Chapter 6

Female Sterilization

Highlights:

- Female sterilization is one of the safest operative procedures; complications are rare and occur in fewer than 1% of all female sterilization procedures.
- Female sterilization procedures can be grouped into two broad categories: procedures for reaching the fallopian tubes (primarily abdominal approaches, such as minilaparotomy, laparoscopy, and laparotomy), and methods for occluding the fallopian tubes (mainly ligation and excision, mechanical devices such as clips or rings, and electrocoagulation).
- In the United States, the overall 10-year cumulative method failure rate following tubal sterilization is 1.85% for all occlusion methods, but the cumulative failure rate varies by method, with the lowest rates for postpartum partial salpingectomy and unipolar coagulation and the highest rates for clips and silicone bands or rings.
- About 2–6% of sterilized women in developed countries and 0.2% of sterilized women in developing countries are estimated to seek information about reversal, but the actual rate may be substantially higher. In developing countries especially, women's potential interest in restoration of fertility is probably greatly underestimated, given the inaccessibility of such services and the corresponding lack of knowledge about them.

Female sterilization is the most commonly used method of family planning; more than 180 million couples worldwide have chosen it as their contraceptive method (see Chapter 2). In this chapter, we present descriptive information about female sterilization (also referred to as tubal ligation or tubal occlusion), including different surgical approaches, data on effectiveness and complications, issues related to reversal, and an overview of innovations that might improve current procedures.

Female sterilization is a relatively simple procedure that involves permanently blocking the fallopian tubes to prevent fertilization. The procedure was first used in the early 19th century by James Blundell (Speert, 1996), and the first published report of this procedure was in 1881 (Lungren, 1881). By the mid-20th century, female sterilization had begun to gain popularity. Many modifications and new techniques have been developed since, to improve effectiveness, safety, and reversibility. Today, greatly simplified procedures performed under local anesthesia and in ambulatory settings have helped minimize the complications associated with general anesthesia (a primary risk factor for female sterilization) and have permitted the expansion of services to lower levels of the health service system in many countries. Serious complications are rare and occur in fewer than 2% of all female sterilization procedures (Pati & Cullins, 2000).

Requirements for a Safe Procedure: An Overview

Essential elements of quality sterilization services include counseling and client assessment and screening, informed consent, infection prevention, selection of appropriate procedures, safe anesthesia regimens, and postoperative care and instructions.

Counseling and client assessment and screening are important prerequisites to sterilization procedures. Since female sterilization is intended to be a permanent method of contraception, it should be provided only to women who have decided they do not want more children. Clients should be counseled about all available methods of contraception before deciding on sterilization.

Preoperative client screening is performed to ensure every client's physical and emotional fitness for the sterilization procedure, to assess client characteristics such as age and number and ages of living children (WHO, 1992), and to rule out known and identifiable physical or medical risk factors (Layde et al., 1983). Client assessment consists of taking a history (medical history and obstetric and gynecological history) and performing a physical examination (vital signs, heart, lung, abdomen, and pelvic and speculum examination).

The minimum recommended laboratory tests include tests to screen for anemia and to rule out current pregnancy. If laboratory tests are not possible, then clinical assessment for these two conditions should be performed. To minimize the chances of pregnancy at the time of a procedure, sites should have criteria for being reasonably sure that a woman is not pregnant (e.g., performing the procedure within 10 days of the last menstrual period, within seven days of an abortion, within seven days of a term delivery, or in women using reliable methods of contraception).

There are no absolute medical restrictions for female sterilization (WHO, 1992). While they are not contraindications for surgery, such problems as previous abdominal surgery, obesity, current or past history of pelvic inflammatory disease (PID), diabetes mellitus, and cardiac and lung diseases are all considered potential risk factors, as these represent conditions in which difficulties with the surgical procedure and complications can be anticipated (WHO, 1996). Hence, special precautions may have to be taken before, during, or after the surgery. Client assessment will facilitate decision making on when best to perform the surgery safely and effectively, the surgical approach to be used, the institution where it should be performed, and who should perform it.

The surgeon should verify that the client has signed an informed consent form before beginning the procedure. Although the purpose of signing the form is to document informed consent, the principal focus should be on confirming that the client has made an informed choice of tubal occlusion as a contraceptive method (see Chapter 1).

Strict adherence to good infection prevention practices at all times (before, during, and after surgery) is also crucial to the safety of the procedure. Proper aseptic technique is essential to prevent both immediate and long-term infectious morbidity and mortality. Inadequate infection prevention practices can lead to surgical-site infections, tetanus, and infections such as HIV and AIDS, hepatitis B, and hepatitis C (Grimes et al., 1982a; IPPF, 1997; Mangram et al., 1999). Shaving or clipping the hair at the operation site is no longer recommended: Studies have clearly demonstrated that shaving surgical sites significantly increases the chances of infection (Cruse & Foord, 1980; Seropian & Reynolds, 1971).

Client safety and satisfaction should be the primary considerations in the choice of the anesthesia regimen used in the performance of female sterilization procedures. The purpose of anesthesia is to ensure that the client is free from pain and discomfort during the operation. Three choices of anesthesia regimen—local, general, or regional—can be used for female sterilization procedures. Each regimen has advantages and disadvantages, as well as risks and benefits. Factors to be considered in the choice of anesthesia include the type of surgical technique, the skills of the surgeon, the availability of appropriate drugs, the safety and comfort of the client, and the ability of the surgeon to manage complications, should they occur (WFHAAVSC, 1995; WHO, 1992). The presence of a provider skilled in administering regional or general anesthesia is important if these regimens are being considered. (More detailed information about anesthesia is presented below.)

It is important for all clients and their accompanying family members to be provided with clear written and oral postoperative instructions on postoperative wound

Table 6.1. Approaches to the fallopian tubes, surgical procedures, timing of procedure, and related occlusion techniques

Approach	Surgical procedure and timing	Occlusion techniques
Abdominal	Minilaparotomy (postpartum, postabortion, or interval)	• Ligation and excision • Mechanical devices (clips, rings)
	Laparoscopy (interval only, contraindicated postpartum)	• Electrocoagulation (unipolar, bipolar) • Mechanical devices (clips, rings)
	Laparotomy (in conjunction with other surgery—e.g., cesarean section, salpingectomy, ovarian cystectomy)	• Ligation and excision • Mechanical devices (clips, rings)
Transvaginal (no longer recommended)	Colpotomy	• Ligation and excision • Mechanical devices (clips, rings)
	Culdoscopy	• Electrocoagulation (unipolar, bipolar) • Mechanical devices (clips or rings)
Transcervical* (experimental)	Hysteroscopy (interval only)	• Physical occlusion (plug) • Chemical agents (e.g., quinacrine)

* Transcervical approaches for tubal occlusion have been studied for several years, but to date none of these methods have been found to be completely safe and effective enough for implementation into routine service delivery.

care, venue for follow-up, warning signs, and appropriate advice on restriction of activities following the surgery.

Female Sterilization Procedures

The many variations in female sterilization procedures can be grouped in two broad categories: procedures for reaching the fallopian tubes (i.e., incisions and instruments), and methods for occluding the fallopian tubes.

Reaching the fallopian tubes

Three approaches provide adequate access to the fallopian tubes (Table 6.1): abdominal (such as minilaparotomy, laparoscopy, and laparotomy), transvaginal (colpotomy and culdoscopy),[1] and transcervical (blind transcervical manipulation and hysteroscopy). The transcervical approach is in large part experimental and is discussed in the Innovations section.

Many factors help to determine what sort of sterilization procedure is done. These include the timing of the sterilization in relationship to pregnancy; the need for other gynecological procedures; the woman's health characteristics (such as obesity, previous pelvic infections, and previous abdominal surgery); the training, expertise, and experience of the provider; the cost and logistics of maintaining equipment and occlusion systems, especially for laparoscopy; and the availability of back-up services (a special consideration in low-resource settings).

Timing of the procedure

The timing of the sterilization procedure is an important consideration in the choice of approach. Female sterilization procedures can be performed in conjunction with a term delivery (i.e., soon after a vaginal delivery or in conjunction with a cesarean section performed for obstetric indications), immediately following an uncomplicated first-

[1] In general, these procedures are no longer recommended, due to higher complication rates.

trimester abortion, or independent of pregnancy (during a period of time when a woman has not recently been pregnant, otherwise known as the interval period).

- *In association with term delivery.* Postpartum procedures (such as subumbilical minilaparotomy) are usually performed during the first 48 hours following vaginal delivery, or with special care 3–7 days after delivery. Sterilization procedures should not be performed between eight and 41 days postdelivery because of an increased risk of complications before the uterus has fully returned to its prepregnancy size (Blumenthal & McIntosh, 1996; Pati & Cullins, 2000; WHO, 1992). Minilaparotomy is recommended as the safest and easiest approach for postpartum sterilization because during the postpartum period the uterus is enlarged and the fallopian tubes are easily accessible. Laparoscopy is not recommended for postpartum procedures, as the postpartum enlargement of the uterus makes laparoscopic surgery difficult and injury likely (WHO, 1992). Sterilization can also be accomplished by ligation and excision of a portion of the fallopian tubes during a cesarean section. However, cesarean section should never be performed solely for the purpose of sterilization.
- *In association with abortion.* At the time of uncomplicated first-trimester abortion procedures, such procedures as laparoscopic sterilization and interval minilaparotomy can be performed (WHO, 1992).
- *Not associated with pregnancy.* Interval sterilization is performed at six or more weeks after delivery (i.e., after the uterus has fully involuted) or at any other time not associated with a pregnancy. Acceptable approaches include minilaparotomy, laparoscopy, or laparotomy (Stewart & Carignan, 1998).

