

Counseling Issues in Tubal Sterilization

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Female sterilization is the number one contraceptive choice among women in the United States. Counseling issues include ensuring that the woman understands the permanence of the procedure and knowing the factors that correlate with future regret. The clinician should be aware of the cumulative failure rate of the procedure, which is reported to be about 1.85 percent during a 10-year period. Complications of tubal sterilization include problems with anesthesia, hemorrhage, organ damage, and mortality. Some women who undergo tubal ligation may experience increased sexual satisfaction. While the procedure is commonly performed postpartum, it can be done readily, without relation to recent pregnancy, by laparoscopy or, when available, by minilaparotomy. Surgery should be timed immediately postpartum, or coincide with the first half of the woman's menstrual cycle or during a time period when the woman is using a reliable form of contraception. (Am Fam Physician 2003;67:1287-94,1301-2. Copyright© 2003 American Academy of Family Physicians.)

▶ *A patient information handout on tubal sterilization, written by the authors of this article, is provided on page 1301.*

Female sterilization is the most commonly used "modern" contraceptive in the United States.^{1,2} The most recent cycle of the National Survey of Family Growth (1995) indicates that 27 percent of women who have chosen to use contraception have opted for tubal sterilization.¹ In the United States, women are three times more likely to undergo sterilization than are men.¹ The widespread prevalence of female sterilization becomes more understandable considering the high incidence of unintended pregnancy. Sterilization is one of the most effective means of preventing unintended pregnancy.³ Almost 50 percent of all pregnancies each year are unintended, and the majority occur among women who are using contraception.⁴ Despite the recent availability of additional, extremely effective, reversible contraceptive methods, demand for sterilization continues from women who desire ongoing contraception that does not contain hormones and does not require periodic or postcoital contraceptive efforts.

In the United States, interval sterilizations are usually same-day procedures performed under general anesthesia in an outpatient facility.⁵ Most U.S. women who have undergone sterilization experience either a postpartum minilaparotomy procedure or an interval (timing of the procedure does not coincide with a recent pregnancy) laparoscopic procedure.⁶ In October 2002, the U.S. Food and Drug Administration approved Essure, the first transcervical hysteroscopically placed sterilization method. Counseling issues regarding procedural details, permanence of the procedures, sterilization alternatives, benefits, and risks, including sterilization regret, apply equally to abdominal and transcervical approaches. Regardless of the tubal sterilization procedure chosen, the woman should be confident that sterilization is her choice and her best contraceptive option.

Counseling Issues

Counseling for reversible contraceptive methods generally involves clinician and patient dialogue regarding safety, efficacy, potential side effects, and integration of the method into the woman's lifestyle. All health care professionals who counsel women about contraception should recognize the advantages and disadvantages of female sterilization compared with nonpermanent, long-acting methods (Table 1).^{3,7-10} Sterilization counsel-

Counseling for sterilization should include discussing permanence of the method, possibility of future regret, and information about the surgical procedure.

