



## ACOG technical bulletin Sterilization

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Over 170 million couples worldwide use surgical sterilization as a safe and reliable method of contraception. In the United States, sterilization is the most commonly used method among married or formerly married women. An estimated 640,000 female sterilization procedures and 500,000 male sterilization procedures are performed each year (1, 2). In 1988, sterilizations accounted for 39% of contraceptive method use by all women 15-44 years old; 27.5% of women using contraception had undergone tubal sterilization, and 11.7% reported that their partners had undergone vasectomy (3).

### Patient Counseling and Selection

Patients should be informed about both male and female sterilization as well as the risks and benefits of alternative long-acting, temporary contraceptive methods (see the box). When appropriate, the male partner can be included in such initial counseling. Many men and women have the impression that sterilization operations are easily reversible. The clinician should make clear to the patient that all operative sterilizations are intended to be permanent. Counseling should take into account risk factors that affect regret of sterilization. In the United States, the strongest indicator of future regret is young age at the time of sterilization, regardless of parity or marital status. Women between the ages of 20 and 24 years at sterilization are twice as likely to experience poststerilization regret as women sterilized between the ages of 30 and 34 years (4). Marital instability increases the probability of regret. Approximately

6% of sterilized women report regret or request information about sterilization reversal within 5 years of the procedure; urologists estimate that close to 1-2% of the total number of men they sterilize seek information on

### Components of Presterilization Counseling

- Alternative methods available, including male sterilization
- Reasons for choosing sterilization
- Screening for risk indicators for regret
- Details of the procedure, including anesthesia with attendant risks and benefits
- The permanent nature of the procedure and information on reversal
- The possibility of failure, including ectopic pregnancy
- Post tubal ligation physiology, including the possibility of unrelated change in menstruation
- The need to use condoms for protection against sexually transmitted diseases and human immunodeficiency virus infection if at risk of exposure
- Answers to all questions to the satisfaction of the patient
- Completion of informed consent document

Modified from Pollack AE, Soderstrom RM. Female tubal sterilization. In: Corson SL, Derman RJ, Tyrer LB, eds. Fertility control. 2nd ed. London, Ontario: Goldin Publishers, 1994:295-296

vasectomy reversal (4,5). Although success rates in vas and tubal reanastomosis have improved dramatically in recent years, successful reversal and subsequent pregnancy depend on many factors, including the type of sterilization, interval between sterilization and reversal, age, and length of the remaining tube.

Preoperative counseling should include an explanation of the causes and probability of sterilization failure. When the patient has considered and accepted the risks of regret or failure, the physician can provide information about operative approaches, including a review of the possible complications from both the operation and the anesthesia. The patient should be informed about the advantages and disadvantages of local and general anesthesia, pain likely to be associated with the operation, and possible complications, including damage to organs or major vessels, infection, and subsequent ectopic pregnancy. The patient should be informed of her need for adequate postoperative care and support, and she should plan accordingly.

The patient should be given an opportunity to ask questions about the procedure. Both this discussion and the fact that the patient was given the opportunity to ask questions should be noted in the patient's record by the physician. All this is best accomplished at a preoperative visit scheduled far enough in advance of the operation to allow the patient ample time to weigh the factors involved in the decision. Physicians should be aware of state laws or insurance regulations that may require a specific interval between obtaining consent and performance of sterilization procedures. State law may mandate the use of special consent forms. Written informed consent should be obtained following counseling in a relaxed and unpressured environment. It is best not to obtain consent concurrent with labor or an abortion procedure because these events are associated with stress and a high incidence of regret of sterilization.

Patients should be advised that female and male sterilization offer no protection against sexually transmitted diseases (STDs) such as human immunodeficiency virus (HIV) infection. Patients should be encouraged to use condoms or have their partners use condoms when they are at risk of exposure. In the United States, studies indicate that sterilized women with risk factors for STDs have low rates of condom use and infrequently attend clinics for preventive reproductive health services (6, 7).