Abdominal approaches

Minilaparotomy and laparoscopy are the two most commonly used procedures for interval sterilization worldwide (Speroff & Darney, 1996). Subumbilical minilaparotomy is the most commonly used procedure for postpartum sterilization.

- *Minilaparotomy.* Often referred to as minilap, minilaparotomy is defined as a laparotomy (or abdominal entry) with an incision less than 5 cm in size. The incision is located over the pubic bone during an interval procedure and under the umbilicus for a postpartum procedure. The abdomen is opened in layers, with care being taken to avoid injury to underlying structures such as the uterus, bowel, or bladder. Tubal occlusion is generally performed under local anesthesia, with or without sedation. It is also usually conducted as an ambulatory service, meaning that the client can go home shortly after the procedure. The small size of the incision, the refinement of the surgical technique, and the use of local anesthesia have contributed to the establishment of outpatient minilaparotomy services and to increased access for women desiring interval procedures.

Minilaparotomy has several advantages: First, it can be used for both interval and postpartum procedures under local anesthesia. In addition, under local anesthesia, minilaparotomy can be provided by nonspecialized doctors or by appropriately trained and supervised nurse-midwives working in modestly equipped facilities, where general or regional anesthesia usually is not available (Dusitsin & Satyapan, 1984; Kanchanasinith et al., 1990).

Furthermore, minilaparotomy requires only basic laparotomy instruments. Two additional instruments are also recommended for interval procedures—the uterine elevator or manipulator and the tubal hook, which makes locating and reaching the tubes easier. These are not used during postpartum procedures, as the uterus is enlarged and access to the fallopian tubes is enhanced by the fallopian tube's proximity to the abdominal wall.

Finally, minilaparotomy with local anesthesia is appropriate for carefully selected clients for whom surgery is not contraindicated and for whom local anesthesia with light sedation is sufficient. Postpartum minilaparotomy is a safe and effective procedure that does not increase hospitalization time and that allows women access to female steriliza-

tion during their delivery-related hospitalization (Chi, Gates, & Thapa, 1992; WHO, 1982a; WHO, 1992).

• *Laparoscopy.* A laparoscope consists of a small telescope combined with a light source, and it allows the provider to visualize the pelvic contents and identify the fallopian tubes. The telescope and equipment for tubal occlusion are inserted into the abdominal cavity through an incision underneath the umbilicus. Only one incision is required with laparoscopes that are designed with the operating mechanism for tubal occlusion incorporated directly into the scope (e.g., the Laparocator®). Other laparoscopes require an additional puncture for inserting the operating instrument (Berek, Adashi, & Hillard, 1996).

Laparoscopy can be performed satisfactorily under general, regional, or local anesthesia with light sedation. The equipment needed to perform laparoscopy includes a trocar and a scope, a gas source, a light source, an insufflation needle (to fill the abdomen with air and create room to see and operate), a uterine elevator (similar to that used with minilaparotomy), and an occlusion device—either a clip or ring applicator, or a bipolar coagulator.

Laparoscopy can be safely performed immediately after an uncomplicated first-trimester abortion or at any time unassociated with pregnancy (Coddington, 1999). It should not be performed immediately postpartum both because the risk of injury to the enlarged postpartum uterus is increased and because visibility and access to the fallopian tubes are limited.

In some locations (e.g., in Nepal), use of laparoscopy has significantly increased the availability of sterilization services. The equipment is expensive to buy and maintain, however, and laparoscopy requires a higher level of training to perform than does minilaparotomy. The risk of major complications is also higher with laparoscopy than with minilaparotomy (Liskin et al., 1985; Pati & Cullins, 2000; Ross, Hong, & Huber, 1985). Open laparoscopy was introduced in 1971 to reduce the risk of blind entry into the abdomen. This method has not gained wide acceptance, however. Many practitioners consider it to be more cumbersome and time-consuming than the use of conventional instruments and techniques (Peterson et al., 1993). Furthermore, studies have failed to show consistently lower complication rates for open laparoscopy than for conventional approaches (Levy et al., 1994).

• *Laparotomy.* Laparotomy is defined as abdominal entry through an incision greater than 5 cm and is performed under general or regional anesthesia. It is associated with more complications and a longer recovery time than either minilaparotomy or laparoscopy. Laparotomies are not usually outpatient procedures.

Laparotomy is not recommended for the sole purpose of female sterilization. Typically, sterilization may be done when laparotomy is being performed for other indications—most commonly, at the time of caesarean section for obstetric indications, or when salpingectomy is being performed concurrently with the management of an ectopic pregnancy or ovarian cystectomy. Occasionally, a minilaparotomy incision will not provide adequate exposure, as in the case of obesity or abdominal or pelvic adhesions, and a laparotomy incision will be needed.

Transvaginal approaches

Access to the fallopian tubes through the vagina is gained through a small incision below the cervix, in the posterior vaginal wall, either by direct visualization (colpotomy) or with a specially designed scope (culdoscope). Female sterilization by the transvaginal approach is used infrequently, because of higher infection rates and greater technical difficulties in accessing the fallopian tubes (Akhter, 1973; Gupta et al., 1980; WHO, 1982c). Moreover, use of the transvaginal approach is associated with increased complication rates (2–26%) (Gupta et al., 1980; Miesfeld, Giarratano, & Moyers, 1980; WHO, 1982b). Therefore, it is not recommended for tubal sterilization (RCOG, 1999; WHO, 1992).

Occluding the fallopian tubes

There are three types of occlusion procedures (Table 6.1): ligation and excision, use of mechanical devices (such as clips or rings), and electrocoagulation (the burning of the fallopian tube).

Ligation and excision methods

Ligation involves tying each fallopian tube with suture material and cutting it. Ligation and excision techniques also include removing a section of the tube. These methods, also called partial salpingectomy, are used with minilaparotomy (interval or postpartum), laparotomy, and colpotomy. They cannot be used during laparoscopy without highly specialized techniques and equipment.

The most commonly used methods are the Pomeroy and Parkland techniques (Figure 6.1). The Pomeroy technique entails identifying the fallopian tube, tying off a 2-cm loop of the tube's midportion, and cutting away the tube above the tie. Absorbable suture is used for this procedure, so the stumps of the tube will separate when the suture reabsorbs (Peterson, Pollack, & Warshaw, 1997b). In the Parkland method, the tube is tied in two places and the piece in between is cut away, leading to the immediate separation of the tubal stumps (Peterson et al., 1997b).

These techniques are highly effective, have low complication rates, are inexpensive, and do not require a specialist surgeon. They are preferred over the Uchida and Irving techniques (which are technically difficult and take longer to perform) and over fimbriectomy, or the Kroener technique (which has a higher rate of complications and failure) (Metz, 1978).

Mechanical devices

The surgeon can apply mechanical occlusion devices externally to the fallopian tube to block the tube without having to actually remove a segment. These methods are usually used in conjunction with laparoscopy, though they can also be applied directly to the fallopian tubes during interval sterilization using laparotomy or minilaparotomy (RCOG, 1999). Such mechanical devices save time and minimize tubal damage, and in theory make reversal easier. Mechanical methods require devices and applicators specific to sterilization procedures.

Two groups of mechanical occlusion devices are commonly used: silastic rings or bands, and clips (Figure 6.1). To apply silastic bands (the Falope ring or Yoon ring), the surgeon must use a special applicator to stretch a small round elastic band over a loop of the fallopian tube. The clip (the Filshie clip or the Hulka clip), also applied with a specially designed applicator, compresses a narrow segment of the fallopian tube (Soderstrom, 1998).

Electrical methods

Cautery, or burning a segment of the fallopian tube, can be used with laparoscopy and a bipolar coagulation set-up to occlude the tubes (Figure 6.1). Bipolar current has replaced unipolar electrocoagulation to reduce the risk of thermal injuries. However, the shift to bipolar electrocoagulation has not resulted in a corresponding reduction of internal injuries. Many injuries attributed to unipolar electrocoagulation may have been caused by trauma from such instruments as the verres needle, trocar, penetrating forceps, or knife (Pati & Cullins, 2000). Electrical methods require special equipment and supplies not normally found in places performing basic surgery.

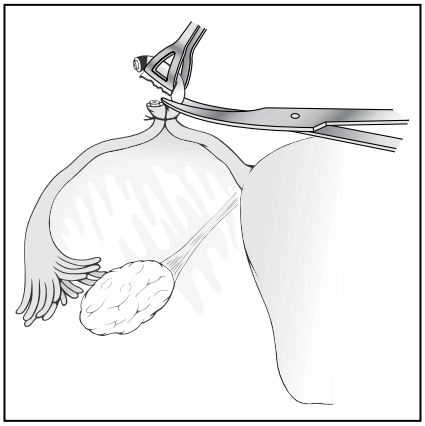
Other procedures resulting in sterilization

In addition to the tubal occlusion procedures described above, several other procedures—which are performed for purposes other than sterilization—may or do result in sterility. None of these procedures should be used solely for the purpose of sterilization.

