

Permanent Contraception

FEMALE CONTRACEPTION

Female permanent contraception methods are the most popular contraceptive methods worldwide,¹ and are the fourth most commonly used method of contraception in Canada.² They are intended to be irreversible, and women should be counselled about the importance of being certain that they do not desire a pregnancy in the future. They should also be counselled on the availability of reversible contraceptive methods, including LARCs, which may confer additional non-contraceptive benefits. The decision to have a procedure for permanent contraception should be made without pressure or coercion.

Female permanent contraception methods may be performed laparoscopically, abdominally, or hysteroscopically. They include tubal interruption, salpingectomy (total or fimbriectomy), and transcervical tubal occlusion (Microinserts; Figure 11).

Procedures for female permanent contraception may be performed remote from a pregnancy (also called interval sterilization), post-abortion, or postpartum. Postpartum permanent contraceptive procedures are usually performed at the time of Caesarean section or after a vaginal delivery and should not extend a patient's hospital stay.^{3,4} Post-abortion permanent contraceptive procedures, either by laparoscopy or mini-laparotomy, can be performed immediately after an uncomplicated induced abortion with no increased risk compared to an interval procedure.⁵ A single anaesthetic can be used for both the abortion and the permanent contraceptive procedures.³

Efficacy

Although tubal ligation is highly effective, failures do occur and can occur many years after the surgery. The U.S. CREST study found a 5-year cumulative failure rate of 1.3% and a 10-year cumulative failure rate of 1.85%.⁶ (Table 15) A Canadian study found a 20-year cumulative failure rate of 0.9%.⁷ The risk of pregnancy varies by the occlusion technique used and by the age of the woman at the time of the procedure.⁶⁻⁸

In the CREST study, the most effective methods of tubal permanent contraception were postpartum partial

salpingectomy and laparoscopic unipolar coagulation, while the least effective was laparoscopic spring (Hulka) clip application.⁶ After adjusting for age, race/ethnicity, and study site, postpartum partial salpingectomy was significantly less likely to have a failure compared to interval partial salpingectomy, spring clip application, and bipolar coagulation. Women who had a permanent contraceptive procedure at 34 years and older were at significantly less risk of failure than women who were less than 33 years of age at the time of the procedure.⁶ Similarly, a Canadian study showed higher rates of sterilization failure in younger women compared to women over the age of 35 (1.5% versus 0.4%).⁷ The titanium Filshie clip was not included in the CREST study; subsequent large studies have documented a 0.2% failure rate 5 years or more after Filshie clip application.^{9,10}

The timing of permanent contraception failure may also vary by method. A high proportion of pregnancies after clip application occur in the first 3 years after the procedure, whereas pregnancies after bipolar coagulation occur at about the same rate year after year.^{6,11} Failure following a permanent contraceptive procedure may result from incomplete occlusion at the time of the procedure, application of the clip/coagulation on the wrong structure, or incorrect placement of the clip. Failures after partial salpingectomy, coagulation, and clip or band application may be due to tuboperitoneal fistula formation.¹¹ In a clinical trial of the transcervical tubal occlusion device, no pregnancies were reported among the 643 women who had tubal occlusion confirmed by HSG after the occlusion procedure.¹² In another study, out of 50 000 women who had the transcervical tubal occlusion procedure, 64 pregnancies were reported to the manufacturer between 1997 and 2005 (failure rate of 0.13%).¹³ Similarly, a large 10-year retrospective study reported a failure rate of 0.15%.¹⁴ Most failures occurred in women that did not have appropriate follow-up, while other causes included misread HSGs, undetected pre-procedure pregnancies, and failure to follow the product labeling guidelines.¹³⁻¹⁵ A systematic review concluded that among women who were followed beyond 3 months after hysteroscopic sterilization, pregnancies were rare and generally occurred among women who had no imaging follow-up or had inadequate confirmation of placement or

Figure 11A. A flexible insert is inserted under hysteroscopic visualization into each of the tubal ostia.

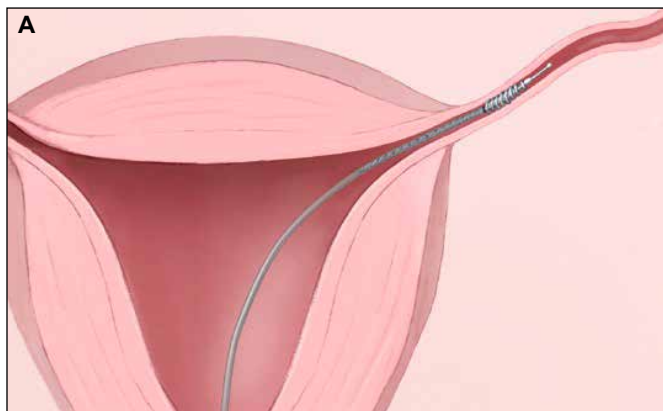


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occlusion.¹⁶ A French cohort study found that women who underwent transcervical tubal occlusion had significantly lower pregnancy rates compared to laparoscopic procedures (0.36% vs. 0.46%, hazard ratio 0.62, 95% CI 0.40 to 0.96).¹⁷ However, an evidence-based Markov model to estimate probability of pregnancy over 10 years after 3 different female permanent contraception procedures (hysteroscopic, silicone bands, and bipolar coagulation) estimated the expected pregnancy rates at 1-year were 5.7%, 0.7%, and 0.3%, respectively, and 10-year cumulative pregnancy rates were 9.6%, 2.4%, and 3.0%.¹⁸

There is potential for luteal phase pregnancies with interval procedures, even if there is a negative pregnancy test on the day of the procedure. Women should thus be counselled to consistently use a highly effective method of contraception up until the procedure and for the first week after the permanent contraceptive procedure is performed (laparoscopy or laparotomy).¹⁹ A pregnancy test should be done on the day of the procedure.³ If a woman has an intrauterine device in situ prior to a laparoscopic/laparotomy procedure, it should be left in place and not removed for at least one week after the tubal occlusion procedure.¹⁹ Women who are having a transcervical tubal occlusion procedure must continue to use an effective method of contraception for the first 3 months after successful coil placement and until an imaging study has confirmed bilateral tubal occlusion.