## Tubal Sterilization

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### Timing

Tubal sterilization can be performed postpartum, post-abortion, or as an interval procedure (unrelated in time to a pregnancy). The timing of the procedure will influence both the surgical approach and the method of tubal occlusion used.

Postpartum sterilizations are performed at the time of cesarean delivery while the abdomen is open or following a vaginal delivery using a 2-5-cm subumbilical minilaparotomy incision. The subumbilical minilaparotomy approach allows for easy entry into the abdomen and access to the tubes because the anterior abdominal wall is thin just below the umbilicus over the fundus. It is best to **perform** postpartum minilaparotomy before the onset of significant uterine involution but following full assessment of maternal and neonatal well being. The likelihood of postpartum hemorrhage in multiparous women subsides after the first 12 hours postpartum. Postpartum minilaparotomy may be performed safely and comfortably using local anesthesia with sedation or regional or general anesthesia.

Postabortion sterilizations can be performed safely following uncomplicated spontaneous or induced abortion. Following a first-trimester abortion, laparoscopic sterilization or minilaparotomy using a suprapubic approach are both acceptable. In either case, a single anesthetic for the abortion and the sterilization may be used to avoid additional risk. Following a second-trimester abortion, minilaparotomy via a small midline vertical incision at the level of the fundus can be used safely. Open laparoscopy or the Hasson cannula may be used, thereby avoiding the risk of perforation of the soft, enlarged uterus associated with introduction of the laparoscopic trocar. Alternatively, an interval procedure can be performed once complete uterine involution has occurred.

Tubal sterilization can be performed as an interval procedure at any time during the menstrual cycle. Although performance of the sterilization procedure during the patient's estimated follicular phase and confirmation of patient use of a highly effective method of contraception before sterilization will reduce the risk of luteal phase pregnancy (a pregnancy diagnosed after sterilization in which conception occurred before sterilization), **highly sensitive pregnancy testing will further reduce the risk. A same-day presterilization urine**

test capable of detecting human chorionic gonadotropin levels as low as 20 mIU/ml or a qualitative serum assay for the beta subunit of human chorionic gonadotropin will suffice (8). Tests this sensitive will allow for pregnancy detection as early as 1 week after conception. Performance of dilation and curettage concurrent with all interval sterilizations as a routine practice is not recommended on the basis of effectiveness, cost, and morbidity (9). Interval sterilization is usually performed using laparoscopy or minilaparotomy with local, regional, or general anesthesia. Transvaginal approaches have been described, and transcervical hysteroscopic approaches are being investigated.

## Surgical Approach

### *Laparoscopy*

Modern laparoscopy was first developed in Europe in the 1960s and became a popular method for direct visualization of the abdominal and pelvic organs. In the 1970s, it was introduced in the United States for tubal sterilization. In 1987, approximately one third of all tubal sterilizations in the United States were laparoscopic procedures. Most of these were performed under short-acting, general anesthesia in an outpatient setting.

In the United States, closed laparoscopy is used more often than open laparoscopy. In laparoscopic sterilization, an endoscope is inserted through a small incision made just below the umbilicus. Closed laparoscopy is performed through a small subumbilical skin incision just large enough to admit a sharp trocar. The trocar is used to puncture the abdominal wall, gaining entry into the peritoneal cavity blindly. Open laparoscopy is performed through a 1.5-cm semilunar or vertical subumbilical incision made through the layers of the abdominal wall until the peritoneal cavity has been entered under direct visualization (10).

Advantages of laparoscopy over other surgical approaches for sterilization include the opportunity to inspect the abdominal and pelvic organs, barely visible-incision scars, and a rapid return to full activity for the patient. The disadvantages of laparoscopic sterilization include the cost and the fragility of the equipment, the special training required, and the risk of bowel, bladder, or major vessel injury following insertion of the needle or trocar.