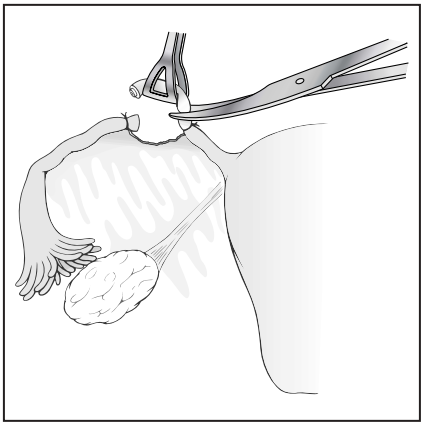
Figure 6.1. Selected methods for occluding the fallopian tubes

Ligation and excision

Pomeroy technique

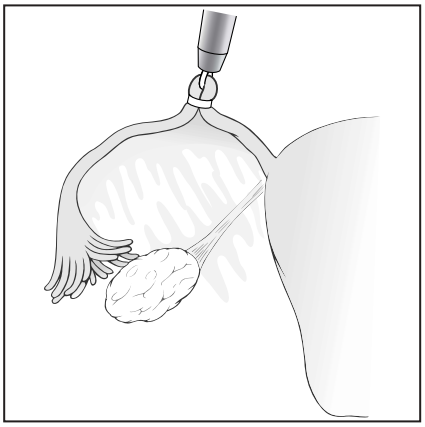


Parkland technique

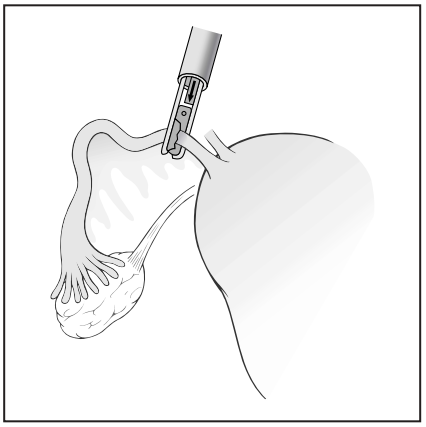


Mechanical devices

Falope ring

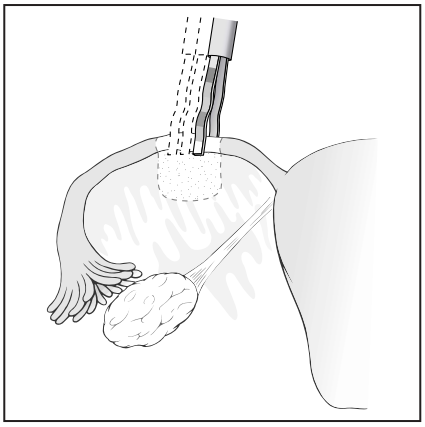


Filshie clip



Electrical method

Bipolar electrocoagulation



Factors in the Successful Use of Local Anesthesia in Sterilization Procedures

- **Preparation and screening of the client.** It is essential that the client understands what will happen during the procedure and that she is in agreement with it. Providing information beforehand about the steps of the procedure and what to expect can help to relieve clients' anxiety or can help clinicians identify particularly anxious clients. Preparation also alerts the client to what is expected from her in terms of communicating her needs and level of comfort.
- **Good communication with the client throughout the operation.** Continuous, open communication between the surgical staff and the client facilitates reassurance and relaxation for the client and increases the surgical staff's awareness of her overall comfort and well-being.
- **Timing and patience.** Local anesthesia can take several minutes to take effect. Premedications, if given orally or by injection, also need time to act.
- **Gentleness and efficiency.** Rough handling and prolonged manipulation of tissues increase client discomfort and the need for anesthesia.
- **Attentiveness and flexibility.** The surgical team must be aware of the possible need to change the anesthesia regimen and be willing and able to do so when a client experiences significant discomfort or when the surgical time is prolonged by difficulties in reaching the tubes.
- **Emergency preparedness.** As for all anesthetic regimens, the medications, equipment, knowledge, and skills to manage anesthetic complications should be available at all sites.

Source: WHO, 1992.

Common examples include hysterectomy, a major surgical procedure that involves removal of the uterus; endometrial ablative techniques, which use electrocoagulation or laser via a hysteroscope to destroy the lining of the uterus, resulting in sterility; and removal or irradiation of both ovaries, which is occasionally performed to manage malignancy (Neuwirth, 1995).

Safe Anesthesia Regimens

The goals of anesthesia are to minimize the client's psychological and emotional distress and trauma, free her from pain and discomfort, and minimize her surgical risk. Factors to be considered in the choice of anesthesia include the type of surgical technique, the skills of the surgeon, the availability of appropriate drugs, the safety and comfort of the client, and the ability of the surgeon to manage complications should they occur (WFHAAVSC, 1995; WHO, 1992). Three broad categories of anesthesia are commonly used in female sterilization: local, general, and regional.

Local anesthesia

The most commonly used regimen worldwide, local anesthesia eliminates pain at the incision site and surrounding tissues, with or without mild, systemic analgesia (diminishment of pain), so the client is awake, comfortable, responsive, and cooperative during the procedure and recovers rapidly. Additional advantages include a decreased risk of anesthesia-related complications, low cost, and ease of administration. The risks associated with local anesthesia are low and are primarily the extremely rare risk of allergic reaction to the agent or overdose generally associated with poor infiltration technique (i.e., intravascular injection).

With local anesthesia, clinicians generally need additional training to learn more gentle surgical technique and better client communication skills. This is because surgeons generally are trained to operate on clients under general anesthesia, and thus must learn how to communicate with a client who is awake during the procedure. Factors that improve the successful use of local anesthesia in sterilization procedures include preparation and screening of the client, communication with the client, timing and patience, gentleness and efficiency, attentiveness and flexibility, and emergency preparedness (see at left).

General anesthesia

General anesthesia provides unconscious sedation with amnesia, relaxation, and complete absence of pain, so the surgeon can operate on a quiet and relaxed client. The method usually requires a skilled anesthetist and special equipment for proper administration. Recovery time is prolonged, and the risk of anesthesia-related complications is higher than for local or regional anesthetic regimens (see below), regardless of the skill of the anesthetist. Because of the increased risk associated with general anesthesia, local anesthesia is usually preferred.

Occasionally, in the case of a complication or unexpected difficulty with a client who was given local anesthesia, it is necessary to administer general anesthesia to manage the problem. Ketamine can be used to induce general anesthesia rapidly, but should be administered after premedication with atropine and with diazepam or promethazine, to minimize the risk of psychotropic reactions. These medications should be administered by personnel trained in their use.

Regional anesthesia

Regional (spinal or epidural) anesthesia (through administration of an anesthetic injection into the subarachnoid or peridural space of the spine) provides complete anesthesia to the desired operative level in a conscious client. Regional anesthesia requires a skilled

anesthetist and additional supplies; as a result, it is a more costly and more complicated procedure. Recovery time is prolonged compared with local anesthesia, and the risk of anesthesia-related complications is greater. Because of these disadvantages, local anesthesia is usually preferred.

Successful use of anesthesia

Using safe, standardized regimens

There has been clear progress in making anesthesia regimens for sterilization safe, simple, and accessible. Anesthetic complications should continue to diminish as providers become more familiar with standard regimens, as medications with better safety profiles are introduced, and as greater attention is given to client monitoring. Though regimens vary from location to location and change over time, depending on differences in supplies, facilities, introduction of new anesthetic agents, and techniques, the guiding principles remain: a safe and simple-to-use regimen, good client communication, and careful monitoring of the client.

Monitoring

For any anesthetic regimen, careful and frequent monitoring of the client includes an assessment of her vital signs, level of consciousness, comfort, and sense of well-being. When performed before, during, and after the procedure, such monitoring allows the surgical staff to detect possible complications related either to the anesthesia or to the surgery early and to assess the adequacy of pain relief.

Detecting and managing complications promptly

Anesthetic complications are commonly caused by overdosage, rapid or improper administration of drugs, and inadequate monitoring (Bhatt, 1991). Successful management of anesthesia-related complications depends on early identification of a problem and an immediate and correct response. Equipment, medications, and supplies for managing emergencies should be readily available. Staff should be familiar with and should practice effective emergency management, including basic resuscitation and support (establishing an open airway, assisting breathing and supplementing oxygenation, and supporting or reestablishing circulation).

Postoperative Care and Instructions

Careful postoperative monitoring is the most effective way to detect immediate postoperative complications, such as bleeding. It is important for all clients and their accompanying family members to be given clear written and oral postoperative instructions on postoperative wound care, information on where to go for follow-up, a description of warning signs, and appropriate advice on restricting activities after surgery, so that delayed complications can be prevented or quickly detected and managed.

Effectiveness

In general, if female sterilization is performed correctly, it is one of the most effective contraceptive methods available. The risk of pregnancy following female sterilization is lower than the risk associated with other contraceptive methods during the first year of use (Stewart & Carignan, 1998).

Any pregnancy occurring after the procedure, be it in utero or ectopic, is a failure (see the Complications section for a discussion of ectopic pregnancy). Pregnancies that began before the time of tubal occlusion (known as luteal-phase pregnancies) but that are not recognized until after the procedure arise from problems with client screening

Preventing Failure following Female Sterilization

There are five common causes of sterilization failure:

- An undetected luteal-phase pregnancy that was present at the time of the sterilization
- Surgical "occlusion" of a structure other than the fallopian tube (most often, the round ligament)
- Incomplete or inadequate occlusion of the tube
- Misplacement of the mechanical device
- Development of a tuboperitoneal fistula

Given these common causes of failure, two methods can be used to prevent failures:

- The incidence of undetected pregnancy can be decreased by scheduling the procedure within the first 7–10 days of the start of a menstrual cycle.
- The fallopian tube can be identified properly by tracing it to the fimbrial end prior to occlusion.

Meticulous attention should be paid to technique, whichever method is used.

