This clinical practice guideline has been prepared by the Contraception Consensus Working Group, reviewed by the Family Physicians Advisory, Aboriginal Health Initiative, Clinical Practice – Gynaecology, and Canadian Paediatric and Adolescent Gynaecology and Obstetrics (CANCAGO) Committees, and approved by the Executive and Board of the Society of Obstetricians and Gynaecologists of Canada.

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Abstract

Objective: To provide guidelines for health care providers on the use of contraceptive methods to prevent pregnancy and on the promotion of healthy sexuality.

Outcomes: Guidance for Canadian practitioners on overall effectiveness, mechanism of action, indications, contraindications, non-contraceptive benefits, side effects and risks, and initiation of cited contraceptive methods; family planning in the context of sexual health and general well-being; contraceptive counselling methods; and access to, and availability of, cited contraceptive methods in Canada.

Evidence: Published literature was retrieved through searches of Medline and The Cochrane Database from January 1994 to January 2015 using appropriate controlled vocabulary (e.g., contraception, sexuality, sexual health) and key words (e.g., contraception, family planning, hormonal contraception, emergency contraception). Results were restricted to systematic reviews, randomized control trials/controlled clinical trials, and observational studies published in English from January 1994 to January 2015. Searches were updated on a regular basis and incorporated in the guideline to June 2015. Grey (unpublished) literature was identified through searching the websites of health technology assessment and health technology-related agencies, clinical practice guideline collections, clinical trial registries, and national and international medical specialty societies.

Values: The quality of the evidence in this document was rated using the criteria described in the Report of the Canadian Task Force on Preventive Health Care (Table 1).

Key Words: contraception, family planning, hormonal contraception, emergency contraception, barrier contraceptive methods, contraceptive sponge, spermicide, natural family planning methods, tubal ligation, vasectomy, permanent contraception, intrauterine contraception, counselling, statistics, health policy, Canada, sexuality, sexual health, sexually transmitted infection (STI)


This document reflects emerging clinical and scientific advances on the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the SOGC.
Table 1. Key to evidence statements and grading of recommendations, using the ranking of the Canadian Task Force on Preventive Health Care

<table>
<thead>
<tr>
<th>Quality of evidence assessment*</th>
<th>Classification of recommendations†</th>
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<tbody>
<tr>
<td>I: Evidence obtained from at least one properly randomized controlled trial</td>
<td>A. There is good evidence to recommend the clinical preventive action</td>
</tr>
<tr>
<td>II-1: Evidence from well-designed controlled trials without randomization</td>
<td>B. There is fair evidence to recommend the clinical preventive action</td>
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<tr>
<td>II-2: Evidence from well-designed cohort (prospective or retrospective) or case–control studies, preferably from more than one centre or research group</td>
<td>C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making</td>
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<td>II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category</td>
<td>D. There is fair evidence to recommend against the clinical preventive action</td>
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<tr>
<td>III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees</td>
<td>E. There is good evidence to recommend against the clinical preventive action</td>
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<td></td>
<td>F. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making</td>
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*The quality of evidence reported in these guidelines has been adapted from The Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.
†Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.


Chapter 4.
Natural Family Planning

Summary Statements

21. Natural family planning methods may be appropriate methods of contraception for couples who are willing to accept a higher rate of contraceptive failure than with other more effective contraceptive methods. (III)

22. The exact effectiveness of natural family planning (NFP) methods is difficult to estimate. When NFP methods are not adhered to and intercourse takes place during the fertile window, the risk of conception from a single failure is high. (III)

23. Many women and couples have used natural family planning methods, particularly withdrawal, at some point in their reproductive lives. (III)

24. Coitus interruptus ("withdrawal") as a risk-reduction strategy is preferable to no contraception at all, but typical-use failure rates are relatively high and it does not reliably protect against sexually transmitted infections. (II-2)

25. Lactational amenorrhea is an effective method of birth control when used by women who are less than 6 months postpartum, fully or nearly fully breastfeeding, and have not resumed menses postpartum. (II-2)

26. Abstinence is a contraceptive choice that requires supportive counselling and information-sharing from health care providers. (III)

Recommendations

23. Health care providers should respect the choice of a natural family planning (NFP) method, be aware of options for NFP, and be able to provide appropriate resources/counselling on the correct use of a woman or couple’s chosen method. (II-2B)

24. Natural family planning methods should not be proposed to women solely based on contraindications to another contraceptive method without a thorough review of other potentially safe and more effective methods. (II-2B)

