

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN-GYNECOLOGISTS

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# Benefits and Risks of Sterilization

Bilateral tubal sterilization and vasectomy are both safe and effective permanent methods of contraception; more than 220 million couples worldwide use them as their contraceptive method of choice (1). Sterilization continues to be the most commonly used contraceptive method in the United States, with 11 million U.S. women relying on the method. Approximately 700,000 tubal sterilizations (2) and 500,000 vasectomies (3) are performed in the United States annually. The purpose of this document is to review the evidence for the safety and effectiveness of sterilization in comparison with other forms of contraception, as well as evidence of the likelihood that a woman will regret having had a sterilization procedure.

# Background

#### Prevalence of Sterilization Compared With Other Contraceptive Methods

Sterilization accounts for 39% of contraceptive method use by U.S. women of reproductive age (15–44 years) and their partners. Of those, 28% had tubal sterilization, and 11% have partners who had a vasectomy. In comparison, 27% of the same population use oral contraceptives, 21% use male condoms, 3% use injectable contraceptives, 2% use diaphragms, and 1% use intrauterine devices (IUDs) (4). Tubal sterilization is the only permanent female contraceptive method available to U.S. women.

### **Tubal Sterilization**

#### Timing

Tubal sterilization can be performed postpartum, after spontaneous or therapeutic abortion, or as an interval procedure (unrelated in time to a pregnancy).

This Practice Bulletin was developed by the ACOG Committee on Practice Bulletins-Gynecology with the assistance of Amy Pollack, MD. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

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Key factors affecting the choice and timing of sterilization are a mix of individual patient preference, medical assessment of acute risk, and access to services. The timing of the procedure influences both the surgical approach and the method of tubal occlusion. In the United States, approximately one half of all tubal sterilizations are performed as interval procedures (2). Postpartum sterilization is performed after 10% of all hospital deliveries (5); approximately 3.5% of all sterilizations are performed after an elective or spontaneous abortion (6).

Postpartum sterilization is performed at the time of cesarean delivery or after a vaginal delivery and should not extend the patient's hospital stay. Ideally, postpartum minilaparotomy is performed before the onset of significant uterine involution but following a full assessment of maternal and neonatal well-being. Postpartum minilaparotomy may be performed using local anesthesia with sedation, regional anesthesia, or general anesthesia. Postpartum sterilization requires counseling and informed consent before labor and delivery (7, 8). Consent should be obtained during prenatal care, when the patient can make a considered decision, review the risks and benefits of the procedure, and consider alternative contraceptive methods. In all cases of intrapartum or postpartum medical or obstetric complications, the physician should consider postponing sterilization to a later date (5). The federal and state regulations that address the timing of consent also are important to consider (9).

Postabortion sterilization can be performed safely after uncomplicated spontaneous or induced abortion without added risk over interval sterilization (10). After a first- or second-trimester abortion, both laparoscopic and minilaparotomy sterilization are acceptable. With either approach, a single anesthetic for the abortion and the sterilization may be used to avoid additional risk.

Tubal sterilization can be performed as an interval procedure at any time during the menstrual cycle. A sameday, highly sensitive, pregnancy test (urine test capable of detecting human chorionic gonadotropin levels as low as 20 mIU/mL) (11) will detect pregnancies as early as 1 week after conception (12). Performing the procedure during the patient's follicular phase and patient use of an effective method of contraception before sterilization further reduces the likelihood of concurrent pregnancy. Dilation and curettage concurrent with all interval sterilizations as a routine practice is not recommended on the basis of effectiveness, cost, and morbidity (13).

#### Methods of Surgical Sterilization

Laparoscopy. The laparoscopic approach is the one most commonly used for interval sterilization procedures and

usually is performed as an outpatient procedure. The advantages of laparoscopy over other surgical approaches include the opportunity to inspect the abdominal and pelvic organs. Furthermore, laparoscopy results in barely visible incision scars and a rapid return to full activity for the patient. The disadvantages of laparoscopy include the cost and fragility of the equipment; the special training required; and the risk of bowel, bladder, or major vessel injury after insertion of the needle or trocar. The use of general anesthesia also increases risk.