Source: Soderstrom, 1985; WHO, 1992.

prior to the procedure (see at left). The estimated rate of luteal-phase pregnancies is 2–3 per 1,000 sterilization procedures (Peterson et al., 1997b). Ruminjo and Lynam (1997), in their 15-year review of 12,000 Kenyan clients who had minilaparotomy under local anesthesia, reported that luteal-phase pregnancy accounted for 50% of all failures following female sterilization. (The total failure rates reported in the study were 0.4% in the first year and 0.1% in the second year.)

Technical errors in the performance of the surgery and failures in the occlusive methods used result in pregnancies occurring after the procedure and reflect true failures of the sterilization procedure (Chi, Gardner, & Laufe, 1979; Liskin et al., 1985; Peterson et al., 1996; Peterson et al., 1999). Until recently, reported failure rates following female sterilization ranged from 0.2% to 0.9% but were based on data obtained after 1–2 years of poststerilization follow-up (Trussell et al., 1990). Koetsawang et al. (1990) and Peterson et al. (1996) have shown that sterilization failures (both in utero and ectopic pregnancies) can occur beyond the first few years following the procedure.

The Collaborative Review of Sterilization (CREST), a large prospective study conducted in 16 teaching hospitals in the United States between 1978 and 1986, reported that the overall 10-year cumulative failure rate following sterilization is 1.85% for all occlusion methods (Peterson et al., 1996). (All reported pregnancies were due to method failure only.) The cumulative failure rate varied with the occlusive method used, with the lowest rates for postpartum partial salpingectomy and unipolar coagulation (7.5 per 1,000 procedures each) and the highest rates for Hulka clips (36.5 per 1,000 procedures) and silicone bands or rings (17.7 per 1,000). The risk of failure correlates with the amount of tube destroyed. That study also showed that for all methods except interval partial salpingectomy, the 10-year pregnancy rate was higher for women younger than 28 at the time of sterilization than for women older than 34 (see Table 6.2).

In 1999, Peterson et al. reanalyzed the CREST data on pregnancy rates following bipolar sterilization. According to the reanalysis, the five-year cumulative failure rate dropped from 1.95% in the group that had female sterilization between 1978 and 1982 to 0.63% for procedures performed between 1985 and 1987. They concluded that the reduction in the cumulative failure rate of bipolar coagulation was probably related to better attention to technique and to the level of destruction of the fallopian tube.

Overall, the CREST study findings cannot necessarily be generalized to settings beyond the teaching hospitals from which the data were gathered. Limitations include the unknown qualifications of the physicians who performed the procedures (i.e., they may have been inexperienced residents) and the lack of a representative sample for each of the occlusive methods studied (Pati, Carignan, & Pollack, 1998).

In China, the 1988 National Demographic and Family Planning Survey, which used a nationally representative sample of more than 2 million respondents, found steriliza-

Table 6.2. Among women undergoing female sterilization, 10-year cumulative probability of pregnancy per 1,000 procedures (and 95% confidence intervals), by age at sterilization, according to method of occlusion

Occlusion method	No. of women	Age at sterilization			
		18–44	18–27	28–33	34–44
Postpartum partial salpingectomy	1,637	7.5 (2.7–12.3)	11.4 (1.6–21.1)	5.6 (0.0–11.9)	3.8 (0.0–11.4)
Unipolar electrocoagulation	1,432	7.5 (1.1–13.9)	3.7 (0.0–11.1)	15.6 (0.0–31.4)	1.8 (0.0–5.3)
Silicone (silastic) band or Yoon ring	3,329	17.7 (10.1–25.3)	33.2 (10.6–55.9)	21.1 (6.4–35.9)	4.5 (0.6–8.4)
Interval partial salpingectomy	425	20.1 (4.7–35.6)	9.7 (0.0–28.6)	33.5 (0.0–74.3)	18.7 (0.0–39.6)
Hulka clip application	1,595	36.5 (25.3–47.7)	52.1 (31.0–73.3)	31.3 (15.1–47.5)	18.2 (0.0–36.4)
Bipolar electrocoagulation	2,267	24.8 (16.2–33.3)	54.3 (28.3–80.4)	21.3 (9.6–33.0)	6.3 (0.1–12.5)

Source: Peterson et al., 1996.

tion failure rates that were comparable to those seen in U.S. studies. The one-year cumulative failure rate was 0.5 failures per 100 sterilized cases, the three- and five-year rates were 1.2 and 1.4 per 100, respectively, and the rate 10 years after female sterilization was 1.7 per 100. The survey identified 125,483 female sterilization cases, including 2,989 performed with nonsurgical methods (i.e., instillation of phenol-atabrine paste, or PAP). Analysis of the 10-year cumulative female sterilization failure rate by level of hospital showed that failure rates at lower-level hospitals in China were similar to those at higher-level facilities. This contrasted with a finding that male sterilization failure rates were significantly higher in the lower-level facilities (Chen, 1999).

Complications

Female sterilization is one of the safest operative procedures. Complications are rare and occur in fewer than 1% of all female sterilization procedures (Stewart & Carignan, 1998). The World Health Organization (WHO) definition for complications following female sterilization is: "problems directly related to the surgery or the anesthesia that occur within 42 days and that require intervention and management beyond what would be normally provided." Examples include infection, bleeding, unintended injury to internal organs, and depressed respiration or blood pressure due to anesthesia (WHO, 1992).

Complications can be categorized as minor or major. Major complications require unintended hospitalization or surgery, blood transfusion, or treatment of life-threatening events or events that result in death (WHO, 1992). Minor complications are those that require intervention and management beyond what would normally be provided, but do not progress to any of the five events mentioned above (WFHAAVSC, 1995; WHO, 1992).

Complication rates vary by the quality of care provided at the service site, the expertise of the surgeon, the approach and occlusion technique used for sterilization, the type of anesthesia, the timing of the procedure, and the characteristics of the client (e.g., obese clients or those with a history of pelvic infections). The accuracy and completeness of reporting also affect reported complication rates.

Intraoperative and early postoperative complications

Most intraoperative and early postoperative complications can be prevented or reduced by meticulously screening clients, using local anesthesia, avoiding heavy sedation, monitoring clients both intraoperatively and postoperatively, adhering to infection prevention practices, and using good surgical technique. Early recognition and prompt management can help reduce the severity of complications (Bangladesh FPCST, 1990; WHO, 1992).

Minilaparotomy complications

During minilaparotomy, minor intraoperative difficulties in entering the abdomen, in visualizing the fallopian tube, and in grasping the tube have been reported; obesity is cited as the main reason for these difficulties (Githiari & Kibanga, 1989). Technical failures during minilaparotomy may require abandoning the procedure or changing the approach (Ruminjo & Ngugi, 1993). Other minor complications include wound infection and self-limited hematoma.

Major intraoperative complications associated with minilaparotomy are uncommon (occurring in fewer than 1% of procedures). Such complications include bowel injury, bladder injury, uterine perforation, unintended intraoperative surgery (due to lacerations of the tube or ligament), and excessive intraperitoneal bleeding (Chi, Potts, & Wilkens, 1986; WHO, 1992).

Postpartum minilaparotomy is associated with a major complication rate of 0.3% and a minor complication rate of 4.2%, as reported by the 1982 WHO Task Force study (WHO, 1982a). The main complications reported included abandonment of the surgery, bleeding, injuries to internal organs, and anesthetic complications. The study also

showed that minor complications consisted of the need to enlarge the incision, blood loss of less than 50 ml (but not requiring additional treatment), local infections, and urinary tract infections.

Laparoscopy complications

Laparoscopy carries a greater risk of bowel or vascular injury than does minilaparotomy, while minilaparotomy is associated with a greater risk of bladder injury, uterine perforation, and wound infection (WHO, 1982b). The American Association of Gynecologic Laparoscopists has reported major complication rates (problems requiring laparotomy) for sterilization of 1.4 per 1,000 procedures (Peterson et al., 1993). A Finnish study reported national rates of about 0.5 per 1,000 procedures (Harkki-Siren, Sjoberg, & Kurki, 1999).

Anesthesia complications

In the United States, anesthesia complications are the leading cause of mortality associated with contraceptive sterilization (ACOG, 1996). The WHO Task Force (1982b) reported major morbidity such as prolonged apnea and cardiac arrest (both responding to resuscitation) among women who had minilaparotomy under general anesthesia. However, complications of anesthesia, which historically have contributed significantly to sterilization-related morbidity and mortality, have declined significantly since 1985, in both developed and developing countries (ACOG, 1996; Akhter, 1973; Bhatt, 1991). This improvement has been achieved as a result of the shift away from general and regional anesthesia toward regimens of local anesthesia, with or without light sedation, in conjunction with better training and standardization of the dosages used (Bhatt, 1991; Bishop & Nelms, 1930). The majority of tubal ligations worldwide are performed under local anesthesia (Pati & Cullins, 2000).

In a multicountry longitudinal study of sterilization-associated mortality conducted by EngenderHealth (Khairullah, Huber, & Gonzales, 1992), anesthesia-related mortality was decreased by more than half between the periods 1973–1981 and 1982–1988, from 2.5 deaths to one death per 100,000 cases. Numerous studies and widespread use of local anesthesia with or without sedation have confirmed its safety, efficacy, high client satisfaction, and cost-effectiveness, for laparoscopy and minilaparotomy as well as vasectomy (Akhter, 1973; Chi et al., 1995; Chi, Petta, & McPheeters, 1991; Chi et al., 1987; de Villiers & Morkel, 1987; Duffy & diZerega, 1994; Grimes et al., 1982b).