25. Couples using natural family planning methods, including withdrawal and abstinence, should be provided with information about effective methods of emergency contraception and screening for sexually transmitted diseases. (III-B)

26. All pregnant or postpartum women should receive clear instructions on the lactational amenorrhea method of birth control and the criteria that must be met to achieve reliable contraception. (III-B)

Chapter 5.
Barrier Methods

Summary Statements

27. Latex condoms, used consistently and correctly, will provide protection against pregnancy (II-2) and sexually transmitted infections (STIs), including human immunodeficiency virus infection (II-1). However, no barrier contraceptive method can provide 100% protection from all STIs. (III)

28. Polyurethane and other non-latex male condoms have an increased incidence of breakage and slippage than latex condoms; hence, the protection they provide against sexually transmitted infections (STIs) and human immunodeficiency virus (HIV) infection is inferior to that of latex condoms (I). Polyurethane and polisoprene condoms remain important options for contraception and reduction of STIs in the presence of latex allergies. Lambskin condoms do not protect against HIV infection. (III)

29. The effectiveness of barrier methods can be complemented by the use of emergency contraception. (III)

30. The contraceptive sponge and spermicides used alone are not highly effective contraceptive methods; their effectiveness may be enhanced when used in combination with another contraceptive method. (II-2)
31. Contraceptive products containing nonoxynol-9 may cause vaginal epithelial damage and increase the risk of human immunodeficiency virus infection. (I)

**Recommendations**

27. Health care providers should promote the consistent and correct use of latex condoms to improve protection against pregnancy, human immunodeficiency virus infection, and other sexually transmitted infections. (II-2A)

28. Health care providers should educate women and men about the correct use of barrier methods. They should emphasize the need for dual protection against pregnancy and infections. (II-2B)

29. Women who use barrier methods of contraception should be counselled about emergency contraception. (III-B)

30. The use of spermicide-coated condoms should no longer be promoted. (I-A)

31. Diaphragms and cervical caps should continue to be available in Canada and appropriate training should be available for health care providers to become proficient in fitting diaphragms. (III-C)

32. Nonoxynol-9 products should not be used to reduce the risk of sexually transmitted infections and human immunodeficiency virus infection (HIV) and should not be used by women at high risk for HIV transmission. (I-A)

**Chapter 6. Permanent Contraception**

**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)

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 ≤ 100 000 non-motile sperm, the risk of contraceptive failure is 1 in 2000 (0.05%). Repeat vasectomy is necessary in ≤ 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**

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-2A)

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 ≤ 100 000 non-motile sperm/mL. (III-B)

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Natural Family Planning

NFP refers to methods of contraception that do not rely upon medical devices, compounds, or drugs. There are a range of NFP contraceptive strategies including FAB methods, lactational amenorrhea, withdrawal, and abstinence from penile–vaginal intercourse.¹ Health care providers may underestimate the effectiveness of these methods² or may not be familiar with how to appropriately counsel women or couples who wish to use NFP methods.

FERTILITY AWARENESS-BASED METHODS

FAB methods rely upon the knowledge that virtually all conceptions arise from intercourse that occurs from 5 days before to 1 day following ovulation.³ FAB methods of contraception rely upon avoiding unprotected intercourse during this “fertile window,” and can be used in combination with abstinence or barrier methods during the fertile time.

The fertile window can be identified by one of 2 means: by symptoms and signs of ovulation (the cervical mucus method, the symptothermal method, and the two-day method) or by calendar calculations of the fertile days (and SDM).

Effectiveness

It is challenging to calculate an accurate estimate of the effectiveness of FAB. With perfect use, the 1-year pregnancy rates are 0.4% for the symptothermal method and 4% and 5% for the standard days and two-day methods, respectively. With typical use, however, the 1-year pregnancy rate for all FAB methods is estimated to be 24%.⁴ When NFP methods are not adhered to and intercourse takes place during the fertile window, the risk of conception from a single contraceptive failure is high. Failure rates are affected by several known and suspected factors, including motivation on the part of both partners to avoid pregnancy, belonging to a country of origin where FAB methods are practised more widely, health care provider knowledge, quality of teaching given to women, coital frequency, and method of contraception used during the fertile window (abstinence vs. withdrawal vs. barrier method).⁵⁶ One-year continuation rates are low⁴ and 5% to 62% of couples using FAB methods report difficulty with mandated abstinence.⁷

Mechanism of Action

The mechanism of action of FAB methods is to avoid UPI when there is a high probability of fertilization.