Postpartum permanent contraceptive procedures usually use a tubal excision method rather than an occlusion method and postpartum salpingectomy has one of the lowest failure rates of all the permanent contraception techniques.⁶ The titanium Filshie clip is significantly less effective than partial salpingectomy when used in the postpartum period^{4,20} and is not recommended immediately postpartum or at the time of Caesarean section.⁴

Figure 11B. A tissue barrier forms over the next 3 months.



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Mechanism of Action

Tubal ligation techniques result in the occlusion of the fallopian tubes, preventing the ovum and spermatozoa from meeting. The Filshie titanium clip works by exerting continuous pressure on the fallopian tube, which causes avascularization of the area it encompasses, a decrease in fallopian tube size, and fibrosis with subsequent peritonealization of the clip. The choice and timing of permanent contraceptive methods depends upon patient preference, medical and risk profile, health care provider's training, and access to services and technical facilities. Timing of the procedure (interval, post-abortion, or postpartum) influences the surgical approach and method of permanent contraception.

Hysteroscopic tubal occlusion techniques involve inserting a 4-cm coil containing occlusive material into the intramural portion of each fallopian tube under direct hysteroscopic guidance. The coil fibres elicit an inflammatory reaction and tissue in-growth occurs, creating tubal occlusion. An alternative method of birth control must be continued until tubal occlusion is verified by imaging studies.

Interval and post-abortal permanent contraceptive procedures are most commonly performed via laparoscopy using electrocoagulation, mechanical devices, or tubal excision. Bipolar electrocoagulation involves completely coagulating a 3 cm isthmic portion of the fallopian tube. Unipolar electrocoagulation is rarely used now due to past associations with thermal bowel injury.²¹ Mechanical occlusion devices such as silicone rings, spring-loaded clips (Hulka), or titanium clips lined with silicone rubber (Filshie) require a special applicator. The clips are applied to the mid-isthmic portion of the tube at right angles to the full axis of the tube so that they fully enclose the tube and the lower jaw of the clip is visible through the

Table 15. Pregnancy rates by sterilization method⁶

Method	5-year rate %	10-year rate % (95% CI)
Bipolar tubal coagulation	1.65	2.48 (1.63–3.33)
Unipolar tubal coagulation	—	0.75 (0.11–1.39)
Silicone ring	1.00	1.77 (1.01–2.53)
Spring clip (Hulka)	3.17	3.65 (2.53–4.77)
Interval partial salpingectomy	—	2.01 (0.47–3.56)
Postpartum partial salpingectomy	0.63	0.75 (0.27–1.23)
All methods	1.3	1.85 (1.51–2.18)
Titanium clip (Filshie)	0.2 ¹⁰	—
Hysteroscopy (Essure)	0.13 ¹²	0.15% ¹³ –9.6% ¹⁴ (—)

mesosalpinx. Mechanical devices are most effective when used to occlude a normal fallopian tube; the presence of tubal adhesions or dilated/thickened tubes may increase the likelihood of poor application and failure. In the presence of abnormal fallopian tubes, complete or partial salpingectomy is preferable.³ Although interval permanent contraceptive procedures may also be performed via a small (“mini”) laparotomy incision, mini-laparotomy procedures are generally reserved for postpartum procedures. Mini-laparotomy after a vaginal delivery is performed through a small infra-umbilical incision before the onset of significant uterine involution. The most common techniques used by mini-laparotomy, such as the Pomeroy, modified Pomeroy, and Parkland methods, involve a complete transection of the tubal lumen and excision of a sufficient section of the fallopian tube. Tubal segments should be sent to pathology to confirm complete transection.

Indications

Women who do not desire a future pregnancy and who do not wish to use a reversible method of contraception, particularly LARCs, may be candidates for a permanent contraceptive procedure. These procedures are intended to be irreversible, particularly transcervical tubal occlusion. In the case of regret, reversal procedures may be difficult to obtain, may be prohibitively expensive, may not be successful in restoring fertility, and may have associated procedural risks.^{7,22,23}

Only individuals who have capacity to give informed consent can agree to a permanent contraceptive procedure. While Canadian courts have the power to act on behalf of those who cannot care for themselves, that power can't be used to order sterilization for non-medical reasons without a person's consent. According to a 1986 Supreme Court ruling, a proxy decision-maker cannot consent to the

non-therapeutic sterilization of a mentally incompetent person.²⁴

The choice for permanent contraception has personal, social, and medical implications. It is important to provide adequate counselling and ensure informed consent.²⁵ Women should be aware of risk factors for regret, efficacy, safety, reversible contraceptive alternatives, and available sterilization techniques. In one British study, only 41% of women who had appointments for permanent contraception counselling had the procedure;²⁶ many women were unaware of highly effective LARCs and decided against permanent contraception after counselling.

If a woman is well informed about alternative contraceptive methods, as well as the permanency and risks of permanent contraceptive procedures, and she is making the decision free of coercion, then age, parity, and other practical concerns should not be a barrier to obtaining permanent contraception.³

In the case of hysteroscopic tubal occlusion procedures, only women who are willing to use an effective method of contraception for at least 3 months after the procedure and have a confirmatory test to confirm tubal occlusion should be considered. Because it can be performed in an outpatient clinic, transcervical tubal occlusion is associated with significant cost savings compared with tubal ligation procedures; however, this cost savings may not be as great when both procedures are performed in the operating room setting.^{27–29} At this time, access to transcervical permanent contraceptive procedures may be limited by a lack of trained providers and by the cost of the device; in some cases the cost is borne by the hospital, which may limit numbers, while in other cases it is borne by the individual, who may find it too costly as a contraceptive option.

Contraindications

There is no medical condition that would absolutely restrict a woman's eligibility for permanent contraception,³⁰ although there are some conditions in which the procedure should be delayed until the condition is evaluated and/or corrected.³¹ These include:

- Systemic health problems, especially cardiopulmonary conditions that may be aggravated by general anaesthesia (laparoscopic methods only).
- Pregnancy (unless a laparoscopic or mini-laparotomy procedure is done at the time of abortion or immediately postpartum). Hysteroscopic tubal occlusion is contraindicated in the first 6 weeks postpartum or post-abortion.
- Current or recent (within last 3 months) pelvic inflammatory disease or current sexually transmitted infection.
- Cervical, ovarian, or endometrial cancer (awaiting treatment) or malignant trophoblastic disease.
- Known allergy to contrast media (hysteroscopic tubal occlusion only).
- Uncertainty about whether permanent contraception is desired.