TABLE 1

Advantages and Disadvantages of Contraceptive Methods*

Method	Advantages	Disadvantages	Failure rate—pregnancies per 100 women in the first 12 months of use	
			Typical use	Perfect use
Levonorgestrel implant (Norplant; currently unavailable in the United States)	<ol style="list-style-type: none"> At least 5-year duration of effectiveness; as effective as sterilization for 5 years Prompt return of fertility Other advantages are similar to those listed below for medroxyprogesterone acetate (items 3 through 7) Not dependent on user compliance 	<ol style="list-style-type: none"> Minor surgical procedure to initiate and discontinue; requires skilled insertion and removal by physician High initial cost Contour of implant may be visible through skin. Some patients experience "nuisance symptoms," such as nausea, poor cycle control, acne, weight gain, and depression. May require more than one year from stopping to resume normal cycle and fertility No protection against STDs of the lower genital tract Slight increase in failure rate if user weighs 90 kg (200 lb) or more 	0.05	0.05
Vasectomy	<ol style="list-style-type: none"> Male method Safer and quicker procedure than tubal sterilization Permanent contraception 	<ol style="list-style-type: none"> High initial cost Surgical procedure; surgical risks include infection, bleeding, failure Complications are rare. Post-sterilization regret No protection against STDs Permanent Becomes effective several weeks after procedure (when all stored sperm have been ejaculated or absorbed) 	0.15	0.1
Medroxy-progesterone acetate/estradiol cypionate (Lunelle)	<ol style="list-style-type: none"> Highly effective Eventual cycle irregularity Readily reversible 	<ol style="list-style-type: none"> Monthly injections Irregular cycles are common initially Some women experience "nuisance symptoms," such as nausea, poor cycle control, acne, weight gain, and depression. No protection against STDs 	To be determined	0.05
Medroxy-progesterone acetate (Depo-Provera)	<ol style="list-style-type: none"> User compliance 4 times per year Highly effective No estrogen-related side effects May decrease episodes of crises in patients with sickle cell disease Cost effective Decreased risk of PID Improves endometriosis 	<ol style="list-style-type: none"> Some women experience "nuisance symptoms," such as nausea, poor cycle control, acne, weight gain, and depression. May require more than one year from stopping to resume normal cycle and fertility No protection against STDs of the lower genital tract May decrease bone density (reversible) 	0.3	0.3
Tubal sterilization	<ol style="list-style-type: none"> Permanent contraception Low failure rate/highly effective Decreased risk of PID Decreased risk of ovarian cancer 	<ol style="list-style-type: none"> High initial cost Surgical procedure; surgical risks as outlined in article text Risk of tubal pregnancy varies by method Post-sterilization regret No protection against STDs Permanent 	0.5 (1.85 at 10 years of cumulative use)	0.5
IUD	<ol style="list-style-type: none"> Ease of compliance Highly effective; as effective as female sterilization 10-year duration of effectiveness (ParaGard); 5-year duration of effectiveness (Mirena) Reduced menstrual bleeding and dysmenorrhea with Mirena 	<ol style="list-style-type: none"> High initial cost Proximal increased risk of PID, although not a documented long-term risk Requires skilled insertion and removal by physician Risk of uterine perforation greatest at insertion Pain and bleeding in some users lead to discontinuation in 5 to 15 percent of women. If pregnancy occurs with IUD in place, it may be complicated. Expulsion, especially in first three months of use No protection against STDs 	ParaGard: 0.8 Mirena: 0.1	ParaGard: 0.6 Mirena: 0.1

Table continued on next page

TABLE 1 (Continued)