Initiation

For all FAB methods, women and their partners must be educated about the fertile window and given specific instructions on how to use the method.

Standard Days Method

This method requires avoiding unprotected sexual intercourse on days 8 to 19 of the menstrual cycle in women who have a menstrual cycle from 26 to 32 days in length.⁸⁹ Several aids exist to help couples track their fertile window, including tracking on a calendar or use of cycle-tracking beads, web-based trackers, or mobile applications. Couples who use electronic applications to time intercourse should be familiar with the algorithm used by the program.

Calendar Days Method

Although this method has now largely been replaced by SDM, it may be useful to women whose cycles are not in the range of 26 to 32 days. A woman must track her natural menstrual cycle length for 6 to 12 months prior to using this method (during which time the risk of conception is significant). To determine the start of the fertile window, subtract 20 days from the length of her shortest cycle. To determine the end of the fertile window, subtract 10 days from the length of the longest cycle. Unprotected intercourse should be avoided during that time.

Symptothermal Method

The symptothermal method is a double-check method that evaluates cervical mucus to determine the first fertile day and then cervical mucus and temperature to determine the last fertile day.

Cervical Mucus (Billing’s Method)

Women are taught to monitor the volume and changes in cervical mucus throughout the cycle. As ovulation approaches, mucus becomes abundant, clearer, and more elastic. Fecundability is decreased 3 days after the clearest and most elastic mucus is produced. If the follicular response is very rapid, there may be mucus present during
menstruation. After ovulation, mucus first becomes thick, opaque, and reduces in volume significantly. Some practitioners advocate that couples using this method should have a coital frequency less than once every 2 days to allow vaginal contents to clear and allow better assessment of cervical mucus.

**Basal Body Temperature**

Wake-up body temperature is measured every day, using a special BBT thermometer, after at least 6 hours of sleep. The BBT is then recorded on a chart (or entered into a computer program) so that the woman can observe the rise in her BBT following the post-ovulatory elevation of progesterone. The BBT should rise by at least 0.5°C. To avoid pregnancy, there should be no unprotected intercourse from the beginning of the cycle until after 3 consecutive days of temperature elevation. For this reason, the BBT is usually used in combination with another contraceptive method for pregnancy prevention.

**Two-Day Method**

The two-day method is based on evaluation of cervical mucus and uses a simplified algorithm to identify a woman's fertile window. If cervical secretions were present “today” and “yesterday” a woman is “very fertile.” If cervical secretions were present either “today” or “yesterday” she is “fertile.” If there was no cervical mucus “today” or “yesterday” a woman’s fertility is low.

**USE OF FERTILITY MONITORS FOR CONTRACEPTION**

**Ovulation Predictor Kits**

OPKs use saliva patterns or urine LH measurements to assess when ovulation may occur. They are primarily indicated and marketed for those wishing to conceive, but they can be used to assist those using NFP. Because most conceptions occur from intercourse that precedes the LH surge, OPKs are only useful to indicate that ovulation has passed (once the LH reading returns to negative) and fertility is low until menses.

**Electronic Hormonal Fertility Monitors**

EHFM can be used to enhance NFP methods. A handheld device will indicate when after menses testing should commence. The device measures urinary LH and estrone-3-glucuronide (an estrogen metabolite) to indicate periods of high fertility. In one randomized trial comparing the fertility monitor to cervical mucus self-screening (with internet-based guidance for both groups), 12-month unintended pregnancy rates were significantly lower in the EHFM group (7% vs. 18.5%).

**Indications**

Fertility awareness-based methods may be a contraceptive option for:
- women and couples who wish to avoid contraceptive devices or drugs,
- women and couples wishing to augment the effectiveness of another (non-hormonal) contraceptive method by avoiding unprotected intercourse during the fertile window,
- women and couples for whom a relatively high risk of contraceptive failure is acceptable, and
- women and couples who wish to adhere to cultural or religious norms about contraception.

**Contraindications**

In general, FAB methods can be used without concerns for adverse health effects. However, some conditions may make their use more complex and require special counselling. FAB may not be suitable options when:
- women or their partners are unwilling to comply with abstaining from unprotected vaginal intercourse during fertile periods;
- women are unable to observe and chart the signs of fertility;
- women have conditions affecting body temperature regulation (fever, insomnia, irregular sleeping habits, shift workers);
- women have unpredictable or irregular menstrual cycles (e.g. polycystic ovarian syndrome, postpartum, perimenopause);
- women have difficulty assessing cervical mucus because of vaginal infection or use of vaginal agents (e.g., lubricants, spermicides);
- women are at high risk of acquiring an STI or HIV; or
- women have medical conditions for which pregnancy poses an unacceptable health risk or for personal reasons must avoid pregnancy, and thus a more effective method would be advisable.