Postoperative complications

Postoperative complications appear after the woman has left the hospital. It is difficult to determine how many postoperative female sterilization complications occur. In many countries, clients do not return for routine follow-up examinations, and analysis of information from client records is a challenge. In two poststerilization follow-up studies conducted in Kenya, researchers found that more than 97% of clients did not develop any complications following tubal sterilization (Githiari & Kibanga, 1989; Ruminjo & Lynam, 1997). Minor wound hematoma (0.3–2%) and wound infection (0.9–6%) are the most common minor complications (Githiari & Kibanga, 1989; Ruminjo & Lynam, 1997; Ruminjo & Ngugi, 1993; WHO, 1982a; WHO, 1982b). None of these studies have reported opening of the incision following minilaparotomy (Chi, Potts, & Wilkens, 1986; Githiari & Kibanga, 1989; Ruminjo & Lynam, 1997; Ruminjo & Ngugi, 1993; WHO, 1982a; WHO, 1982b; WHO, 1982c).

Long-Term Effects

Ectopic pregnancy

Because the overall risk of sterilization failure is low, the absolute risk of ectopic pregnancy is lower among sterilized women than among nonsterilized women (Franks et al.,

1990; Peterson et al., 1997a). When a pregnancy does occur after sterilization, however, there is a high probability that it will be ectopic. Data from the CREST study, which was conducted in the United States, reported a 10-year cumulative probability of ectopic pregnancy of less than 1% (7.3 ectopic pregnancies per 1,000 procedures) for all methods of female sterilization combined (Peterson et al., 1997a). An important finding from this study is that ectopic pregnancy may occur 10 or more years after the sterilization. This study also reported an association between ectopic pregnancy and the tubal occlusion method used (see Table 6.3). The highest 10-year cumulative probability of ectopic pregnancy occurred among women who had undergone bipolar electrocoagulation (17.1 ectopic pregnancies per 1,000 procedures), while the lowest probability was found among women who had undergone postpartum partial salpingectomy (1.5 per 1,000 procedures). Other investigators have reported a lower risk associated with postpartum partial salpingectomy as well (Holt et al., 1991). Additionally, women younger than 30 have a greater probability of ectopic pregnancy, probably because of their higher fecundity (Peterson et al., 1997a).

Key Points about the Long-Term Effects of Female Sterilization

- The absolute risk of ectopic pregnancy is lower among sterilized women than among other women, but when a pregnancy occurs, it is likely to be ectopic.
- The latest evidence questions the existence of poststerilization syndrome.
- The likelihood that a woman will have a hysterectomy at some time following sterilization cannot be explained based on biological facts.
- Sterilization has been shown to have a protective effect against ovarian cancer.
- Female sterilization does not protect users against HIV or sexually transmitted infections.

Poststerilization syndrome

Alterations in menstrual cycle flow or length or in menstrual pain have been attributed to female sterilization and are referred to as poststerilization syndrome. However, because experts do not agree regarding the definition of poststerilization syndrome, it has been difficult to study (Peterson et al., 2000). Many early studies failed to control appropriately for factors that can affect menstrual cycles, such as previous contraceptive use and previous menstrual dysfunction. In the United States, where 30% of women who undergo sterilization have used oral contraceptives prior to surgery, changes in the menstrual cycle can be expected once oral contraceptive use ends. Women who experienced increased menstrual bleeding and pain prior to sterilization are likely to report these same problems poststerilization (DeStefano et al., 1985; Fortney, Cole, & Kennedy, 1983).

In a recent publication of data from the CREST study, a sample of women who had a sterilization and a sample of women whose partners had a vasectomy were followed for five years in a multicenter prospective cohort study. All women were asked the same six questions about their menstrual cycles during annual follow-up telephone interviews. Women who had a sterilization were no more likely than those who had not undergone sterilization to report changes in their menstrual cycles (Peterson et al., 2000). These new data offer additional evidence to argue against the existence of poststerilization syndrome.

Table 6.3. Number of women who had undergone tubal sterilization, number who experienced an ectopic pregnancy within 10 years postpartum, and cumulative probability of an ectopic pregnancy per 1,000 sterilization procedures, by tubal occlusion method, United States

Occlusion method	No. of women	No. of ectopic pregnancies at 10 years poststerilization	Cumulative probability per 1,000
Bipolar electrocoagulation	2,267	24	17.1
Interval partial salpingectomy	425	3	7.5
Silicone (silastic) band	3,329	10	7.3
Postpartum partial salpingectomy	1,637	2	1.5
Unipolar electrocoagulation	1,432	1	1.8
Spring clip application	1,595	7	8.5

Source: Adapted from Peterson et al., 1997a.

Hysterectomy and female sterilization

Evidence provided by large, long-term, controlled studies supports the view that in the United States, at least, hysterectomy rates are higher among sterilized women than among nonsterilized women (Goldhaber et al., 1993; Hillis et al., 1998; Stergachis et al., 1990). This increased rate of hysterectomy, not seen in other areas of world, is especially evident among women who were younger than 30 at the time of sterilization (Cohen, 1987; Goldhaber et al., 1993). The various methods of tubal occlusion have also shown increased risks of hysterectomy (Goldhaber et al., 1993; Hillis et al., 1998). Hillis et al. (1997), in their long-term study (14 years), reported that the risk for future hysterectomy was increased when certain gynecological conditions existed prior to tubal sterilization. These conditions included a history of heavy menstrual flow, severe menstrual pain, more than seven days of bleeding during the menstrual cycle, PID, ovarian cysts, endometriosis, and uterine fibroids. Taking this into consideration, it is important to note that Hillis et al. (1997) found a greater than 80% cumulative probability of not having a hysterectomy 14 years poststerilization.

No biological explanation for the increased risk of hysterectomy has been identified, and nonbiological explanations are more likely. One major nonbiological reason may be that both a physician and a client have a lower threshold for choosing a definitive surgical intervention (such as hysterectomy) when the woman has previously been sterilized (Pati & Cullins, 2000).

Ovarian cancer

Available evidence consistently shows a decreased risk for ovarian cancer among women who have had tubal ligation (Greene et al., 1997; Hankinson et al., 1993; Irwin et al., 1991; Miracle-McMahill et al., 1997). The etiology of ovarian cancer is not known at present. There are two hypothesized reasons for the protective effect. The first is the disruption of the fallopian tube as a consequence of surgical sterilization, thus minimizing the chance that the ovaries will be exposed to potential carcinogens that travel from the vagina into the uterus and fallopian tubes. The second is the incidental screening of gross ovarian pathology during the sterilization procedure, which can lead to diagnosis and management of the cancer. Whatever the cause, the protective effect is present in the first 15 years following sterilization; the extent of protection from ovarian cancer beyond 15 years is unknown, because few women have been followed for more than 15 years (Pati & Cullins, 2000).

PID and sexually transmitted infections

Sterilization does not protect against HIV and other sexually transmitted infections (STIs). Women who are at risk for these infections need to be counseled about the use of condoms. Some studies report that PID is less common in women who are sterilized than in those who are not; however, protection is not absolute, since there are a few reports of PID in women who have had a sterilization (immediately following the procedure and in later years) (Levgur & Duvivier, 2000; Pati & Cullins, 2000).

Mortality

Overall, mortality related to female sterilization is rare. By comparison, estimates of maternal mortality in developing countries are much higher, ranging from 300 to 1,700 maternal deaths per 100,000 live births (WHO and UNICEF, 1996). The risk of death from using any method of contraception, including sterilization, is much lower than the risk from pregnancy.

Deaths following female sterilization can be “associated with” or “attributable to” sterilization (WFHAAVSC, 1995):

- A death is **attributable** to sterilization when it occurs within 42 days of the surgery and results from a chain of events initiated by the operation or

anesthesia or from aggravation of an unrelated condition by the physiological or pharmacological effects of the operation or anesthesia.

- A death is **associated** with sterilization when it occurs within 42 days of the surgery but is not causally related to the operation, the anesthesia, their complications, or their management.

In a survey of the American Association of Gynecologic Laparoscopists, only one death was reported among almost 23,000 laparoscopic procedures (Hulka et al., 1995), making mortality attributable to laparoscopy a rare event. According to Escobedo et al. (1989), case-fatality rate estimates for the United States, based on 1979–1980 records and considering only deaths directly attributed to female sterilization (both minilaparotomy and laparoscopic sterilization), were between one and two per 100,000 procedures. The case-fatality estimate in the United States is around nine per 100,000 tubal sterilizations when all deaths *associated* with tubal sterilization are considered (Escobedo et al., 1989). Within recent memory, mortality associated with hysterectomy (the second most common operation, after cesarean section) has been about 0.2%, or two per 1,000 cases, in the United States (Peterson et al., 1997b; Thompson & Warshaw, 1997).

Early reports on mortality rates for minilaparotomy vary from six deaths per 100,000 sterilized women between 1973 and 1988 worldwide (Khairullah, Huber, & Gonzales, 1992) to 19 per 100,000 sterilized women between 1979 and 1980 in Bangladesh (Grimes et al., 1982b). However, 1997 data on female sterilization–related mortality (for both minilaparotomy and laparoscopy) reported by the Family Planning Clinical Supervision Team of Bangladesh shows a mortality rate of nearly three deaths per 100,000 in 1996 (one death in 37,024 procedures) and no reported mortality in 1997 (in 47,282 sterilization procedures) (Bangladesh FPCST, 1998).

The most common causes of mortality reported from developing countries include peritonitis, with and without injuries to internal organs, and postoperative septicemia (Bhatt, 1991; Tewari & Rathee, 1997). Complications related to anesthesia account for significant mortality associated with female sterilization both in developed and developing countries (Grimes et al., 1982b; Intaraprasert, Taneepanichskul, & Chaturachinda, 1997; Khairullah, Huber, & Gonzales, 1992; Peterson et al., 1983). Common causes of death from female sterilization are respiratory and cardiovascular complications related to anesthesia, infections (including tetanus), surgical errors (such as injuries to internal organs), excessive bleeding, and pulmonary and gas embolism (reported, though less common) (Aubert, Lubell, & Schima, 1980; Bhatt, 1991; Grimes et al., 1982b; Khairullah, Huber, & Gonzales, 1992; Tewari & Rathee, 1997).