With special training and experience, both closed and open laparoscopy can be performed with local

anesthesia while maintaining a high level of patient comfort. Small studies have indicated that many women prefer the use of local anesthesia for sterilization procedures (11).

### *Minilaparotomy*

The minilaparotomy approach may be performed by using local anesthesia with sedation, regional anesthesia, or general anesthesia. In contrast to laparoscopy, minilaparotomy requires only basic surgical instruments and training. Minilaparotomy is performed by using a 2-3-cm incision placed in relation to the uterine fundus. For interval sterilization, a uterine manipulator may be used to bring the uterine fundus toward the incision. For women undergoing either laparoscopic or minilaparotomy procedures with local anesthesia, placement of a paracervical block before insertion of the uterine manipulator reduces discomfort (12). Although most surgeons prefer to perform tubal occlusion using suture ligation and excision techniques, clips or rings may be applied through the minilaparotomy incision. With minilaparotomy, a segment of the tube can be removed for pathologic confirmation that both tubes were sterilized.

## Methods of Occlusion

### *Electrocoagulation*

Electrocoagulation for tubal occlusion is used exclusively with laparoscopic sterilization. Unipolar electrocoagulation with or without tubal excision was the first laparoscopic method of tubal occlusion. However, because uncommon but serious complications, including thermal bowel injury, were reported, bipolar coagulation was introduced and is now the most commonly used laparoscopic method in the United States. Bipolar coagulation also results in a more localized injury to the fallopian tube than does the unipolar method. Therefore, to maximize its effectiveness, at least 3 cm of the isthmic portion of the fallopian tube must be completely coagulated. Adequate coagulation requires sufficient energy of 25 W delivered in a cutting waveform (13). Use of a current meter, rather than a visual endpoint or a defined period of time, more accurately indicates complete coagulation.

### *Mechanical Methods*

Mechanical occlusion devices commonly used in the

United States include the silicone rubber band (Falope ring) and the spring-loaded clip (Hulka-Clemens clip). A new titanium clip lined with silicone rubber (Filshie clip) has been widely used in Great Britain with low reported failure rates (14, 15).

Special applicators are necessary for each of the mechanical occlusive devices, and each requires skill for proper application. The band can only be applied to a fallopian tube that is sufficiently mobile to allow it to be drawn into the applicator. Both types of clips should be applied perpendicular to the long axis of the proximal isthmus of the fallopian tube. Both types of clips and the silicone rubber band are most likely to be effective when used to occlude a normal tube. Tubal adhesions or a thickened or dilated fallopian tube increase the risk of misapplication and subsequent failure (16).

All of the mechanical methods of tubal occlusion destroy much less oviduct (about 5 mm for clips and 2 cm for rings) than electrocoagulation methods. Therefore, if reversal is attempted, there is a greater chance of success.

#### *Ligation Methods*

Tubal occlusion at the time of cesarean delivery, laparotomy for other indications, or minilaparotomy is usually performed by using ligation techniques. A variety of techniques have been well described (17). Care should be taken to excise a sufficient section of fallopian tube to ensure complete transection of the tubal lumen.

#### *Efficacy*

#### *Failure*

Precise failure rates for each method of tubal occlusion and long-term cumulative failure rates have been difficult to measure because of the methods' high effectiveness rates. A generally accepted failure rate of less than 1% is based on combined small studies in which different occlusion methods were used (18). Preliminary findings from the U.S. Collaborative Review of Sterilization indicate that cumulative failure rates are higher than expected, with significant differences between methods (19). The risk of failure persists for years after the procedure and varies by method of tubal occlusion and age. In a total of 143 sterilization failures, cumulative 10-year probabilities of pregnancy were highest

after spring-loaded clip sterilization (36.5 per 1,000 procedures) and lowest after unipolar coagulation (7.5 per 1,000) and postpartum partial salpingectomy (7.5 per 1,000). The cumulative risk of pregnancy was highest among women sterilized at a young age with bipolar coagulation (54.3 per 1,000) and spring-loaded clip application (52.1 per 1,000). It is important to note, however, that in another study of sterilization failures, all spring-loaded clip failures were found to be due to misapplication (16).