**Non-contraceptive Benefits**

The main non-contraceptive benefit of any FAB method is that it provides a valid alternative for women and couples who wish to avoid medical devices or drugs to prevent pregnancy. NFP also helps women to learn about their own bodies and menstrual cycle, and can help women identify fertile days when conception is desired.

**Risks and Side Effects**

There is a relatively high probability of failure with all FAB methods if they are not used consistently and correctly. FAB methods do not provide protection against STIs.
CHAPTER 4: Natural Family Planning

Troubleshooting
Couples who chose FAB methods should be counselled about emergency contraception.

LACTATIONAL AMENORRHEA METHOD

This is an inexpensive and effective method of contraception used worldwide.

Effectiveness
LAM is only effective when all 3 following key criteria are met: \(^{14-16}\)

- the woman is less than 6 months postpartum;
- she is fully or nearly fully breastfeeding; \(^{1,17,18}\) and
- she has remained amenorrheic. \(^{14,15}\)

When used correctly, LAM is 98% effective. \(^{14}\) In a Cochrane review on LAM, no differences in effectiveness were seen in women who were taught and used LAM with the goal of contraception and those women who simply were fully breastfeeding for infant well-being (and by chance met the additional criteria for LAM). \(^{19}\)

Fully breastfeeding includes exclusive (infant receives no other liquid or food, not even water) and almost-exclusive (infant receives vitamins, water, juice, or other nutrients once in a while) breastfeeding. Nearly fully breastfeeding means that more than three quarter of all feeds are breast milk. \(^{20}\)

Mechanism of Action
The primary mechanism of action of LAM is suppression of the hypothalamic–pituitary–ovarian axis via disruption of GnRH pulsatility, resulting in decreased LH production and anovulation. \(^{21}\) Although ovulation may occur during LAM in the first 6 months postpartum, ovulation and the luteal phase rarely have normal characteristics. Only 60% of ovulations that precede the first menses have an adequate luteal phase to support a pregnancy. \(^{22}\)

Indications
The indications for LAM include:

- women and couples who wish to avoid and/or cannot afford contraceptive devices or drugs during the postpartum period,
- women and couples wishing a temporary method of fertility regulation during the postpartum period,
- women and couples for whom other family planning methods are either not readily available or not desired, and
- women and couples who wish to adhere to cultural or religious norms about contraception.

Contraindications
There are few medical conditions for which use of LAM is absolutely contraindicated as a contraceptive method. LAM is contraindicated when:

- any of the 3 conditions for LAM are not met,
- a woman has difficulties with breastfeeding that cannot be overcome with regular pumping,
- a woman has a medical condition for which another pregnancy or a short interval between pregnancies poses an unacceptable health risk, and thus a more effective method would be advisable,
- a woman has a contraindication to breastfeeding including maternal HIV, untreated active tuberculosis, use of drugs contraindicated with breastfeeding, and maternal drug abuse, or \(^{16,23}\)
- the newborn has a condition that makes it difficult to breastfeed (small-for-date or premature; needing intensive neonatal care; unable to digest food normally; or having deformities of the mouth, jaw, or palate) and the mother is not able to pump her milk regularly.

Non-contraceptive Benefits
The Canadian Paediatric Society recommends exclusive breastfeeding until the age of 6 months for healthy, term infants due to the numerous benefits it has for infants. \(^{24}\) Breastfeeding is also much less expensive than formula feeding, and is beneficial to maternal–child attachment. LAM does not have an effect on breast milk production.

Risks and Side Effects
Failure to use LAM correctly results in a relatively higher risk of failure from even one act of vaginal intercourse. Ovulation occurs as early as 26 days postpartum in non-lactating women, and fertility can be restored quickly when breastfeeding is reduced. \(^{22}\) Knowledge about LAM is poor across most populations, due partly to inconsistent information provided by health care practitioners. Evidence-based, factual instructions and information should be given to all couples regarding postpartum contraception. \(^{25}\)

LAM does not protect against STIs or HIV. In general, the use of LAM and breastfeeding in HIV-positive women should be discouraged. The Canadian Paediatric Society considers HIV infection a contraindication to breastfeeding \(^{23}\) and the Centers for Disease Control and Prevention recommend against LAM in HIV-positive women owing to the ease of access and safety of infant formulas in the United States. \(^{16}\) Health care providers should discuss possible contraindications to breastfeeding with women prior to initiating LAM, making use of expert consultation where appropriate.
WITHDRAWAL (COITUS INTERRUPTUS)

The prevalence of withdrawal (coitus interruptus) is largely underestimated by clinicians, as it is often not seen as a legitimate contraceptive method. However, it is widely used, and in a 2006 survey 11.6% of Canadian women reported using withdrawal as a contraceptive method. In one study from the United States, 58.8% reported ever using withdrawal as a contraceptive method.