Method	Advantages	Disadvantages	Failure rate—pregnancies per 100 women in the first 12 months of use	
			Typical use	Perfect use
Evra contraceptive patch (0.15 mg norelgestromin/0.02 mg ethinyl estradiol per day)	<ol style="list-style-type: none"> Once prescribed, use controlled by woman New patch once a week for three weeks, no patch during fourth week; therefore, not coitally-related Cycle regularity Potential for same noncontraceptive benefits listed below for OCPs 	<ol style="list-style-type: none"> Prescription required No protection against STDs Possible skin irritation “Nuisance symptoms” such as weight changes, breakthrough bleeding, or breast tenderness Unrecognized patch detachment Slight increase in failure rate if user weighs 90 kg (200 lb) or more 	To be determined	0.3
NuvaRing (etonogestrel, 0.12 mg/ethinyl estradiol 0.015 mg per day vaginal ring)	<ol style="list-style-type: none"> Once prescribed, use controlled by woman Worn for three continuous weeks, then removed for menstruation; therefore not coitally-related, undetectable by partner Reduced incidence of nausea and vomiting that can occur with OCP use Cycle regularity Potential for same noncontraceptive benefits listed below for OCPs 	<ol style="list-style-type: none"> Requires comfort with vaginal insertion and removal Prescription required. If expelled or removed from the vagina for more than three hours during the three weeks of required intra-vaginal use, another contraceptive should be used until the ring has been in place for seven days. No protection against STDs Possible vaginal irritation Possible changes in character of vaginal discharge “Nuisance symptoms” such as weight changes, breakthrough bleeding, or breast tenderness Unrecognized expulsion of NuvaRing 	To be determined	0.3
OCP	<ol style="list-style-type: none"> Readily available Protection against ovarian and endometrial cancer Decreased benign breast disease Relief of dysmenorrhea and iron deficiency anemia Cycle regularity Decreased risk of PID and ectopic pregnancy Improved complexion (decreases acne) Easily reversible Improvement of endometriosis 	<ol style="list-style-type: none"> Increased risk of cardiovascular and thromboembolic diseases in smokers older than 35 years May exacerbate migraine headaches Requires daily user compliance Effectiveness can be decreased by other medications (e.g., anti-seizure medications) No protection against STDs “Nuisance symptoms” such as weight gain, breakthrough bleeding, and breast tenderness (less common in current low-dose preparations) Slight increase in failure rate if user weighs 90 kg (200 lb) or more 	6 to 8	0.1
Male and female condoms	<ol style="list-style-type: none"> Protection against STDs, including AIDS Available over-the-counter Cost effective 	<ol style="list-style-type: none"> Disruption of coitus Compliance variability (“condom roulette”) May break or slip User sensitivity to latex or spermicide 	14 to 21	3 to 5
Diaphragm	<ol style="list-style-type: none"> Readily reversible May be inserted up to four hours before intercourse Some protection against STDs 	<ol style="list-style-type: none"> Requires highly motivated user Possible user sensitivity to spermicidal creams/gels Yearly replacement Refitting recommended if significant weight gain or loss or intervening childbirth occurs 	16	6
Fertility awareness-based method (natural family planning)	<ol style="list-style-type: none"> No cost 	<ol style="list-style-type: none"> Requires highly motivated user Some techniques depend on cycle regularity Few physicians are knowledgeable in teaching the various techniques No protection against STDs 	20	1 to 9
Spermicides	<ol style="list-style-type: none"> Some protection against STDs Available over-the-counter 	<ol style="list-style-type: none"> User sensitivity/allergy is possible Fair to poor contraceptive effectiveness Disruption of coitus Compliance variability (“condom roulette”) 	29	15

STDs = sexually transmitted diseases; PID = pelvic inflammatory disease; IUD = intrauterine device; OCPs = oral contraceptive pills; AIDS = acquired immunodeficiency syndrome.

*—Listed in ascending order based on typical failure rates.

Information from references 3 and 7 through 10.

Women contemplating sterilization can be reassured that long-term failure rates are as low as those of the intrauterine device and levonorgestrel (Norplant) implant system.

ing should include discussing permanence of the method, possibility of future regret, and information about the surgical procedure. Assessment of whether the woman's partner might consider undergoing sterilization rather than the woman also is appropriate (Table 1).^{3,7-10}

Whether a reversible method or sterilization is being considered, the goal of clinician-patient dialogue is to ensure that the woman has enough information and time to determine the best method for her at that point in her life. If sterilization is chosen, the clinician should assess, through two-way dialogue, whether the woman has adequately considered the implications of ending her child-bearing potential. Each woman's knowledge base, cultural context, and experiences are different; each woman has her own unique contraceptive history and contraceptive re-

quirements. As a facilitator, the clinician should strive to convey information that is medically accurate yet understandable, unbiased, and provided at such a time and in such a manner as to permit sufficient time for patient deliberation. Helpful clinician-patient conversations vary in detail and focus as dictated by individual patient circumstances.

Any woman who has completed childbearing is a potential candidate for sterilization. Parity, once considered important in determining eligibility for sterilization, does not correlate with sterilization regret and is not a reason to deny the procedure.^{11,12} While regret is associated with having the procedure performed at ages younger than 30,^{11,12} age is not a criterion for procedure eligibility. However, younger age should signal the need for a careful, thoughtful dialogue about how desire for sterilization can change with changing life events.

FEARS AND MISPERCEPTIONS

When assessing the content and context of patient decision-making, open-ended questions tend to provide the most insight into fears and misperceptions about the procedure. For example, the clinician might ask, "What have you heard or read about sterilization?" or "What concerns do you have about the procedure?"