Fecundity declines significantly after the age of 35 years. In one study, patients younger than 35 years were 1.7 times more likely to become pregnant following sterilization than women over the age of 35 years (20). In another study, among women 18-27 years of age who underwent bipolar coagulation, 2.8% became pregnant between 5 and 10 years after the procedure (19).

Pregnancies after sterilization may occur without any technical error. Technical error leading to failure occurs less frequently with minilaparotomy regardless of the occlusion method used (21). In one study, the location of the suture on the ligated tube affected estimated minilaparotomy failure rates, which were approximately 3% in 3 years for fimbriectomy with infundibular ligation, approximately 1.7% for ampullary ligation, and approximately 0.34% for isthmic ligation (20).

#### *Ectopic Pregnancy*

When sterilization failure occurs, the subsequent pregnancy is more likely to be ectopic than intrauterine. The degree of increased risk depends on the occlusion method used. The results of several reports suggest that over half of the pregnancies that occur after electrocoagulation sterilization procedures may be ectopic (22, 23). If an ectopic pregnancy occurs, the physician should evaluate both proximal tubes and manage any acute problems that are present.

#### **Complications**

In the United States, female sterilization has a mortality rate of 1-2 deaths per 100,000 procedures (24). Complications of general anesthesia are the leading cause of death from tubal sterilization. Other causes include sepsis and hemorrhage. Between 1977 and 1981, most of those deaths from sepsis resulted from thermal bowel injury following unipolar electrocoagulation, while most of those deaths from hemor-

rhage followed major vessel lacerations associated with abdominal entry for laparoscopic sterilization (25).

Studies in the United States indicate that women undergoing interval minilaparotomy are at approximately twice the risk of having any complication than are women undergoing interval laparoscopic sterilization. However, women who undergo minilaparotomy often have medical risk factors, including certain cardiac and pulmonary problems, that are contraindications to laparoscopy and therefore are intrinsically at greater surgical risk (26, 27).

### Late Sequelae

The long-term health effects of tubal sterilization on menstrual pattern disturbance, pelvic pain, and the need for pelvic surgery are controversial. Early studies of menstrual disturbance following sterilization failed to account for confounding variables such as presterilization use of hormonal contraceptives that generally mask underlying menstrual dysfunction. Most recent prospective studies that account for these factors have found little or no difference in menstrual function between women before and after sterilization, or between sterilized women and nonsterilized control subjects in the first 2 years of follow up. Findings from reports that include follow up for more than 2 years have been less consistent, yet no single method of occlusion, regardless of the amount of tubal destruction, has been associated with an increase in risk for poststerilization menstrual disturbance (28).

Two studies have evaluated the likelihood of hospitalization for menstrual disorders in women who have undergone sterilization. A U.S. population-based cohort study showed an increased relative risk of 1.6 (95% confidence interval of 1.3-2.1) for hospitalization for menstrual disorders compared with a control group of wives of men who have had vasectomies (29). Follow up of a large British cohort for 6 years failed to identify a significant increase in risk (30).

Some sterilized women may be more likely to undergo subsequent hysterectomy. Women who have been sterilized before age 30 have a higher risk of a hysterectomy than women sterilized after age 30. This risk has not been related to an increase in menstrual disturbance or the extent of tissue damage based on the method of occlusion used (31).

### Ovarian Cancer

In several older studies, an inverse relationship be-

tween tubal occlusion and subsequent ovarian cancer has been found, although the strength of this relationship has varied widely (32, 33, 34). A controlled, prospective study reported a reduced risk of ovarian cancer among women who had tubal occlusion or hysterectomy (35). The study monitored 77,544 women for 12 years. For those women who had a tubal ligation, the relative risk of ovarian cancer was 0.33. The reduced risk persisted after the investigators controlled for risk factors such as smoking and protective factors (e.g., use of oral contraceptives). Cases of reported ovarian cancer, identified within the first 4 years after sterilization, were excluded to eliminate possible screening bias (32, 33).