**Minilaparotomy.** In the United States, minilaparotomy is most commonly used for postpartum procedures and in patients considered at high risk for laparoscopic procedures. Minilaparotomy is performed by using a 2–3-cm incision placed in relation to the uterine fundus. In contrast with laparoscopy, minilaparotomy requires only basic surgical instruments and training.

**Transcervical Approaches.** Transcervical approaches to sterilization involve gaining access to the fallopian tubes through the cervix. A device or occlusive material is then placed hysteroscopically or blindly to block each tube. In November 2002, the U.S. Food and Drug Administration approved the use of Essure, a new transcervical sterilization device that is placed hysteroscopically, which avoids entry into the peritoneal cavity. Backup contraception is needed for 3 months, at which time a hysterosalpingography is performed to confirm occlusion. Short-term efficacy studies suggest a rate equal to or greater than other tubal sterilization methods. However, long-term efficacy rates are not yet available (14).

**Transvaginal Approach.** Although performed infrequently, sterilization by the vaginal route remains an option. Fimbriectomy, Pomeroy, and other tubal occlusion methods traditionally used with laparoscopic techniques can be performed via posterior colpotomy. The advantages include less patient preparation (eg, bladder catheterization), the absence of abdominal incision, and potentially less pain for the patient with an earlier return to routine activity. Contraindications include suspicion of major pelvic adhesions, enlarged uterus, and inability to place the patient in the lithotomy position. One major disadvantage is the need for adequate vaginal surgical training (15) to minimize potential complications, such as cellulitis, pelvic abscess, hemorrhage, proctotomy, or cystotomy.

#### **Methods of Occlusion**

**Electrocoagulation.** Electrocoagulation for tubal occlusion is used exclusively with laparoscopic sterilization. Bipolar coagulation is now the most commonly used

laparoscopic occlusion method in the United States. It results in a more localized injury to the fallopian tube than does the unipolar method, which is associated with thermal bowel injury. To maximize the effectiveness of bipolar coagulation, at least 3 cm of the isthmic portion of the fallopian tube must be completely coagulated by using sufficient energy (25 W) delivered in a cutting waveform (16, 17). Use of a current meter, rather than a visual endpoint or a defined period, more accurately indicates complete coagulation.

Mechanical Methods. Mechanical occlusion devices commonly used in the United States include the silicone rubber band (Falope ring), the spring-loaded clip (Hulka-Clemens clip), and the titanium clip lined with silicone rubber (Filshie clip). Mechanical methods have no associated risk of electrical burn and destroy less of the fallopian tube (approximately 5 mm for clips and 2 cm for rings), making microsurgical reversal more likely to succeed. Special applicators are necessary for each of these mechanical occlusion devices, and each requires skill for proper application. The silicone band can only be applied to a fallopian tube that is sufficiently mobile to allow it to be drawn into the applicator. All of these devices are most likely to be effective when used to occlude a normal fallopian tube; tubal adhesions or thickened or dilated fallopian tubes increase the risk of misapplication and subsequent failure. Spontaneous clip migration or expulsion is rare (18, 19).

**Ligation Methods.** A variety of techniques for ligating and resecting a portion of both fallopian tubes have been described, including the Pomeroy, modified Pomeroy, and Parkland methods; the Uchida and Irving methods are rarely used in the United States (8). Tubal occlusion at the time of cesarean delivery, laparotomy for other indications, and minilaparotomy usually are performed by using ligation techniques. Care should be taken to excise a sufficient section of the fallopian tube to ensure complete transection of the tubal lumen.

**Chemical Methods.** Chemical sclerosing agents have been investigated for many years for their potential use as blindly placed transcervical tubal blocking agents. Although some have shown promise, none are currently approved for use in the United States (20, 21).