Women who have risks for, or contraindication to, laparoscopic procedures and who do not have a uterine or tubal anomaly may be candidates for transcervical tubal occlusion procedures. Women with uterine or tubal anomalies that may make insert placement difficult, may not be good candidates for a transcervical tubal occlusion procedure. Patients with a nickel allergy may have an allergic reaction to the inserts. Although there are reports in the literature,³² the manufacturer does not recommend performing a transcervical tubal occlusion and endometrial ablation at the same time because intrauterine adhesions may limit the ability to assess tubal patency. If both procedures are desired, an ablation may be performed after tubal occlusion has been documented.^{3,33}

Non-contraceptive Benefits

Tubal ligation, although initially invasive, provides women with an ongoing private, cost effective, coitally-independent method of contraception that does not rely on ongoing user adherence.

Multiple studies have shown an approximately 40% decreased risk of ovarian cancer after tubal sterilization.^{34–37} The degree of protection appears to be subtype-specific with a greater magnitude of risk reduction seen for endometrioid and clear cell cancers than for serous cancer.^{34,35,37} The protective effect provided by

tubal occlusion persists for over 30 years following the procedure and was not associated with age at the time of the procedure,³⁷ BRCA status, use of oral contraceptives, and parity.³⁸ This protective effect is likely attained by altering ovarian function, or by providing a barrier to ascending cancer cells or carcinogens.³⁹ Differences in subtype-specific protective effects of tubal ligation may be explained by their different cells of origin and the extent to which tubal ligation ablates or obstructs these cells from seeding the ovaries.³⁷ Most serous ovarian cancers appear to originate from precursor lesions at the fimbriated end of the fallopian tube,^{40–42} whereas most endometrioid and clear cell cancers seem to originate from exfoliated endometrial cells and are associated with endometriosis.⁴³ Excisional methods may confer greater risk reduction than other tubal ligation methods;³⁶ however, studies are needed to determine if tubal ligation procedures, such as salpingectomy, that ablate/remove a greater portion of the fallopian tube would result in greater reductions in the risk of ovarian cancer.³⁷

Permanent contraceptive methods do not protect against STIs/HIV and ongoing correct and consistent use of condoms is recommended if there is a risk of STI/HIV.^{30,31} However, permanent contraceptive procedures have been associated with a decreased risk of hospitalization for pelvic inflammatory disease presumably by preventing organisms from ascending into the upper genital tract and causing a bacterial peritonitis.⁴⁴

Side Effects

Following laparoscopic permanent contraception procedures, women may experience shoulder tip pain secondary to intraperitoneal CO₂, bruising or bleeding from incision sites, and lower abdominal pain or cramping. Prospective studies that have adjusted for possible confounders, such as previous use of oral contraceptives, have demonstrated that tubal ligation has little or no effect on menstrual bleeding patterns.^{45–48} Data from the CREST study found no difference in menstrual cycle length or intermenstrual bleeding but did find decreased amounts of bleeding and number of bleeding days compared to controls.⁴⁹ Current data on the effect of hysteroscopic transcervical tubal occlusion on menstrual patterns are conflicting.^{50,51}

Risks

Procedure-related Risks

The incidence of complications depends on the procedure performed (laparoscopy, laparotomy, hysteroscopy; mechanical, thermal, excisional, microinserts), the anaesthesia used (local or general), and the experience of the surgeon. Major complications from laparoscopic tubal ligation are

uncommon and overall complication rates are estimated to be 0.9% to 1.6%.⁵² Intraoperative complications include anaesthesia-related risks, uterine perforation with uterine manipulator, mesosalpingeal tears and trans-section of the tube from ring or clip application, injury to blood vessels, intestines or other organs (0.6 per 1000 cases), and unintended conversion to laparotomy (1.4 to 3.1/1000 cases).¹⁹ Thermal bowel injuries during tubal electrocoagulation may result in delayed bowel perforation and peritonitis.^{53–55} Independent risk factors for complications include diabetes, general anaesthesia, previous abdominal or pelvic surgery, and obesity.⁵² Postoperative complications include fever, wound infection, and bruising.

The overall complication rate with hysteroscopic transcervical tubal occlusion is approximately 2.7%.⁵⁶ In a review of over 4300 women who had office-based transcervical tubal occlusion procedures, none had a complication requiring more than 2 hours of observation.⁵⁶ Potential complications of hysteroscopic tubal occlusion include^{50,56–58}

- tubal perforation (1–5%),⁵⁸
- uterine perforation,
- hypervolemia from uterine distension medium,⁵⁷
- intraperitoneal (0.5–3.0%) or improper (0.5%) placement of the coil,
- coil expulsion (0.4–2.2%), and
- vasovagal syncope (0.9–5.0%).^{50,56,57}

Rates of unsuccessful bilateral coil placement at one session vary from 1.5% to 11.6%,^{51,56,59} and a follow-up procedure may be required. Subsequent procedures such as electrocautery, endometrial biopsy, dilatation and curettage, or endometrial ablation could potentially dislodge a microinsert or interrupt its ability to prevent pregnancy.