Misperceptions (e.g., "it will reverse itself in five years") and fears often reflect misinformation about intended permanence, failures, procedural details, complications, and side effects of sterilization.¹³

FAILURE

While tubal sterilization is intended to permanently prevent conception, failures do occur. Reasons for failure include undetected luteal pregnancy, occlusion of an incorrect structure (most commonly the round ligament), incomplete or inadequate occlusion,

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slippage of a mechanical device, development of a tuboperitoneal fistula, and spontaneous re-anastomosis or recanalization of the cut ends.¹¹

The U.S. Collaborative Review of Sterilization (CREST) is the landmark prospective, multicenter, observational study¹⁴ on the use of sterilization in this country. The CREST study was conducted by the Centers for Disease Control and Prevention with support from the National Institute for Child Health and Human Development. CREST recently reported a 10-year (1978 to 1987) cumulative failure rate for sterilization of 1.85 percent in 10,685 women.¹⁴ CREST, which reports failure rates that are higher than previously expected, is the largest body of data, thus far, for this length of follow-up.

The CREST study found a higher-than-expected failure rate (i.e., 2.01 per 100 women over 10 years) for interval minilaparotomy sterilization, an office-based procedure.¹⁴ Most likely, this was a consequence of the low numbers of minilaparotomy cases (i.e., 425 women among a total of 10,685). The higher failure rate also might be caused by the fact that in the United States, interval minilaparotomy often is performed in surgically challenging circumstances, such as when severe pelvic adhesions are present and laparoscopy is deemed inappropriate.¹⁴

The risk of sterilization failure persisted throughout the study period.¹⁴ This finding contradicts the widely held but inaccurate belief that if pregnancies are to occur after sterilization procedures, they will do so within one to two years after the operation. Although the CREST study revealed cumulative 10-year failure rates higher than previously thought, the study confirms that sterilization, when performed with appropriate technique by an experienced clinician, continues to be an extremely effective long-term contraceptive. Contraceptive candidates can be reassured that long-term risk of failure is

The two most common factors associated with regret are young age and unpredictable life events, such as change in marital status or death of a child.

low and that only the intrauterine device and levonorgestrel (Norplant) implant system (currently unavailable in the United States) have comparable, long-term failure rates.⁸⁻¹⁰

The CREST study did not include data on the Filshie clip, which was unavailable in the United States at the time of study enrollment. A 10-year cumulative failure rate of 0.5 percent for 200 women was recently reported for the Filshie clip.^{11,15}

By preventing pregnancy, female sterilization has an overall protective effect on the risk of ectopic pregnancy. However, when pregnancy does occur it is likely to be ectopic. Of the 143 pregnancies reported in the CREST study, one third were ectopic.¹⁶

REGRET

The two most common factors associated with regret are young age and unpredictable life events, such as change in marital status or death of a child.^{11,17} Regret also has been shown to correlate with external pressure by the clinician, spouse, relatives, or others.¹¹ Interestingly, marital status at the time of the operation, level of education, and the absence of children do not, in many studies, correlate with regret.^{11,12,17}

Regret is difficult to measure because it encompasses a complex spectrum of feelings that can change over time. This helps to explain that while some studies have shown "regret" on the part of 26 percent of women, fewer than 20 percent seek reversal and fewer than 10 percent actually undergo the reversal procedure.^{11,18,19}

Depending on such factors as the technique

Deaths associated with tubal sterilization are rare and are most commonly associated with complications of anesthesia, sepsis, hemorrhage, or myocardial infarction.

used for sterilization, the resulting length and portion of undamaged fallopian tube remaining, the woman's age, and the surgeon's skill, success rates for reversal range from 47 to 90 percent.¹¹ Women who are ambivalent about the permanence of the procedure should be counseled to strongly consider another contraceptive method.