#### Vasectomy

#### **Prevalence and Practice**

Vasectomy performed as an outpatient procedure has been popular in the United States since 1965. More than 5 million men had undergone vasectomy by 1988 (22). No nationwide surveillance system exists to monitor trends in vasectomies performed; however, surveys in 1991 and 1995 found that almost 500,000 men had a vasectomy in each of those years (3, 23). When compared with tubal sterilization, vasectomy is safer, less expensive, and appears to be at least as effective. In the United States, urologists, general surgeons, and family physicians perform vasectomy procedures in their offices using local anesthesia. Vasectomy failure rates range from 0% to 2%, with most studies reporting pregnancy rates of less than 1% (24).

#### Complications

Minor complications of vasectomy, such as infection at the site of incision, bleeding and hematoma formation, granuloma formation, and epididymitis, are reported to occur at rates of 5-10% (25). In comparison with the incisional technique, the no-scalpel vasectomy technique has a lower incidence of hematoma formation (0.1–2.1% versus 0.3–10.7%) and infection (0.2–0.9% versus 1.3–4%) (24, 26, 27). Vasectomy-related major morbidity and mortality are extremely rare in the United States (24).

#### Late Sequelae

Multiple large epidemiologic studies have examined the relationship of both atherosclerosis and immunologic disease with vasectomy and have concluded there is no causal relationship (28–30). In 1994, both a retrospective cohort study of 74,000 men and a case–control study of 794 men provided convincing evidence that vasectomy is not associated with an increased risk of testicular cancer (31, 32).

In 1993, researchers published the first large cohort studies to show a weak but statistically significant increased risk for prostate cancer in a subgroup of men at least 20 years after vasectomy (33). Two subsequent studies failed to confirm these findings (30, 31). Recently, a large, national, population-based, randomized, case–control study from New Zealand concluded that vasectomy does not increase the risk of prostate cancer even when men are examined 25 years postvasectomy (34).

The nerves involved in male erectile function and ejaculation are not affected by vasectomy, and, when studied, measures of impotence were similar in men who had undergone vasectomy and those who had not. "Postvasectomy pain syndrome," or chronic testicular pain, has been described in the literature and is poorly understood.

## Clinical Considerations and Recommendations

#### *How safe is tubal sterilization?*

Tubal sterilization is a safe method of contraception. Death from tubal sterilization is a rare event, and overall complication rates are low. Mortality rates in the United States have been estimated at 1–4 deaths per 100,000 procedures (35–38). Most deaths in the United States have been attributed to hypoventilation and cardiopulmonary arrest during general anesthesia. In an early U.S. study, 11 of 29 sterilization-related deaths occurred in women with underlying medical conditions (39). A more recent study found no mortality among 9,475 women who underwent interval laparoscopic tubal ligation (40).

Major complications from tubal sterilization are uncommon and vary by study definition, occurring at levels that range from 1% to 3.5% (18, 19, 40). Using a standard definition of complications, including intraoperative and postoperative events, overall complication rates for tubal sterilization are estimated to be 0.9-1.6 per 100 procedures (40); unintended major surgery (laparotomy) represented 0.9 per 100 cases. This complication rate did not vary significantly according to the method of occlusion used. Intraoperative complications include unintended, unplanned major surgery needed because of a problem related to the tubal surgery, transfusion, a lifethreatening event, or death. Postoperative complications include unintended major surgery, transfusion, febrile morbidity, a life-threatening event, rehospitalization, or death caused by a complication within 42 days of surgery. General anesthesia, previous abdominal or pelvic surgery, obesity, and diabetes were independent predictors of complication (40).

When sterilization is performed concurrent with cesarean delivery, any higher associated morbidity has been attributed to the indications for which the cesarean delivery was performed (41). The risk of complications was similarly low for women undergoing tubal sterilization after abortion when compared with the risks of sterilization alone (10).

#### How effective is tubal sterilization compared with other female contraceptive methods?

Tubal sterilization is far more effective than short-term, user-dependent, reversible contraceptive methods. Data from the 1995 U.S. National Survey of Family Growth indicate that within 1 year of starting any reversible method, 90 per 1,000 typical users experience a contraceptive failure (42). By method, contraceptive failure occurs in the first year of use for 70 per 1,000 women using oral contraceptives, 90 per 1,000 women relying on the male condom, 32 per 1,000 women using injectable methods, 81 per 1,000 women using the diaphragm, and 198 per 1,000 women using periodic abstinence.