Post-Procedure Risks

Regret is one of the most common complications following a permanent contraceptive procedure. In a large American cohort study, the 5-year cumulative probability of regret among women after tubal sterilization was 7%.⁶⁰ Other recent studies among various countries have shown probabilities of regret varying from 2% to 5.5% in the years following permanent contraceptive procedures.^{10,61–63} In Western countries, the cumulative likelihood of expressing regret, requesting information about reversal of a permanent contraceptive procedure, and obtaining reversal, generally increases over the years following sterilization.^{7,64,65}

Younger age is a major risk factor for regret.^{22,62,64,66–68} During a follow-up interview within 14 years of tubal ligation,

20.3% of women who have had the procedure before age 30 expressed regret about undergoing the procedure, compared to 5.9% of those who had it after age 30.⁶⁴ A Canadian study showed that the cumulative probability of obtaining a reversal within 20 years of a tubal ligation was 4.2% in women who had the procedure before 31 years compared to 0.4% and 0.2% in women who had the procedure at age 31–35 years and 36–49 years, respectively.⁷

Other known risk factors for regret and reversal are the subsequent death of a child; having had fewer children than desired; having a current partner with no children prior to the current union or a change of partner after the tubal ligation; experiencing couple disharmony; pressure of the partner; and having less information about permanent contraceptive procedures and other contraceptive methods.^{7,64,65,67,68}

Ectopic pregnancy should be ruled out whenever a woman has signs of pregnancy following tubal occlusion. Of the pregnancies that occurred in the CREST study, 32.9% were ectopic; however, the overall rate of ectopic pregnancy was decreased compared to the general population with a 10-year probability of only 0.73%.⁶ The proportion of pregnancies that were ectopic varied by method, with the highest proportion occurring in women undergoing bipolar coagulation and the lowest proportion occurring in the spring clip group.⁶⁹ A more recent study found a 10-year and 15-year probability of ectopic pregnancy of 0.24% and 0.29%; the 10-year cumulative probability was 3.5 times higher for women who had the procedure before aged 28 compared to those who had it after age 33.⁷⁰

Myths and Misconceptions

“There is a risk of menstrual disturbance after tubal ligation.”

Fact: Prospective studies that have adjusted for possible confounders, such as previous use of oral contraceptives, have demonstrated that tubal ligation has little or no effect on menstrual bleeding patterns.^{45–48} Data from the CREST study found no difference in menstrual cycle length or intermenstrual bleeding but did have decreased amount of bleeding and number of bleeding days.⁴⁹

“A woman cannot have an MRI after a hysteroscopic transcervical tubal occlusion procedure or mechanical tubal occlusion.”

Fact: Women who have Essure inserts or who have had a tubal ligation using Filshie or Hulka clips may have an MRI. The Essure inserts are MR-conditional meaning that they do not pose any known hazards in a specified MRI environment with specified conditions of use.

“Patients with a nickel allergy cannot use Essure.”

Fact: Nickel sensitivity is not a contraindication to hysteroscopic tubal occlusion. However, patients with nickel sensitivity should be counselled that the microinserts do contain trace amount of nickel and that an adverse event secondary to nickel hypersensitivity is possible but very unlikely (< 0.01%).³

Initiation

Women who request permanent contraception should be carefully and comprehensively counselled. They should understand that the procedure is not intended to be reversible and that some factors, such as young age and other factors may increase the risk of regret. Alternate effective methods of contraception, particularly long-acting reversible contraceptives and vasectomy, should be discussed. Counselling should include the risk of failure (including the risk of ectopic pregnancy), the risk of regret, and the need for an effective contraceptive method to be used up until the day of the procedure; contraception should be continued for an additional week after laparoscopic procedures and an additional 3 months after hysteroscopic procedures (until tubal occlusion is verified).^{30,57} If compliance with abstinence or another method of contraception for 3 months will be problematic, health care providers may consider an injection of depot medroxyprogesterone acetate at the time of hysteroscopic sterilization to ensure adequate contraception for 3 months.

The choice of permanent contraceptive procedure should involve consideration of the woman's medical health, ability to tolerate office procedures, ability to comply with follow-up testing, the safety of abdominal surgery and general anaesthesia, insurance coverage, health care provider expertise and training, ovarian cancer risk reduction, and patient preference. Hysteroscopic tubal occlusion procedures may offer advantages over other permanent contraception procedures: no incision is required; it is performed under local anaesthesia and/or minimal sedation, in an office setting with a rapid recovery; and it has been shown to be highly effective and cost effective. It may thus be a better permanent contraceptive choice for women who are obese, have significant coexisting medical conditions, or who have intra-abdominal adhesive disease. Women who consent to a hysteroscopic procedure should be aware of the possibility that bilateral coil placement may not be possible in every patient.

Some experts are of the opinion that given the equivalent complication rates seen with tubal interruption and salpingectomy⁷¹ (even at Caesarean section), that salpingectomy does not leave women at risk of an intrauterine or ectopic pregnancy, and that salpingectomy

decreases the risk of ovarian cancer, bilateral salpingectomy should be routinely offered to women who are certain about their request for permanent contraception.⁷²

A medical and contraceptive history is essential. Key elements in the medical history are the woman's age, marital status, type of relationship, number and age of children, contraceptive experience, reasons for permanent contraception, and systemic health problems. The medical history should inquire about history of pelvic disease, previous abdominal or pelvic surgery, heart or lung disease, bleeding problems, allergies, medication, and previous problems with general anaesthesia.

Information about the type of operation—including risks and benefits, contraceptive alternatives, the possibility of failure, and the possibility of reversal—must all be discussed so that the individual can provide informed consent for surgical sterilization.

If a laparoscopic approach is chosen and a clip is used for the procedure, the clip should be applied after the fallopian tube has been identified out to its fimbriated end and placed on stretch. The clip should be placed on the isthmic portion of the tube, approximately 3 cm distal to the uterotubal junction, at a 90-degree angle relative to the long axis of the fallopian tube. The clips should be advanced over the tube until the tube reaches the hinge of the clip. When closed, the clip should include a small portion of mesosalpinx. When bipolar coagulation techniques are used, the surgeon should use a cutting wave form at 25 to 35 watts and coagulate 3 contiguous areas of the isthmic portion of the tube (approximately 3 cm), taking care to avoid transecting the tube.

With hysteroscopic procedures, a confirmatory test for tubal occlusion such as transvaginal ultrasound (TVUS),⁷³ pelvic X-ray, or HSG should be performed 3 months after insertion of intra-fallopian microinserts.^{19,74} This confirmatory test must be performed by a gynaecologist or radiologist who is trained in the assessment of microinsert position.⁷⁴ Although pelvic ultrasound^{59,75–79} or HSG can be used as a confirmatory test in Canada,⁷⁴ HSG is recommended in the following circumstances:⁷⁴

- suspicion of possible perforation during the procedure;
- difficulty identifying the tubal ostia due to anatomical variation or technical factors;
- uncertainty regarding placement at time of insertion;
- procedure time > 15 minutes;
- microinsert placement with zero (0) or > 8 trailing coils (i.e. coils protruding into the uterine cavity);

- transient or persistent post-procedure pain without any identifiable cause; or
- if X-ray or TVUS is equivocal or unsatisfactory.