COMPLICATIONS

Overall, major complications of tubal ligation are rare, occurring in fewer than 0.5 percent of cases.^{11,20-22} Complications are influenced by factors such as choice of anesthetic, patient characteristics, positioning, technique, and operator experience.¹¹

Short-term complications (e.g., anesthetic difficulties and hemorrhage) occur in the operating room and manifest immediately or in the first several weeks after surgery. Trauma to organs such as the bowel, bladder, ureter, uterus, and cervix can result from cautery, occlusion, and sharp and blunt traumas. Death, a rare outcome of tubal ligation, occurs in only one or two of every 100,000 cases in the United States.²³ Currently, the U.S. death rate secondary to complications of pregnancy is seven per 100,000 live births.²⁴ The 29 sterilization-associated deaths reported in the United States between 1977 and 1981 were associated with complications of anesthesia (11 women), sepsis (seven women), hemorrhage (four women), myocardial infarction (three women), and "other causes" (four women).²⁵

Women may fear long-term complications of tubal sterilization, such as future risk of hysterectomy and changes in menstrual pat-

tern. Although hysterectomy rates are higher among U.S. women who were sterilized before the age of 30, a plausible biologic effect of sterilization on hysterectomy risk is unlikely.^{6,11} Increased risk of hysterectomy is a finding unique to the United States. Studies from other countries, where hysterectomy is less common, consistently do not report an increased risk.⁵ Recent studies also show no association between tubal sterilization and menstrual cycle change.^{11,26}

NONCONTRACEPTIVE BENEFITS

Tubal sterilization has been found to confer noncontraceptive health benefits. A number of case control and cohort studies in the United States and other countries report a protective effect of sterilization against ovarian cancer.^{11,27,28} While sterilization does not protect against sexually transmitted diseases (STDs), several case control and cohort studies have reported that pelvic inflammatory disease is less common in sterilized women.^{11,29}

Although retrospective studies have reported both improvement and deterioration of sexuality after sterilization, most prospective cohort studies have shown either no change or improvement in sexual function, sexual desire, sexual satisfaction, coital frequency, and self-perceived femininity.³⁰ Some women have reported that tubal sterilization positively affected sexual spontaneity and satisfaction because they felt less anxious about the possibility of unplanned pregnancy.³⁰

Preoperative Assessment

Options for sterilization include laparoscopy or minilaparotomy. Description of the techniques is beyond the scope of this article, but minilaparotomy can be performed by a specially trained nonobstetrician-nongynecologist.^{31,32} Whereas laparoscopy requires more sophisticated training and equipment, minilaparotomy requires only basic surgical skills and equipment. High-risk women who

are obese (greater than 110 percent ideal body weight), and those who have had previous abdominal surgery should be hospitalized. Acute pelvic infection is a contraindication for sterilization, and the procedure should be postponed.

Preoperative assessment consists of a history, physical examination, vital signs, and laboratory testing as indicated to assess for anemia. Ideally, surgery should be scheduled in the follicular phase (first half) of the menstrual cycle or while reliable contraception is being used. If there is concern, a pregnancy test can be performed; however, a pregnancy that occurs seven to 10 days before testing may be undetectable. A preoperative pelvic examination allows identification of infection or other abnormalities before surgery. A retroverted, easily mobile uterus can usually be easily manipulated during surgery, but a fixed uterus cannot.

Final Comment

Permanent sterilization is the contraceptive choice of many women. Whether performed in the interval time period or immediately postpartum, tubal sterilization is a safe and effective procedure. While safety and efficacy should be discussed with each prospective candidate, a more important issue for deliberation is whether the woman is making an informed decision. Is she choosing the best possible option for her current and future life circumstances? While ultimately the decision must be hers, clinicians can facilitate informed decision-making through the counseling content and approach. Counseling dialogue should include the permanence of the procedure, the lack of protection against STDs, the need for continued gynecologic preventive care (e.g., Papanicolaou smears, bimanual examination, mammography), and the context surrounding who may or may not be influencing the woman's decision.

Some women have reported that tubal sterilization positively affected sexual spontaneity and satisfaction because they felt less anxious about the possibility of unplanned pregnancy.

Minilaparotomy under local anesthesia is a safe alternative to conventional interval sterilization by laparoscopy and belongs in any general discussion of provision of this service.

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