Failure rates of tubal sterilization are roughly comparable with those of the IUD. The U.S. Collaborative Review of Sterilization (CREST), a large, prospective, multicenter observational study of 10,685 women conducted by the Centers for Disease Control and Prevention in 1996, concluded that although tubal sterilization is highly effective, the risk of sterilization failure is substantially higher than previously reported (43). Analysis of CREST data found a 5-year cumulative life-table probability of failure of aggregated sterilization methods of 13 per 1,000 procedures (43), compared with a 5-year cumulative failure rate for the copper T 380-A IUD of 14 per 1,000 procedures (44). The 5-year cumulative pregnancy rate for levonorgestrel-releasing IUDs ranges between 5 and 11 per 1,000 procedures (45–47).

The risk of sterilization failure persists for years after the procedure and varies by method, age, and race and ethnicity. The younger a woman was at the time of sterilization, the more likely she was to have had sterilization failure (43).

The CREST data reported that the 10-year cumulative probability for sterilization failure varied by sterilization method and ranged from 7.5 per 1,000 to 36 per 1,000 procedures. Postpartum partial salpingectomy had the lowest 5-year and 10-year cumulative pregnancy rates: 6.3 per 1,000 and 7.5 per 1,000 procedures, respectively. The 5-year and 10-year pregnancy rates, respectively, for other occlusion methods are as follows (43):

- Bipolar coagulation: 16.5 per 1,000 and 24.8 per 1,000 procedures
- Silicone band methods: 10 per 1,000 and 17.7 per 1,000 procedures
- Spring clip: 31.7 per 1,000 and 36.5 per 1,000 procedures

Secondary analysis of 5-year failure rates with bipolar coagulation performed in different decades found that failure was significantly lower in later periods, reflecting improved technique with the method: 19.5 per 1,000 procedures for 1978–1982 versus 6.3 per 1,000 procedures for 1985–1987 (16). The 10-year cumulative risk of pregnancy was highest among women sterilized at a young age with bipolar coagulation (54.3/1,000) and clip application (52.1/1,000). The study cautions that the reported failure rates should not be considered in isolation of other variables that influence overall outcome. Although pregnancy after sterilization is uncommon, there is substantial risk that any poststerilization pregnancy will be ectopic. Analysis of CREST data found that one third of poststerilization pregnancies (47/143) were ectopic (48). For all methods of sterilization except postpartum partial salpingectomy, women younger than 30 years were more likely to experience ectopic pregnancy than women older than 30 years (a reflection of the greater overall fecundity of younger women). Non-Hispanic blacks had 4 times the relative risk (RR) of ectopic pregnancy than non-Hispanic whites. Women with a history of pelvic inflammatory disease (PID) had 2.7 times the RR of women without a history of PID.

#### Does the technique used for sterilization affect the risk of ectopic pregnancy?

The risk of ectopic pregnancy varies substantially with the method and timing of sterilization. Based on CREST study data, the 10-year cumulative probability of ectopic pregnancy after tubal sterilization by any method was 7.3 per 1,000 procedures. Bipolar coagulation had the highest cumulative probability of ectopic pregnancy (17.1/1,000), and postpartum partial salpingectomy had the lowest cumulative probability (1.5/1,000).

Bipolar coagulation had a cumulative probability 10 times higher than unipolar coagulation (17.1/1,000 versus 1.8/1,000) and 2–2.5 times higher than the spring clip (8.5/1,000) and the silicone band (7.3/1,000). It should be noted that these figures reflect procedures that took place before the routine use of a current meter, and pregnancy rates have since decreased (16). Also, current data are not available specifically for ectopic pregnancies. Interval partial salpingectomy was 5 times more likely to result in ectopic pregnancy than was postpartum partial salpingectomy, although this finding was felt to be caused by chance or selection bias (48).