Troubleshooting

Reversal

Couples who desire a pregnancy after a permanent contraception procedure have the option of tubal surgery/re-anastomosis or IVF.^{80,81} Both are expensive, carry health risks, and do not guarantee success. Pre-reversal assessment includes exclusion of possible male infertility factors, female ovulation disorders, and laparoscopic assessment of the tubal segments if the patient had a laparoscopic tubal ligation. IVF may be an option for women who are poor candidates for reversal surgery or who are older.⁸¹ The probability of reversal in one Canadian province, over 20 years, was respectively 4.2% and 3.9% for women and men who had a permanent contraceptive procedure performed before age 30, and 0.2% and 1.0% for those who had the procedure in their late 30s.⁷ Among women who had a reversal procedure performed, 73% of women who were sterilized before age 30 and 46% of those who were sterilized in their late 30s achieved a pregnancy after sterilization reversal.⁷ When using microsurgical tubal re-anastomosis, one study showed that intrauterine pregnancies occurred in 72% after ring procedures, 78% after clip procedures and 67% after Pomeroy procedures.⁸² Another study showed that women less than age 37 were significantly more likely to have a successful delivery after surgical reversal compared to IVF (72.2% vs. 52.4%), whereas women \geq 37 years of age had higher success rates with IVF compared to reversal (51.4% vs. 36.6%).⁸¹ After hysteroscopic tubal occlusion procedure, one small study showed implantation and successful pregnancy outcomes after IVF in 2 patients.⁸³ Another small study reported on successful hysteroscopic sterilization reversal; 19 of 70 patients (27%) who had a tubo-uterine implantation subsequently reported a live birth.⁸⁴

Bilateral tubal occlusion not confirmed on HSG at 3 months

Women **must** have follow-up imaging at 3 months to confirm tubal occlusion. This may include pelvic X-ray, TVUS, or HSG. According to the manufacturer's recommendations,⁸⁵ if occlusion at 3-month HSG is not confirmed, the patient should remain on alternative contraception for 3 more months and have a repeat HSG. If occlusion is again rated as unsatisfactory, then she should be advised not to rely on the microinserts for contraception. In a cohort of 203 patients who underwent hysteroscopic tubal occlusion,⁸⁶ the tubal patency rates at the 90-day and 180-day HSG were 16.1% (95% CI 7.4% to 31.7%) and 5.8% (95% CI 1.2% to 24.4%); the 90-day

patency rate was significantly higher than the 90-day rate of 8% reported in the 2003 multicenter phase III pivotal trial.⁸⁷

The risk of non-compliance with post-procedure imaging is increased with age less than 35 years, having 3 or more children, and the absence of an institutional protocol to keep track of patients after their hysteroscopic procedure.⁸⁶

Summary Statements

32. Women who do not desire a future pregnancy and who do not wish to use a reversible method of contraception, particularly long-acting reversible methods, may be candidates for a permanent contraception procedure. (III)
33. Only individuals who have capacity to give informed consent can agree to have a permanent contraceptive procedure. A proxy decision-maker cannot consent to the non-therapeutic sterilization of a mentally incompetent person. (III)
34. The 10-year cumulative failure rate of female permanent contraceptive procedures is less than 2%. (II-2)
35. Although the risk of pregnancy after a permanent contraception procedure is low, there is a substantial risk of an ectopic pregnancy if a pregnancy occurs after tubal ligation. (II-2) The absolute risk of ectopic pregnancy is lower than the risk among women not using contraception. (III)
36. Tubal ligation is associated with a decreased risk of ovarian cancer. (II-2)
37. Regret is one of the most common complications following a permanent contraceptive procedure with young age being a major risk factor. (II-2)
38. Tubal occlusion may not be complete for several months after the hysteroscopic procedure. An additional method of contraception is required for at least 3 months and until imaging confirms bilateral tubal occlusion. (II-2)
39. Salpingectomy may provide women, who are absolute in their decision, the additional benefit of risk reduction against ovarian cancer. (II-2)

Recommendations

33. Before providing permanent contraception, women should be counselled on the risks of the procedure, the risk of regret, and alternative contraceptive methods, including long-acting reversible contraceptives and male vasectomy. Informed consent must be obtained. (II-2A)
34. In a well-informed woman who understands her contraceptive options and the permanency of the procedure and who is capable of consent, age

and parity should not be a barrier to permanent contraception. (III-B)

35. Women should be advised to use an effective method of contraception up until the day of their permanent contraception procedure. A pregnancy test should be performed on the day of the procedure. (III-A)
36. Women undergoing a laparoscopic procedure should continue to use an effective method of contraception for one week following the procedure. (III-B)
37. Women having a hysteroscopic tubal occlusion procedure should use an effective method of contraception up until the day of surgery and for at least 3 months afterward until imaging studies have confirmed bilateral tubal occlusion. (II-A)

MALE VASECTOMY

National survey data indicate that 7.4% of sexually active women use male vasectomy as their method of contraception.² Compared to tubal ligation, vasectomy is safer, more effective, less expensive, and less invasive. It can be performed under local anaesthetic.^{3,19,88,89} Canada is one of only 8 countries in which vasectomy use is equal to or more frequent than tubal ligation for contraception.¹

Efficacy

Although vasectomy is highly effective, failures do occur and can occur many years after the procedure. The failure rate of male vasectomy in the first year is 0.15%⁹⁰ and the risk of pregnancy once post-vasectomy azoospermia or rare non-motile sperm has been confirmed is 1 in 2000.^{91,92}