Sterilization-attributable deaths are rare. However, many of these deaths can be prevented. Preventive measures can be adopted, however, only if data on the number of complications and the cause of death can be determined.

Regret and Sterilization Reversal

Regret

Despite clear intentions, unforeseen events—most commonly, divorce, remarriage, the death of a child, or the desire for more children—may lead a sterilized couple to regret having been sterilized and possibly to seek a reversal procedure. The prevalence of regret varies, with considerable variation among studies in definitions. Evidence from the longitudinal CREST study in the United States suggests that regret is high among women sterilized at a young age—about 20% for women younger than 30 at the time of sterilization, as opposed to 6% for women older than 30 (Hillis et al., 1999). Among women aged 30 and younger, the most commonly cited reasons are remarriage or the desire for another child, while among women older than 30 the most common reason is subsequent gynecological or menstrual problems (Hillis et al., 1999). This is true in less-developed countries as well (Pile & Harper, 1991). Long-identified risk factors for regret include young age, unstable marriage, few children, death of a child, postpartum

sterilization, or sudden decision to undergo the procedure (Henshaw & Singh, 1986; Neamatalla & Harper, 1994; Peterson et al., 1997b; Wilcox, Chu, & Peterson, 1990).

Although 2–6% of sterilized women in developed countries and 0.2% in developing countries are estimated to seek information about reversal (Marcil-Gratton et al., 1988; Ross, Ross, & van Middlekoop, 1982), the actual rate may be substantially higher. For example, in the CREST study, the 14-year cumulative probability that a woman would request information about reversal was 14% overall, and 40% if she was sterilized at ages 18–24 (Schmidt et al., 2000). In developing countries especially, this percentage probably greatly underestimates women's potential interest in restoration of fertility, given the inaccessibility of such services and the corresponding lack of knowledge about them. Variation in the prevalence of regret from country to country will vary largely as a function of the frequency of divorce and of the age and parity at which most sterilizations occur.

Regret of sterilization will continue to occur, despite providers' best efforts at comprehensive counseling, because of unanticipated changes in people's life circumstances. There are several ways to minimize the likelihood of regret. The most important and cost-effective approach is prevention, in the form of quality counseling for all prospective clients, especially those at increased risk for regret. Another is easy access to effective, well-tolerated, long-acting reversible methods for couples who are not yet clear about their decision or who wish to postpone sterilization. Some tubal occlusion techniques are more easily reversed than others, and this could be considered when the sterilization technique is chosen; however, at present, sterilization must continue to be considered a permanent procedure. (See Chapter 5 for more information about regret.)

Reversal

In reversing a tubal ligation (known as tubal reanastomosis), the severed ends of the tubes are rejoined surgically. Success depends on the type of tubal occlusion method originally used (clips cause the least damage and have the highest rate of reversal), on age at the time of reversal, and on reversal technique and surgical experience. A review of many studies reveals the chance of successful pregnancy to be roughly 50%. In actual practice (not in the hands of experts), this percentage is probably much lower. Moreover, the risk of ectopic pregnancy is increased in women who undergo tubal reanastomosis (Henry, Rinehart, & Piotrow, 1980).

Because of advances in the field of assisted reproduction, there are nonsurgical options for addressing reversal. For women ineligible for or uninterested in tubal reanastomosis, in vitro fertilization offers several advantages: It avoids major abdominal surgery, costs can be controlled by limiting the number of cycles attempted,[2] and infertility is resumed following any intended pregnancies. Either surgery or in vitro fertilization may prove to be a better option for reversal, depending on a variety of factors, including the availability of quality services and client characteristics.

Many countries offering sterilization services report that surgical reversal is available; for example, all 28 developing countries surveyed by the World Federation of Health Agencies for the Advancement of Voluntary Surgical Contraception (WFHAAVSC) in 1988 reported that reversal services were available (Pile & Harper, 1991). In reality, however, these services remain inaccessible to most people who might be interested in them. Barriers include a lack of awareness of the existence of these services, a lack of trained specialists and adequate facilities, the potential unsuitability of the client, and cost of the procedure to the client (especially as it relates to the likelihood of success). Results from the U.S. CREST study documented that, over a 14-year period following sterilization, the probability that a sterilized woman actually underwent tubal

[2] The chance of pregnancy with each cycle of in vitro fertilization is currently estimated to be about 20% in centers with good success rates (ASRM, 2002).

reanastomosis was only 1% (Schmidt et al., 2000). Many women were reluctant to pursue surgery, given the high cost and high probability of failure.

Sterilization reversal will likely continue to be inaccessible to many people, even as reversal options become more effective and, possibly, cheaper. Experts are trying to develop sterilization methods that are more easily reversed, reasonably cost-effective, and minimally invasive. These efforts have concentrated mostly on physically blocking the fallopian tubes with a plug that could be easily inserted and then removed when fertility is again desired. To date, none of these methods have shown sufficient promise to be made available anywhere on a commercial basis.

Innovations

Demand for female sterilization services is likely to continue to increase in many regions of the world (see Chapter 8). Given this continuing demand, researchers are working to identify still safer, easier, and more cost-effective techniques. Several innovative methods under development represent attempts to achieve tubal occlusion nonsurgically and to improve current surgical devices.

Nonsurgical mechanisms for occluding the tubes

Currently, a woman desiring female sterilization must undergo surgery. In an attempt to lower the costs associated with the procedure, improve the safety and accessibility of sterilization, and increase its acceptability to clients, researchers have investigated methods of female sterilization that do not require surgery and that might be able to be provided by nonphysicians. One of the possibilities being explored is occluding the tubal lumen by introducing chemical, mechanical, or thermal agents through the cervix, thus gaining direct access to the opening of the fallopian tubes inside the uterus without having to perform surgery. These occlusive methods are collectively categorized as transcervical methods. The tubal openings may be approached blind or with hysteroscopic guidance (Neuwirth, 1995); anesthesia may or may not be used. Further studies are needed to prove the safety and the efficacy of both the approach and the occlusion methods (Wilson, 1995). Presently, all transcervical methods are experimental and have undergone only limited testing for safety and efficacy. Quinacrine and silicon plugs have generated the most interest; newer on the horizon is the Essure® Device.

Silastic plugs are being investigated in Europe. With this method, liquid silicone is placed in the fallopian tubes using a hysteroscope; the gel hardens in about five minutes (Barnett, 1997). European research is also under way on methods that use water-based gel plugs and nylon or plastic threads to block the tube. To date, the problem with all of these methods is that the plugs can migrate or break (Barnett, 1997).

The Essure Device, a new permanent sterilization method under development in the United States, is a plug designed to be placed in the fallopian tubes via a hysteroscope, in an office setting, using local anesthesia. The plug consists of a 4-cm microcoil containing polyester fibers; these generate a localized tissue response in which tissue grows in and around the device, subsequently occluding the fallopian tube. Preliminary studies of tolerance and efficacy have revealed good-to-excellent client tolerance of the procedure, high client satisfaction (96% at 12 months), and a projected one-year effectiveness rate of 96%. Safety and efficacy studies are ongoing in Australia, Europe, and the United States (Carignan, 2000).

The availability of a nonsurgical method of permanent contraception that is safe, cheap, effective, and widely available would most dramatically affect access—where the procedure can be performed and who can perform it. However, these methods also pose increased potential for misuse. For example, women could be sterilized during pelvic examinations without their consent or knowledge. In this regard, the most controversial experimental method in recent years has been quinacrine.

Quinacrine was originally used orally to treat malaria. In the 1970s, the drug was formulated into pellets that can be inserted through the cervix using a device resembling an intrauterine device (IUD) inserter (Zipper, Stacchetti, & Mendel, 1975). The pellets dissolve, causing sclerosis (scarring) and subsequent occlusion of a segment of each fallopian tube. Quinacrine's appeal as a tubal occlusion method is its potential as a low-cost, easy, nonsurgical outpatient method.

Quinacrine has not been approved for general use for nonsurgical sterilization in any country because its safety and efficacy have not been adequately determined. Nevertheless, the drug has been used in many countries, including Bangladesh, Chile, China, Colombia, Costa Rica, Egypt, India, Indonesia, Iran, Pakistan, Romania, Venezuela, and Vietnam (Pine & Pollack, 2000).

The use of quinacrine as a nonsurgical method of sterilization gained widespread attention in 1993 following publication of a study involving more than 30,000 women in Vietnam who had undergone quinacrine sterilization (Hieu et al., 1993). Subsequently, several international organizations, including WHO, reviewed all available research on the use of quinacrine for sterilization to assess its safety and efficacy. A WHO consultative meeting recommended further toxicological testing of quinacrine and further follow-up of women who had received quinacrine in Vietnam (Sokal et al., 2000a).

Because of concerns about its widespread investigational use, but continued belief that the method could be a safe and effective nonsurgical method of sterilization, Family Health International (in collaboration with Vietnamese researchers) began in 1994 a series of studies designed to examine the safety and efficacy of quinacrine. Recently published preliminary findings from a long-term follow-up study of Vietnamese women who had quinacrine sterilizations reported on an interim analysis of long-term pregnancy rates and safety data, including rates of ectopic pregnancy and adverse health events (Sokal et al., 2000a; Sokal et al., 2000b). The efficacy of quinacrine (as measured by pregnancy rates after five years of use) appears to have been reasonable (6.8%) for two insertions of the drug among women aged 35 and older. The authors estimate that the five-year cumulative probability of pregnancy is 12.6 per 100 women for women receiving two insertions (Sokal et al., 2000a).