### Pelvic Inflammatory Disease

It has long been believed that tubal sterilization protects against pelvic inflammatory disease. This would seem to make intuitive sense, as this condition is thought to be caused by the ascent of bacteria through the cervix, uterus, and fallopian tubes and into the peritoneal cavity. This protection is, however, not absolute. Case reports of pelvic inflammatory disease and tubo-ovarian abscess in women who have undergone sterilization are rare but do exist in the literature (36, 37).

### Sterilization in Men

Vasectomy performed as an outpatient procedure has been popular in the United States since 1965. More than 5 million men in the United States have had a vasectomy (38). When compared with tubal sterilization, vasectomy is safer, less expensive, and equally as effective in the United States. Urologists, general surgeons, and family physicians perform vasectomy procedures in their offices using local anesthesia.

Traditionally, vasectomy was performed through two incisions in the scrotum, one overlying each vas deferens. The incisions were then closed with a suture. In 1985, the no-scalpel vasectomy technique was introduced (39). This method makes use of two specially designed instruments: one allows the vas to be fixed externally, while the second is used to puncture the scrotal skin without using a scalpel (40). The technique was developed to increase acceptability of vasectomy by reducing the apprehension related to making an incision on the scrotum (41, 40). It reduces the already low rate of minor complications (less than 3%) seen

with traditional vasectomy, such as wound hematoma and infection (42).

Both traditional and no-scalpel vasectomy use the same methods to occlude the vas. These include excising a segment of the vas and sealing the ends via ligation, electrocoagulation or thermocoagulation, or clips. To decrease the incidence of recanalization, some surgeons further separate the severed ends by folding them back on one another or burying one end in the scrotal fascia.

Pregnancy rates following vasectomy are less than 1% in most studies and usually result from failure to occlude the correct structure, unprotected intercourse too soon after the operation, or spontaneous recanalization. Unlike tubal occlusion in women, vasectomy is not immediately effective: about 3 months or 20 ejaculations are needed to flush the vasa of viable sperm. Postvasectomy semen analysis should be performed to determine the effectiveness of the procedure.

The possibility of long-term side effects from vasectomy has received considerable attention. Nine separate epidemiological studies in men have failed to show a relationship between atherosclerosis and vasectomy (143). An original study in monkeys that suggested such a relationship has not been confirmed (44, 45). Other consequences of vasectomy have been suggested, but none has been proven. In addition, several studies report that in the United States, men who have chosen vasectomies are often healthier than control counterparts (46, 47).

In Western countries, white, upper-middle-class men are more likely to choose vasectomy and are also the group more likely to have testicular cancer. A study of nearly 74,000 men who have had vasectomies showed the incidence of testicular cancer in this group to be no higher than that of the general population (48). It also showed that vasectomy does not accelerate the growth of preexisting testicular tumors.

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 (49, 47). Two subsequent studies have failed to support these findings (50, 51).

The U.S. National Institutes of Health convened a group of experts in 1993 to review the published reports on prostate cancer. The committee found that although additional research into a possible causal relationship between vasectomy and prostate cancer should be con-

ducted, a change in the current practice of vasectomy was not warranted. The National Institutes of Health made the following recommendations (52):

- Providers should continue to offer vasectomy and perform the procedure
- vasectomy reversal is not warranted to prevent prostate cancer
- Screening for prostate cancer should not be any different for men who have had a vasectomy than for those who have not

## Summary

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Sterilization provides a safe and effective contraceptive method. Both female and male sterilization have few long-term sequelae. Several new methods of transcervical sterilization are under development, but laparoscopy and minilaparotomy are likely to remain the most popular methods of female sterilization.

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