The main cause of post-vasectomy conception is the failure of couples to use backup contraception immediately after the procedure.⁹³ Vasectomy is not effective immediately and couples must continue to use another effective method of contraception until one fresh PVSA shows azoospermia or $\leq 100\,000$ RNMS.^{19,92} The time from vasectomy to azoospermia or RNMS varies and may take weeks to months to occur,^{92,94} although most men are azoospermic by 3 months post-vasectomy and 98–99% are azoospermic by 6 months.⁹⁵ Spermatozoa persist in the seminal vesicles, and thus in the ejaculate, for 2 to 3 months or between 10 and 30 ejaculations after vasectomy;⁹⁶ recanalization cannot be assessed before such time or number of ejaculations have passed.⁹⁷ Recanalization is diagnosed when there is persistence of motile sperm or rising sperm concentrations on repeated semen analysis. Vasectomy is considered a failure if there are still motile sperm seen on PVSA at 6 months; at this time, a repeat procedure should

be considered.⁹² When vas occlusion techniques associated with low occlusive failure rates have been used, repeat vasectomy is necessary in $\leq 1\%$ of vasectomies.⁹²

Methods of vas occlusion are CV and MIV, which includes the NSV technique. Efficacy varies slightly with the type of vas occlusion technique used, surgeon experience,⁹² and the use of electrocautery and fascial interposition.^{98–101} In a large multi-centre randomized controlled trial, fascial interposition significantly decreased time to azoospermia, severe oligospermia, and failures based on semen analysis in men who underwent NSV compared with those who did not have fascial interposition.⁹⁸ Reported failure rates with intraluminal cautery and/or fascial interposition are less than 1%.^{91,92} Suture ligation of the vas without fascial interposition is not recommended because of higher failure rates (up to 11.5%).^{92,99}

Mechanism of Action

In a vasectomy procedure, the vas deferens is isolated first and then occluded, thus preventing motile sperm from being in the ejaculate (must be confirmed on PVSA 8 to 16 weeks after the procedure). The methods of vas isolation include MIV, which includes the NSV, and CV, which uses a larger incision. MIV techniques use a small scrotal incision (< 10 mm) and minimal dissection of the vas deferens and perivascular tissues with special instruments.⁹² Due to shorter operating times and decreased rates of hematomas, infections, and intraoperative pain,^{102,103} MIV techniques should be performed to isolate the vas deferens.^{19,92} The ends of the vas should be occluded by any one of 4 techniques that are associated with occlusive failure rates consistently below 1%.⁹² These include the following 3 divisional techniques:

- mucosal cautery with fascial interposition (no clips or sutures applied to vas);
- mucosal cautery *without* fascial interposition (no clips or sutures applied to vas);
- open-ended vasectomy that uses mucosal cautery and fascial interposition on the abdominal end of the vas and leaves the testicular end of the vas unoccluded.⁹²

Alternatively, non-divisional extended electrocautery can be used.⁹²

The goal of mucosal cautery is to destroy only the mucosal layer, which then scars to create a plug in the lumen, while avoiding thermal injury to the muscular layer so that the segment doesn't completely slough off and potentially result in recanalization.⁹¹ The goal of fascial interposition is to separate the 2 newly divided ends of the vas, thereby reducing the chance of recanalization. It is not necessary to remove any length of vas.⁹²

Table 16. Vas occlusion studies and failure rates

Occlusion method	Number of study arms	Number of patients	Range of occlusive failure rates, %
Mucosal cautery and fascial interposition	13	18 456	0.0–0.55
Mucosal cautery of both ends	6	13 851	0.0–1.00
Open testicular end, mucosal cautery of abdominal end, and fascial interposition	4	4600	0.0–0.50
Non-divisional extended electrocautery (Marie Stopes Technique)	1	41 814	0.64

When compared to other vas occlusion techniques, cauterization followed by division of the vas deferens (with or without excision), is associated with the lowest likelihood of early recanalization (failure). Vas occlusion should be followed by diathermy or ligation and fascial interposition due to high failure rates with division alone.¹⁹

Indications

Men who do not wish to have children in the future and would like a permanent method of contraception may be candidates for a vasectomy. Vasectomy procedures are intended to be irreversible. In the case of regret after the procedure, options for fertility include reversal procedures and sperm retrieval with IVF; however, these procedures may be difficult to obtain, may be prohibitively expensive, and may not be successful in restoring fertility.⁹² If the man is uncertain about his desire for future fertility, other reversible methods of contraception should be encouraged. Only individuals who have capacity to give informed consent can agree to have a permanent contraceptive procedure. According to a 1986 Supreme Court ruling, a proxy decision-maker cannot consent to the non-therapeutic sterilization of a mentally incompetent person.²⁴

Contraindications

There are no medical conditions that would absolutely restrict a man's eligibility for permanent contraception,^{31,104} although there are some conditions in which the procedure should be delayed (Category D) until the condition is evaluated and/or corrected (Table 16).³¹ These include

- local infection including scrotal infection, active sexually transmitted infection, balanitis, orchitis, or epididymitis;
- scrotal mass;
- gastroenteritis and systemic infection including currently ill with AIDS-related illness, and
- filariasis or elephantiasis.

Caution (Category C) should be used with men who are young, who have a depressive disorder, who have diabetes,

a previous scrotal injury, a large varicocele or hydrocele (might impair adequate localization of vas deferens), and unilateral undescended testis. Special arrangements (Category S) that include having an experienced surgeon and staff performing the procedure in a setting with equipment to provide general anaesthetic and other medical backup support should be made for men with an inguinal hernia (hernia should be repaired first or at the same time as vasectomy), bilateral undescended testes, AIDS on anti-retroviral therapy, coagulations disorders, and severe thrombocytopenia.³¹

Non-contraceptive Benefits

Vasectomy provides a man with a private and cost-effective method of contraception, with no significant long-term side effects, no adherence issues (other than using contraception until a PVSA demonstrates azoospermia and/or $\leq 100\,000$ non-motile sperm), and no interference with intercourse. At 5 years post-procedure, it is the most cost-effective method of contraception.^{105,106}

Vasectomy does not protect against STIs/HIV and ongoing correct and consistent use of condoms is recommended if there is a risk of STI/HIV.^{30,31}

Side Effects and Risks

The rate of complications has decreased with minimally invasive techniques, with an overall complication rate of 1% to 2%.⁹² Possible complications include:

- infection or hematoma (1–3%),^{91,107}
- epididymitis (1–3%),⁹²
- sperm granuloma (< 5%, rarely symptomatic),⁹²
- vasovagal reaction (up to 30%),
- early recanalization with persistent motile sperm on PVSA requiring reoperation (0.2–5.3%),¹⁰⁴ and
- late recanalization after previous clearance on PVSA (0.03–1.2%).^{104–108}