Published data on safety issues showed ectopic pregnancy rates similar to those reported in the CREST study. Findings on adverse health outcomes were difficult to interpret and therefore inconclusive on this point (Sokal et al., 2000b). Further analysis of findings from these studies will provide more answers to questions about quinacrine's safety and efficacy. In August 2001, Family Health International began one of two planned carcinogenicity studies in neonatal mice; this study is expected to take 18–24 months to complete (Sokal, 2001).

The other key remaining issue that will require attention if quinacrine is introduced in new clinical trials is to ensure that women are fully informed about the method's experimental nature, including short-term and long-term side effects.

To date, when delivered to the fallopian tubes, none of these devices or substances—silicon plugs, the Essure Device, or quinacrine—have shown consistent advantages over surgical sterilization.

New surgical techniques

Another new approach is microlaparoscopy, which utilizes a high-quality, often flexible scope as small as 1.5 mm in diameter. (The conventional rigid laparoscope is 5–15 mm in diameter.) The advantages of microlaparoscopy for the performance of sterilization are that the procedure can be performed in an office setting under local anesthesia and that the technique requires a much smaller incision than do traditional laparoscopy or minilaparotomy. Experience with microlaparoscopy is still too limited to assess the future of this approach for sterilization, however.

References

Akhter, M. S. 1973. Vaginal versus abdominal tubal ligation. *American Journal of Obstetrics and Gynecology* 115(4):491–496.

American College of Obstetricians and Gynecologists (ACOG). 1996. *Sterilization.* Technical Bulletin No. 222. Washington, DC.

American Society for Reproductive Medicine (ASRM). 2002. Frequently asked questions about infertility [online]. Available: http://www.asrm.org/Patients/faqs.html

Aubert J. M., Lubell, I., and Schima, M. 1980. Mortality risk associated with female sterilization. *International Journal of Gynecology and Obstetrics* 18(6):406–410.

Bangladesh Family Planning Clinical Supervision Team (FPCST). 1998. *Report on VSC mortality for the year 1997*. Bangladesh.

Barnett, B. 1997. Search for nonsurgical sterilization continues. *Network* 18(1):16–17, 20. (Available at http://www.fhi.org/en/fp/fppubs/network/v18-1/nt1815.html.)

Berek, J. S., Adashi, E. Y., and Hillard, P. A. 1996. *Novak's gynecology*, 12th Edition. Baltimore: Williams and Williams.

Bhatt, R. V. 1991. Camp laparoscopic sterilization deaths in Gujarat state, India, 1978–1980. *Asia-Oceania Journal of Obstetrics and Gynecology* 17(4):297–301.

Bishop, E., and Nelms, W. F. 1930. A simple method of tubal sterilization. *New York State Journal of Medicine* 39(4):214–216.

Blumenthal, P. D., and McIntosh, N. 1996. *Pocketguide for family planning service providers, 1996–1998,* 2nd edition. Baltimore: JHPIEGO Corporation.

Carignan, C. 2000. EngenderHealth. Personal communication.

Chen, C. H. C. 1999. Female and male sterilization failures in China: Findings from a national survey. Paper presented at the annual meeting of the American Public Health Association, November 7–11, Chicago.

Chi, I. C., Gardner, S. D., and Laufe, L. E. 1979. The history of pregnancies that occur following female sterilization. *International Journal of Gynaecology and Obstetrics* 17(3):265–267.

Chi, I. C., Potts, M., and Wilkens, L. 1986. Rare events associated with tubal sterilization: An international experience. *Obstetrical and Gynecological Survey* 41(1):7–19.

Chi, I. C., et al. 1987. Pregnancy following minilaparotomy tubal sterilization—an update of an international data set. *Contraception* 35(2):171–178.

Chi, I. C., Gates, D., and Thapa, S. 1992. Performing tubal sterilization during women's postpartum hospitalization: A review of the U.S. and international experiences. *Obstetrical and Gynecological Survey* 47(2):71–79.

Chi, I. C., Petta, C. A., and McPheeters, M. A. 1995. A review of safety, efficacy, pros and cons, and issues of puerperal tubal sterilization—an update. *Advances in Contraception* 11(3): 187–206.

Coddington, C. 1999. Gynecologic operative endoscopy. *Obstetrics and Gynecology Clinics of North America* 26(1):1–22.

Cohen, M. M. 1987. Long-term risk of hysterectomy after tubal ligation. *American Journal of Epidemiology* 125(3):410–419.

Cruse, P. J. E., and Foord, R. 1980. The epidemiology of wound infections: A 10-year prospective study of 62,939 wounds. *Surgical Clinics of North America* 6(1):27–39.

DeStefano, F., et al. 1985. Long-term risks of menstrual disturbances after tubal sterilization. *American Journal of Obstetrics and Gynecology* 152(7):835–841.

de Villiers, V. P., and Morkel, D. J. 1987. Post partum sterilization by the Irving technique. *South African Medical Journal* 71(4):253.

Duffy, D. M., and diZerega, G. S. 1994. Is peritoneal closure necessary? *Obstetrical and Gynecological Survey* 49(12):817–822.

Dusitsin, N., and Satyapan, S. 1984. Sterilization of women by nurse-midwives in Thailand. *World Health Forum* 5(3):259–262.

Escobedo, L. G., et al. 1989. Case-fatality rates for tubal sterilization in U.S. hospitals, 1979 to 1980. *American Journal of Obstetrics and Gynecology* 160(1):147–150.

Fortney, J. A., Cole, L. P., and Kennedy, K. I. 1983. A new approach to measuring menstrual pattern change after sterilization. *American Journal of Obstetrics and Gynecology* 147(7): 830–836.

Franks, A. L., et al. 1990. Contraception and ectopic pregnancy risk. *American Journal of Obstetrics and Gynecology* 163(4):1120–1123.

Githiari, J., and Kibanga, G. 1989. A surveillance of female sterilization technique in Nyeri, Kenya. *Journal of Obstetrics and Gynecology Central Africa* 8(7):7–10.

Goldhaber, M. K., et al. 1993. Long-term risk of hysterectomy among 80,007 sterilized and comparison women at Kaiser Permanente, 1971–1987. *American Journal of Epidemiology* 138(7):508–521.

Greene, A., et al. 1997. Tubal sterilization, hysterectomy and decreased risk of ovarian cancer: Survey of Women's Health Study Group. *International Journal of Cancer* 71(6):948–951.

Grimes, D. A., et al. 1982a. Deaths from contraceptive sterilization in Bangladesh: Rates, causes and prevention. *Obstetrics and Gynecology* 60(5):635–640.

Grimes, D. A., et al. 1982b. Sterilization-attributable deaths in Bangladesh. *International Journal of Gynaecology and Obstetrics* 20(2):149–154.

Gupta, I., et al. 1980. Comparative morbidity following tubal ligation by abdominal and vaginal routes. *Indian Journal of Medical Research* 72:231–235.

Hankinson, S. E., et al. 1993. Tubal sterilization, hysterectomy and the risk of ovarian cancer: A prospective study. *Journal of the American Medical Association* 270(23):2813–2818.

Harkki-Siren, P., Sjoberg, J., and Kurki, T. 1999. Major complications of laparoscopy: A follow-up Finnish study. *Obstetrics and Gynecology* 94(1):94–98.

Henry, A., Rinehart, W., and Piotrow, P. T. 1980. Reversing female sterilization. *Population Reports,* series C, no. 8. Baltimore: Johns Hopkins University, Population Information Program, pp. 97–123.

Henshaw, S. K., and Singh, S. 1986. Sterilization regret among U.S. couples. *Family Planning Perspectives* 18(5):238–240.

Hieu, D. T., et al. 1993. 31,781 cases of non-surgical female sterilisation with quinacrine pellets in Vietnam. *Lancet* 342(8865):213–217.

Hillis, S. D., et al. 1997. Tubal sterilization and long-term risk of hysterectomy: Findings from the U.S. Collaborative Review of Sterilization. *Obstetrics and Gynecology* 89(4):609–614.

Hillis, S. D., et al. 1998. Higher hysterectomy risk for sterilized than nonsterilized women: Findings from the U.S. Collaborative Review of Sterilization. *Obstetrics and Gynecology* 91(2): 241–246.

Hillis, S. D., et al. 1999. Poststerilization regret: Findings from the United States Collaborative Review of Sterilization. *Obstetrics and Gynecology* 93(6):889–894.

Holt, V. L., et al. 1991. Tubal sterilization and subsequent ectopic pregnancy risk—a case-control study. *Journal of the American Medical Association* 266(2):242–246.

Hulka, J. F., et al. 1995. Laparoscopic sterilization: American Association of Gynecologic Laparoscopists' 1993 Membership Survey. *Journal of the American Association of Gynecologic Laparoscopists* 2(2):137–138.

Intaraprasert, S., Taneepanichskul, S., and Chaturachinda, K. 1997. Outpatient laparoscopic interval female sterilization. *Contraception* 55(5):283–286.

International Planned Parenthood Federation (IPPF). 1997. *Medical and service delivery guidelines for family planning,* 2nd edition. London.

Irwin, K. L., et al. 1991. Tubal sterilization, hysterectomy and the subsequent occurrence of epithelial ovarian cancer. *American Journal of Epidemiology* 134(4):362–369.