For all methods except postpartum partial salpingectomy, the probability of ectopic pregnancy was greater for women sterilized before age 30 years than for women sterilized at age 30 years or older. Women sterilized by bipolar tubal coagulation before age 30 years had a 10-year cumulative probability of ectopic pregnancy of 31.9 per 1,000 procedures, approximately 4 times the cumulative probability of women aged 30 years and older. Postpartum partial salpingectomy was the only method reported by the CREST study that did not have a higher 10-year cumulative probability of ectopic pregnancy in younger women (48). For all methods of occlusion, the risk of ectopic pregnancy did not diminish with the length of time since the tubal sterilization.

# How do the safety and effectiveness of tubal sterilization compare with the IUD?

Both tubal sterilization and modern IUDs are safe methods of contraception. Death from tubal sterilization is rare, with case fatality levels reported to be between 1 and 4 deaths per 100,000 procedures (35–38). Because IUDs are not inserted under general anesthesia and IUD insertion is not a surgical procedure, death caused by IUD insertion is a rare event, with only anecdotal reports in the literature in the past (49).

Major complications from tubal sterilization are uncommon and vary by study definition. Most major complications associated with the IUD occur around the time of insertion and include uterine perforation and infection. Perforation rates vary based on the type of IUD and study design, but a rate of less than 1 in 1,000 insertions generally is recognized (50). The risk of PID is highest immediately after and up to 20 days after IUD insertion, varies according to geographic region, and is inversely related to age and parity (51, 52). One large study reported an IUD discontinuation rate from PID or infection of 4 cases in 2,795 insertions (51). The PID rate after insertion of a levonorgestrel IUD may be lower (45, 46).

The copper T 380-A IUD and the levonorgestrel IUD are highly effective methods of contraception, roughly comparable with tubal sterilization, with cumulative 5-year failure rates of 1.4 and 0.5 pregnancies per 100 women, respectively (45, 53). The failure rate of levonorgestrel IUDs remains low and stable across all age groups; however, some copper IUDs have a failure rate that varies inversely with the patient's age (54). Sterilization failure rates also are inversely related to the patient's age (43). One third of all sterilization failures will result in ectopic pregnancy, whereas approximately 20% of all IUD failures will result in an ectopic pregnancy (43, 45).

When intrauterine pregnancy occurs after tubal sterilization, there is no known added risk to the woman or her fetus. In contrast, when an intrauterine pregnancy is diagnosed in an IUD user and the IUD is not removed, there is a 3 times greater risk of spontaneous abortion in the first trimester, a highly increased risk of septic abortion in the second trimester (RR, 26; 95% confidence interval, 6–108), and a 3 times greater risk of preterm birth in the third trimester (55–57).

# How do the safety and effectiveness of tubal sterilization compare with vasectomy?

Vasectomy is safer than tubal sterilization because it is a less invasive surgical procedure and because it is performed using local anesthesia. Tubal sterilization involves entry into the peritoneal cavity and usually is performed under general or regional anesthesia.

Although specific data are lacking on mortality related to vasectomy, knowledgeable observers state that such deaths are extremely rare in the United States (24). Mortality from tubal sterilization, although rare, occurs at levels that are measurable, ranging from 1 to 4 deaths per 100,000 procedures (35–38). Major complications from vasectomy also are extremely rare (24). Major complications from tubal sterilization are uncommon and vary by definition.

Short-term effectiveness of vasectomy—with reported failures of less than 1%—is comparable with that of tubal sterilization. Tubal sterilization provides immediate contraceptive protection, whereas men remain fertile for several months after vasectomy and require semen analysis to fully determine the success of the procedure. Neither female nor male sexual function appears to be affected after tubal sterilization or vasectomy (30, 58).

Assuming that vasectomy and tubal sterilization provide similar protection against pregnancy, women who have had tubal sterilization are at increased RR of ectopic pregnancy in the case of failures, with estimated absolute incidence of ectopic pregnancy of 0.32 per 1,000 womenyears in women who had tubal sterilization and 0.005 per 1,000 women-years in women whose partners had vasectomy (59). By comparison, the estimated absolute incidence of ectopic pregnancy in women using no contraception is 2.6 per 1,000 women-years (59).