The risks of intraoperative and early postoperative pain, bleeding, and infection are related mainly to the method of

vas isolation as opposed to the method of vas occlusion.⁹² The risk of complications is also affected by surgeon experience.¹⁰⁷ Rare complications include Fournier's gangrene, vasocutaneous and vaso-urinary fistula, and trauma to neighbouring structures (i.e. perforated small hydrocele).^{98,107}

Post-Procedure Risks

The risk of chronic severe postoperative scrotal or testicular pain that interferes with quality of life is 1% to 2%.^{91,92} Non-steroidal anti-inflammatory medications may be used for symptom relief.¹⁹ Few of these patients will require additional surgery (i.e. vasectomy reversal).^{19,92}

Rates of regret following a vasectomy procedure range from 2 to 6%,^{7,109,110} although a large American cohort found that 19.6% of men who had undergone vasectomy desired more children in the future.¹⁰⁹ One American study found that 2% of men who had a vasectomy had a subsequent reversal procedure,¹⁰⁹ while a Canadian study found a 20-year cumulative probability of obtaining a vasectomy reversal of 2.6% (3.9% in men < 33 years of age, 1.0% in men > 37 years of age).⁷ Risk factors for regret include younger age,^{7,108,110} belonging to a religious group,¹⁰⁹ and having no children.¹⁰⁸ Six percent of women expressed regret within 5 years of their partner's vasectomy; the probability of requesting a reversal was significantly higher in women who reported substantial conflict with their male partner prior to the vasectomy procedure (RR 25.3, 95% CI 2.9 to 217.2).⁶⁰ The likelihood of obtaining a reversal generally increases over the years following sterilization.⁷

Immunological consequences for up to two thirds of vasectomized men include the development of anti-sperm antibodies that may persist for as long as 10 years after surgery.^{107,111} However, vasectomy does not appear to be associated with an increased long-term risk of autoimmune disease such as ankylosing spondylitis, asthma, diabetes, inflammatory bowel disease, multiple sclerosis, myasthenia gravis, rheumatoid arthritis, testicular atrophy, or thyrotoxicosis.¹¹²

Myths and Misconceptions

“Vasectomy increases the risk of prostate cancer.”

Fact: Based on the best available evidence to date, there does not appear to be an association between vasectomy and prostate cancer. One recent meta-analysis found no increased risk of prostate cancer in men with a history of vasectomy (RR 1.08, 95% CI 0.88 to 1.32).⁹² There does not appear to be an association between prostate cancer and age at vasectomy, time from vasectomy, or calendar year of vasectomy.¹¹³ A 2014 cohort study with 24 years of follow-up found that vasectomy was associated with a small increased risk of prostate cancer overall (RR 1.10,

95% CI 1.04 to 1.17).¹¹⁴ However, a subsequent meta-analysis performed by the American Urology Association included the results of the 2014 study and again found no significant increase in the risk of prostate cancer in men who had undergone vasectomy (RR 1.05, 95% CI 0.95 to 1.17).¹¹⁵ There is no evidence of an association between vasectomy and testicular cancer.^{19,116}

“Men who have a vasectomy are at an increased risk of cardiovascular disease and atherosclerosis.”

Fact: There does not appear to be an association between vasectomy and cardiovascular disease, atherosclerosis, thrombotic disease, or stroke.^{19,92,116,117}

“Vasectomy affects sexual function.”

Fact: Vasectomy does not affect sexual function.¹¹⁸ It does not affect the ability to obtain an erection, the duration of erection, or ejaculatory function.

Initiation

Men who request permanent contraception should be carefully and comprehensively counselled and written informed consent should be obtained prior to performing a vasectomy procedure.^{19,91,92,100} They should understand that vasectomy is intended to be permanent and that reversal procedures and other fertility options post-vasectomy are costly, may not be readily available, and may be unsuccessful. A medical, surgical, medication, and social history should be taken and known predictors of regret should be assessed. Failure rates (early and late), possible risks and complications, alternative family planning methods, and common myths and misconceptions should be discussed. Men should also be informed that vasectomy is generally safer, quicker to perform, and is associated with lower failure rates and less morbidity than female tubal ligation.¹⁹ Men who have a vasectomy procedure must be aware that it does not produce immediate sterility and another method of contraception must be used until vas occlusion is confirmed by PVSA.^{19,92,100} The American Urology Association advises that the issues of prostate/testicular cancer, coronary heart disease, stroke, hypertension, and dementia are not required routinely in pre-vasectomy counselling because vasectomy does not increase the risk of these conditions.⁹²

A physical examination of the scrotum should be performed to assess for scrotal abnormalities such as an undescended testis, testicular tumour, hydrocele or varicocele, to manually isolate the vas deferens, and to determine if the patient is a candidate for local anaesthesia. Men who are not able to tolerate manual isolation of the vas or whose vas are difficult to locate or isolate may require sedation or even general anaesthesia for their vasectomy procedure. Preoperative bloodwork is usually not required unless

Table 17. Category of recommendations for permanent contraception procedures

Category A	Accept	No medical reason exists to deny permanent contraception to a person with this condition.
Category C	Caution	The procedure is normally conducted in a routine setting but with extra preparation and precautions.
Category D	Delay	The procedure is delayed until the condition is evaluated and/or corrected. Alternative temporary methods should be provided.
Category S	Special	The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anaesthesia, and other backup medical support. Alternative temporary methods of contraception should be provided, if referral is required or there is otherwise any delay.

there is a suspicion of a coagulopathy.^{91,92} Prophylactic antibiotics are not indicated unless the individual is at an increased risk of infection.^{19,91,92}

Vasectomy should be offered with local anaesthesia with or without oral sedation.^{19,92} If it cannot be tolerated with local anaesthetic with/without oral sedation, it can be performed with IV sedation or under regional or general anaesthetic.⁹²

A minimally invasive approach should be used for vas isolation because it is associated with less pain and fewer early complications than CV.^{19,92,101,103} A technique for vas occlusion with a failure rate of $\leq 1\%$ should be used.⁹² Cauterization followed by division of the vas deferens (\pm excision) is associated with the lowest likelihood of early recanalization when compared with other methods. The use of clips has shown inconsistent results and is not generally recommended because failure rates are higher than those of other methods (Table 17).^{19,91,92} Routine histological examination of the excised parts of the vas deferens is not required.^{19,91,92}

