal could ever be achieved.

- Laparoscopic bipolar coagulation creates a smaller zone of thermal injury (approximately 3 cm) than unipolar and is also not likely to result in indirect thermal injury by capacitive coupling. Three contiguous burns over a 3-cm length of tube, beginning approximately 3 cm from the cornu and moving toward the fimbriated end, are recommended. Also recommended are the use of the cutting waveform, delivering at least 25 W of bipolar energy (continuous waveform by default), and the use of an optical flowmeter to estimate when coagulation (and flow of current) is complete.
- Silastic band application requires familiarity with the applicator and the tendency of its grasping tongs to transect the fallopian tube when trying to retract a knuckle of tube into the hollow applicator cannula. Tethered or thickened tubes are at greatest risk of transection, and an alternative method should be considered. A complete encirclement of the tube by the grasping tongs is necessary if a partial or tangential application of the ligating band is to be avoided.
- Hulka and Filshie clips are reliable methods of tubal interruption but require strict adherence to surgical technique to be successful. Application at right angles to the tube, 2 cm from the uterus, without excessive tubal elevation, and with the tips of the clips advanced onto the mesosalpinx are the key points of the application. Clips are associated with minimal tubal destruction (3 mm) and are therefore the most amenable to tubal reversal.
- Essure microinserts are placed transcervically via hysteroscopy. Care should be taken to create sufficient distention to identify both tubal ostia clearly and to insert the device into the proximal lumen to the level marked on the catheter. Hypervolemia should be avoided, and a confirmation HSG must be performed at 3 months postinsertion. Alternate contraception should be used until occlusion is documented.

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