#### Does tubal sterilization cause menstrual abnormalities?

The long-term health effects of tubal sterilization on menstrual pattern disturbance (posttubal ligation syndrome) appear to be negligible. Early studies of menstrual disturbances after sterilization failed to account for confounding variables, such as presterilization use of hormonal contraceptives, that generally mask underlying menstrual dysfunction and, in particular, heavy bleeding and intermenstrual bleeding (60–62). Most recent prospective studies that account for these factors have found little or no difference in menstrual patterns between women before and after sterilization or between sterilized women and nonsterilized controls in the first 1-2 years of follow-up (61, 63–69).

A recent analysis of the CREST data prospectively examined menstrual patterns of 9,514 women for 5 years after interval tubal sterilization and compared them with those of women whose partners underwent vasectomy (70). The study found that women who underwent sterilization were no more likely than the control group to report persistent changes in their menstrual cycle length or intermenstrual bleeding. However, they were more likely to have beneficial changes in their menstrual cycle, including decreased amount of bleeding, number of days of bleeding, and menstrual pain. Although an increase in "cycle irregularity" was reported in one study subset, this was considered likely to be caused by chance. The method of tubal occlusion did not have a significant impact on the findings.

#### Are women who undergo tubal sterilization more likely to have a hysterectomy?

Women who undergo tubal sterilization appear to be 4-5times more likely to undergo hysterectomy than those whose partners underwent vasectomy (71). In one analysis of CREST data, this increased risk was found to persist across all ages and methods for a 14-year follow-up period (71). The reported association between sterilization and hysterectomy tends to be strong (RR, 1.6-4.4) (67, 71–75). Some older studies suggested a significantly greater risk of hysterectomy for women sterilized at a young age (73, 75), but more recent studies found no difference based on age (71). Increased risk was independent of the method of tubal occlusion used (71, 73) but was associated with a presterilization history of menstrual or other benign gynecologic disorders (71). A history of endometriosis or uterine leiomyomata was associated with the highest long-term probability of hysterectomy at 14 years poststerilization (71). These findings are consistent with the results from previous studies (76-78).

There is no known biologic mechanism to support a causal relationship between tubal sterilization and subsequent hysterectomy. Nonbiologic mechanisms are speculative. Women who choose one surgical procedure may be more likely to undergo another for the management of gynecologic conditions. Women who have had tubal sterilization may be more likely to perceive themselves or be perceived as appropriate candidates for hysterectomy, given that fertility preservation is no longer a factor in decision making (71, 75).

#### Does tubal sterilization have noncontraceptive benefits?

The long-term protective effect of tubal sterilization on ovarian cancer incidence (RR, 0.29–0.69) has been confirmed by multiple observational studies (79–82). This protective effect persists after adjusting for age, use of oral contraceptives, and parity (80). In addition, a case–control study of 4,742 women found no association between tubal sterilization and breast cancer (81). Most prospective studies have shown either no consistent change or no improvement in sexual interest or pleasure after sterilization (83, 84). Although tubal sterilization does not protect against sexually transmitted diseases (including human immunodeficiency virus [HIV]) (85, 86), it has been shown to reduce the spread of organisms from the lower genital tract to the peritoneal cavity and thus protect against PID. This protection is incomplete, however, as suggested by rare case reports of PID and tuboovarian abscess in women who have undergone sterilization (87–89).

#### What is the risk that a patient will regret having had tubal sterilization, and how can the risk be reduced?

Most women who choose sterilization as a contraceptive method do not regret their decision (90–92); however, information and counseling about sterilization should be provided with the intent to minimize regret among individual women. Although there are certain key indicators for future regret—such as young age at the time of sterilization—many indicators of regret are part of individual social circumstances, which should be explored with the patient before a decision is made.

Poststerilization regret measured by self-report or by request for information on reversal ranges from 0.9% to 26% (90, 93–97). Prospective CREST study data analysis found that the cumulative probability of regret over 14 years of follow-up was 12.7% (90). However, the probability was 20.3% for women aged 30 years or younger at the time of sterilization, compared with 5.9% for women older than 30 years at the time of sterilization.