Following the procedure, patients should be advised to use analgesics (non-steroidal anti-inflammatory and/or acetaminophen) and an ice pack as required. They should refrain from ejaculation and strenuous physical activity for one week after vasectomy to allow luminal occlusion to mature.^{91,92} The use of an athletic support/tight underpants may help to relieve symptoms, particularly in the first 48 hours after the procedure.¹⁹ Men should contact their health care provider if there is persistent bleeding, pain, possible infection, fever, or a rapidly enlarging scrotal hematoma.¹⁹ Men who have had a vasectomy procedure must be aware of the need to use additional contraception until sterility is confirmed and be provided with instructions on how and when to perform a PVSA. Up to 30% of men fail to submit a single PVSA hence it is important to reinforce the need for this test.¹⁰⁰

Although most studies advocate performing the first PVSA at 12 weeks post-vasectomy,^{19,91,92} PVSA can be performed

anytime between 8 and 16 weeks post-vasectomy.⁹² Earlier testing increases the probability of requiring additional tests.¹⁹ The number of post-vasectomy ejaculation should not be used as a guide for timing of the first PVSA because it is not reliably related to rates of azoospermia and RNMS.^{92,99,119} The PVSA should be performed on a fresh uncentrifuged specimen¹²⁰ within 2 hours of ejaculation and the report should indicate both the presence or absence of sperm and the presence or absence of sperm motility (non-motile sperm/mL).⁹² Patients can stop using a second method of contraception when the PVSA demonstrates azoospermia or rare non-motile sperm ($\leq 100\,000$ non-motile sperm/mL).^{19,92} A routine second PVSA is not required.¹⁹

Troubleshooting

“Motile sperm are seen on PVSA 12 weeks after the vasectomy procedure.”

Motile sperm should disappear within a few weeks after vasectomy if the vas has been successfully occluded.¹²¹ If motile sperm are seen on PVSA at 6 to 12 weeks, this indicates either recanalization or a technical failure.⁹² Repeat testing should be performed every 4 to 6 weeks until azoospermia or RNMS is seen.⁹¹ Delayed vasectomy success has been shown to occur in more than 50% of men with a first PVSA showing motile sperm.⁹⁴ However, motile sperm at 6 months indicates a vasectomy failure and a repeat vasectomy should be considered.^{19,92}

“More than 100 000 non-motile sperm/mL are seen on PVSA 6 months after vasectomy.”

Non-motile sperm concentrations $\leq 100\,000$ /mL on PVSA have a risk of pregnancy similar to a PVSA with azoospermia.¹²² Patients can discontinue other contraception after one PVSA shows either azoospermia or rare non-motile sperm ($\leq 100\,000$ /mL). If more than 100 000 non-motile sperm/mL are present on PVSA after 6 months, the decision to repeat the vasectomy is based on clinical judgement that includes trends in sperm count, patient preference, and the patient's tolerance for risk of

Table 18. Probability of pregnancy following vasectomy reversal^{125,127}

Time since vasectomy	Sperm in the semen, %	Pregnancy, %
Less than 5 years	91.0–98.6	63.3–88.0
5 to 10 years	88.0–97.6	68.8–82.0
10 to 15 years	91.0–95.3	55.1–86.0
More than 15 years	89.0–97.1	56.5–44.0

pregnancy.^{19,91,92}

“An individual who has had a vasectomy wishes to discuss options for future fertility.”

Options for fertility post-vasectomy include reversal (vasovasostomy or vasoepididymostomy) and assisted reproductive technology involving sperm aspiration and IVF. These options may be expensive and success cannot be guaranteed.⁹² The likelihood of success varies with surgical experience, past surgical history, pre-vasectomy fertility, testicular volume, and female partner age and fertility.^{123–125} The effect of the duration of the obstructive interval (time from vasectomy to reversal) on fertility outcomes is controversial. Some have shown that success rates are lower with a longer obstructive interval,¹²⁶ while other studies have not demonstrated any association between the obstructive interval and postoperative outcomes of vas patency and rates of spontaneous pregnancy (Table 18).^{125,127} The sperm count rises slowly after vasectomy reversal, and usually reaches a plateau by 6 months after surgery. However, recovery of physiologic fertility may take up to 2 years after vasectomy reversal.¹²⁴

In instances of older female partners, vasectomy reversal may have comparable success rates to assisted reproductive technology.¹²⁴ Counselling regarding vasectomy reversal should address fertility potential of the partner, potential complications, probability of success, and cost-effectiveness. Due to lower morbidity and costs, vasectomy reversal is the gold standard for fertility options post-vasectomy; however, in some clinical situations, such as advanced maternal age or decreased ovarian reserve in the partner, assisted reproductive technology may be a better option.¹²⁸

Summary Statements

40. Women and men who do not desire a future pregnancy and who do not wish to use a reversible method of contraception, particularly long-acting reversible methods, may be candidates for permanent contraception (III).

41. Compared to tubal ligation, vasectomy is generally safer, more effective, less expensive, and is a less invasive surgical procedure that can be performed under local anaesthetic. (II-2)
42. Vasectomy is not effective immediately. Once one fresh post-vasectomy semen analysis shows azoospermia or $\leq 100\,000$ non-motile sperm, the risk of contraceptive failure is 1 in 2000 (0.05%). Repeat vasectomy is necessary in $\leq 1\%$ of vasectomies. (II-2)
43. Vasectomy does not increase the risk of prostate/testicular cancer, coronary heart disease, stroke, hypertension, or dementia. (II-2)

Recommendations

38. Isolation of the vas deferens should be performed using a minimally invasive vasectomy technique such as the no-scalpel vas occlusion technique. Vas occlusion should be performed by any 1 of 4 techniques that are associated with occlusive failure rates consistently below 1%. (III-B)
39. Patients who have had a vasectomy should be advised that they may stop using a second method of contraception when one uncentrifuged fresh semen specimen shows azoospermia or $\leq 100\,000$ non-motile sperm/mL. (III-B)

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