Kanchanasinith, K., et al. 1990. Postpartum sterilization by nurse midwives in Thailand. *International Family Planning Perspectives* 16(2):55–58.

Khairullah, Z., Huber, D. H., and Gonzales, B. 1992. Declining mortality in international sterilization services. *International Journal of Gynaecology and Obstetrics* 39(1):41–50.

Koetsawang, S., et al. 1990. Long-term follow-up of laparoscopic sterilizations by electrocoagulation, the Hulka clip and the tubal ring. *Contraception* 41(1):9–18.

Layde, P. M., et al. 1983. Risk factors for complications of interval tubal sterilization by laparotomy. *Obstetrics and Gynecology* 62(2):180–184.

Levgur, M., and Duvivier, R. 2000. Inflammatory disease after tubal sterilization: A review. *Obstetrical and Gynecological Survey* 55(1):41–50.

Levy, B. S., et al. 1994. Operative laparoscopy: American Association of Gynecologic Laparoscopists, 1993 Membership Survey. *Journal of the American Association of Gynecologic Laparoscopists* 1(4, Pt1):301–305.

Liskin, L., et al. 1985. Minilaparotomy and laparoscopy: Safe, effective, and widely used. *Population Reports,* series C, no. 9. Baltimore: Johns Hopkins University, Population Information Program, pp. 125–167.

Lungren. 1881. A case of cesarean section twice successfully performed on the same patient with

remarks on time, indication and details of the operation. *American Journal of Obstetrics* 14: 78.

Mangram, A. J., et al. 1999. The Hospital Infection Control Practices Advisory Committee. Guidelines for the prevention of surgical site infection. *American Journal of Infection Control* 20(4):97–134.

Marcil-Gratton, N., et al. 1988. Profile of women who request reversal of tubal sterilization: Comparison with a randomly selected control group. *Canadian Medical Association Journal* 38(8):711–713.

Metz, K. G. P. 1978. Failures following fimbriectomy: A further report. *Fertility and Sterility* 30(3):269–273.

Miesfeld, R. R., Giarratano, R. C., and Moyers, T. G. 1980. Vaginal tubal sterilization: Is infection a significant risk? *American Journal of Obstetrics and Gynecology* 137(2):183–188.

Miracle-McMahill, H. L., et al. 1997. Tubal ligation and fatal ovarian cancer in a large prospective cohort study. *American Journal of Epidemiology* 145(4):349–357.

Neamatalla, G. S., and Harper, P. B. 1994. *Family planning counseling and voluntary sterilization. A guide for managers.* New York: AVSC International.

Neuwirth, R. S. 1995. Update on transcervical sterilization. *International Journal of Gynecology and Obstetrics* 51(suppl 1):523–528.

Pati, S., Carignan, C., and Pollack, A. E. 1998. What is new with female sterilization: An update. *Contemporary Obstetrics and Gynecology* pp. 91–115.

Pati, S., and Cullins, V. 2000. Female sterilization: Evidence. *Obstetrics and Gynecology Clinics of North America* 27(4):859–899.

Peterson, H. B., et al. 1983. Deaths attributable to tubal sterilization in the United States, 1977–1981. *American Journal of Obstetrics and Gynecology* 146(2):141–143.

Peterson, H. B., et al. 1993. Laparoscopic sterilization: American Association of Gynecologic Laparoscopists 1991 membership survey. *Journal of Reproductive Medicine* 38(8):574–576.

Peterson, H. B., et al. 1996. The risk of pregnancy after tubal sterilization: Findings from the U.S. Collaborative Review of Sterilization. *American Journal of Obstetrics and Gynecology* 174(4):1161–1170.

Peterson, H. B., et al. 1997a. The risk of ectopic pregnancy after tubal sterilization. *New England Journal of Medicine* 336(11):762–767.

Peterson, H. B., Pollack, A. E., and Warshaw, J. S. 1997b. Tubal sterilization. In *TeLinde's operative gynecology*, 8th edition, ed. by J. Rock and J. D. Thompson. Philadelphia: Lippincott-Raven, pp. 529–547.

Peterson, H. B., et al. 1999. Pregnancy after tubal sterilization with bipolar electrocoagulation. *Obstetrics and Gynecology* 94(2):163–167.

Peterson, H. B., et al. 2000. The risk of menstrual abnormalities after tubal sterilization. *New England Journal of Medicine* 343(23):1681–1687.

Pile, J. M., and Harper, P. B. 1991. Reversal of voluntary sterilization: Implications for family planning programs in the developing world. New York: World Federation for Voluntary Surgical Contraception. Unpublished.

Pine, R., and Pollack, A. 2000. Putting an ear to the ground: Where now with quinacrine? *International Journal of Gynaecology and Obstetrics* 69(1):55–65.

Ross, J. A., Hong, S., and Huber, D. H. 1985. *Voluntary sterilization: An international fact book.* New York: Association for Voluntary Sterilization.

Ross, M., Ross, S. M., and van Middlekoop, A. 1982. Female sterilization—a follow-up report. *South African Medical Journal* 61(13):476–479.

Royal College of Obstetricians and Gynecologists (RCOG). 1999. *Guidelines for male and female sterilization.* London: Royal College of Obstetricians and Gynecologists Press.

Ruminjo, J. K., and Lynam, P. F. 1997. A fifteen-year review of female sterilization by minilaparotomy under local anesthesia in Kenya. *Contraception* 55(4):249–260.

Ruminjo, J. K., and Ngugi, F. 1993. Safety issues in voluntary female surgical contraception: Perioperative complications. *Journal of Obstetrics and Gynecology East-Central Africa* 11, 24.

Schmidt, J. E., et al. 2000. Requesting information about and obtaining reversal after tubal sterilization: Findings from the U.S. Collaborative Review of Sterilization. *Fertility and Sterility* 74(5):892–898.

Seropian, R., and Reynolds, B. 1971. Wound infections after postoperative depilatory versus razor preparation. *American Journal of Surgery* 121(3):241–254.

Soderstrom, R. M. 1985. Sterilization failures and their causes. *American Journal of Obstetrics and Gynecology* 152(4):395–403.

Soderstrom, R. M. 1998. *Operative laparoscopy*, 2nd edition. Philadelphia: Lippincott-Raven.

Sokal, D. 2001. Family Health International. Personal communication, August 28.

Sokal, D., et al. 2000a. Long-term follow-up after quinacrine sterilization in Vietnam. Part I: Interim efficacy analysis. *Fertility and Sterility* 74(6):1084–1091.

Sokal, D., et al. 2000b. Long-term follow-up after quinacrine sterilization in Vietnam. Part II: Interim safety analysis. *Fertility and Sterility* 74(6):1092–1101.

Speert, H. 1996. Max Madlener, Ralph Pomeroy, Fredrick Irving and tubal sterilization. In *Obstetrics and gynecology milestones illustrated*, ed. by H. Speert. New York: Parthenon Publication, pp. 591–595.

Speroff, L., and Darney, P. 1996. *A clinical guide for contraception*, 2nd edition. Baltimore: Williams and Wilkins.

Stergachis, A., et al. 1990. Tubal sterilization and the long-term risk of hysterectomy. *Journal of the American Medical Association* 264(22):2893–2898.

Stewart, G. K., and Carignan, C. S. 1998. Female and male sterilization. In *Contraceptive technology*, 17th revised ed., ed. by R. A. Hatcher et al. New York: Ardent Media, pp. 545–588.

Tewari, S., and Rathee, S. 1997. Practice of standards in female sterilization. *Journal of the Indian Medical Association* 95(5):136–137.

Thompson, J. D., and Warshaw, J. 1997. Hysterectomy. In *TeLinde's operative gynecology*, 8th edition, ed. by J. Rock and J. D. Thompson. Philadelphia: Lippincott-Raven, pp. 771–854.

Trussell, J., et al. 1990. Contraceptive failure in the U.S.: An update. *Studies in Family Planning* 21(1):51–54.

Wilcox, L. S., Chu, S. Y., and Peterson, H. B. 1990. Characteristics of women who considered or obtained tubal reanastomosis: Results from a prospective study of tubal sterilization. *Obstetrics and Gynecology* 75(4):661–665.

Wilson, E. W. 1995. The evolution of methods of female sterilization. *International Journal of Gynaecology and Obstetrics* 51(suppl):S3–S13.

World Federation of Health Agencies for the Advancement of Voluntary Surgical Contraception (WFHAAVSC). 1995. *Safe and voluntary surgical contraception*. New York: AVSC International.

World Health Organization (WHO). 1982a. Mini-incision for post-partum sterilization of women: A multicentred, multinational prospective study. *Contraception* 26(5):495–503.

WHO. 1982b. Task Force on Female Sterilization. Minilaparotomy or laparoscopy for sterilization: A multicenter, multinational randomized study. *American Journal of Obstetrics and Gynecology* 143(6):645–652.

WHO. 1982c. Task Force on Female Sterilization, Special Programme of Research, Development and Research Training in Human Reproduction. Randomized comparative study of culdoscopy and minilaparotomy for surgical contraception in women. *Contraception* 26(6): 587–593.

WHO. 1992. *Female sterilization: A guide to provision of services.* Geneva.

WHO. 1996. *Improving access to quality care in family planning: Medical eligibility criteria for contraceptive use*. Geneva.

WHO and United Nations Children's Fund (UNICEF). 1996. *Revised 1990 estimates of maternal mortality*. Geneva: WHO.

Zipper, J., Stacchetti, E., and Mendel, M. 1975. Transvaginal chemical sterilization: Clinical use of quinacrine plus potentiating adjuvants. *Contraception* 12(1):11–21.