Regarding the timing of sterilization, previous reports have identified postpartum sterilization as a risk factor for increased regret (83, 98–101). Analysis of CREST data found similar levels of regret for interval sterilization within 1 year of delivery (22.3%) as for post-partum sterilization after vaginal delivery (23.7%) and cesarean delivery (20.7%). The cumulative probability of regret diminished steadily with the interval between delivery and sterilization (90). Postabortion sterilization was not associated with increased regret when compared with interval sterilization (90, 101–103).

The most common reason for regret is the desire for more children. Younger women who choose sterilization have more time to change their minds and life circumstances. Women sterilized before age 25 years were 18 times more likely to request reversal over the course of follow-up than women older than 30 years at the time of sterilization. Other risk factors for increased regret include having received less information about the procedure, having had less access to information or support for other contraceptive method use (104), and having made the decision under pressure from a spouse or because of medical indications (94, 100). Data from the CREST study have been analyzed to report reversal requests as a different indicator for regret. The 14-year cumulative probability of requesting reversal information was 14.3% but was as high as 40.4% in women who underwent sterilization between ages 18 and 24 years—almost 4 times higher than for women older than 30 years at the time of sterilization (92). The number of living children was not associated with a request for reversal information. Although the overall cumulative probability of obtaining reversal was 1.1%, this number does not include women who selected in vitro fertilization to attempt pregnancy instead of reversal. Data on poststerilization users of in vitro fertilization are not available.

Because tubal sterilization is common and regret is not uncommon, it is important to attempt to reduce regret with thorough and effective counseling that takes into account the risk factors described previously. Both the patient and her partner, when appropriate, should be counseled (see box). Because young age at the time of sterilization, regardless of parity or marital status, is associated with significant levels of regret, individualized counseling of younger women is critical. Full consideration should be given to all temporary contraceptive options. Ambivalence should be addressed directly, taking into account the elective nature of the procedure. In particular, ambivalence displayed in the postpartum period just before sterilization should be seriously weighed against any advantage and considered an indication for interval sterilization.

#### **Components of Presterilization Counseling**

- · Permanent nature of the procedure
- Alternative methods available, including male sterilization
- · Reasons for choosing sterilization
- · Screening for risk indicators for regret
- Details of the procedure, including risks and benefits of anesthesia
- The possibility of failure, including ectopic pregnancy
- The need to use condoms for protection against sexually transmitted diseases, including human immunodeficiency virus infection
- Completion of informed consent process
- Local regulations regarding interval from time of consent to procedure

Data from Pollack AE, Soderstrom RM. Female tubal sterilization. In: Corson SL, Derman RJ, Tyrer LB, editors. Fertility control. 2nd ed. London (ON): Goldin Publishers; 1994. p. 295–6.

## Summary of Recommendations

# The following recommendations are based on good and consistent scientific evidence (Level A):

- Tubal sterilization may be recommended as a safe and effective method for women who desire permanent contraception. Women should be counseled that tubal ligation is not intended to be reversible; therefore, those who do not want permanent contraception should be counseled to consider other methods of contraception.
- Patients should be advised that neither tubal sterilization nor vasectomy provides any protection against sexually transmitted diseases, including HIV infection.
- Patients should be advised that the morbidity and mortality of tubal ligation, although low, is higher than that of vasectomy, and the efficacy rates of the 2 procedures are similar.
- Patients should be counseled that tubal sterilization is more effective than short-term, user-dependent reversible methods.
- Patients should be counseled that failure rates of tubal sterilization are comparable with those of IUDs.

#### The following recommendations are based primarily on consensus and expert opinion (Level C):

- If a patient has a positive pregnancy test result after a tubal ligation, ectopic pregnancy should be ruled out.
- Indications for hysterectomy in women with previous tubal sterilization should be the same as for women who have not had tubal sterilization.

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The MEDLINE database, the Cochrane Library, and ACOG's own internal resources and documents were used to conduct a literature search to locate relevant articles published between between January 1985 and January 2003. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician-gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than 1 center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

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