Withdrawal has no direct associated health risks. It does not affect breastfeeding, it is inexpensive, requires no chemicals or devices, does not require consultation with a health care provider, and is readily available for primary use or as a backup method of contraception.

Effectiveness

The effectiveness of withdrawal depends on the willingness and ability of a couple to use withdrawal with every act of intercourse. Estimates from large population based studies estimate the typical-use failure rate of withdrawal at 22%. With perfect use, 4% of couples will experience pregnancy within 12 months.

Pre-ejaculate fluid consists of secretions from the Cowpers’ glands and the glands of Littre. There is controversy over whether or not there are sufficient quantities of motile sperm in pre-ejaculate fluid to lead to fertilization. In a study of 27 men and 40 samples of pre-ejaculate fluid collected and analyzed within 2 minutes, 37% contained a “reasonable number of motile sperm.” Theoretically, there are enough motile sperm in the pre-ejaculate of some men to fertilize an egg. Interestingly, among those who provided more than one sample, spermatozoa were either consistently present or consistently absent.

Mechanism of Action

During coitus, the male withdraws his penis from the vagina and away from the external genitalia of the female partner prior to ejaculation. Sperm is not ejaculated into the vagina or on the vulva, thereby avoiding contact between spermatozoa and the ovum.

Indications

Withdrawal may be a useful contraceptive option when:

- women and couples wish to augment the effectiveness of other contraceptive methods,
- women and couples wish to use NFP for contraception,
- a higher risk of contraceptive failure is acceptable to a woman or couple, and
- intercourse is infrequent.

Contraindications

This method should be avoided in the following circumstances:

- The man is not sure that he can reliably withdraw prior to ejaculation.
- There is a high risk of STI or HIV transmission, because withdrawal involves unprotected intercourse. Condom use is recommended for STI and HIV prevention.
- Women and couples are not accepting of a method with a relatively high typical-use failure rate.
- A woman has a medical condition for which a pregnancy poses an unacceptable health risk, and thus a more effective method would be advisable.

Non-contraceptive Benefits

In one study of HIV sero-discordant couples (man is HIV+ and woman is HIV−), users of withdrawal had lower rates of seroconversion than those couples having intercourse without withdrawal; however, this potential benefit must be weighed against an overall increased risk of HIV acquisition if barriers are not used because HIV-infected cells have been isolated from pre-ejaculate.

Risks and Side Effects

Use of withdrawal requires self-control. The man must have the ability to recognize impending ejaculation and to resist the urge to pursue coital orgasm. Withdrawal does not reliably protect against STIs or HIV. Correct and consistent use of condoms is recommended to decrease the risk of STIs and HIV transmission.

Initiation

Health care providers should inquire about use of withdrawal and provide information about its effectiveness. It can be used to augment the effectiveness of other contraceptive methods and for some couples may be a valid contraceptive strategy. For couples using only withdrawal and in need of very effective birth control, the reasons for choosing this method should be explored, and acceptable alternatives should be offered.

Troubleshooting

All couples using withdrawal should be counselled about currently available options for emergency contraception.
Emergency contraception should be strongly considered when there is any contact between ejaculatory fluid and the vulva or vagina. In some circumstances, STI testing\textsuperscript{31} and post-exposure prophylaxis\textsuperscript{32,33} may also be considered.

**ABSTINENCE**

Abstinence refers to delaying or avoiding some or all sexual behaviours. Abstinence may mean different things to different people. From a family planning perspective, it is only necessary for couples to avoid sexual acts that involve the introduction of seminal contents into the vagina; however, certain STIs may be transmitted from skin-to-skin contact. Primary abstinence refers to delaying some or all sexual behaviours by those who have never been sexually active. Secondary abstinence refers to the conscious decision to delay or avoid some or all sexual behaviours among those who have been sexually active in the past. Periodic abstinence refers to abstaining from penile–vaginal intercourse during the fertile window of the menstrual cycle.

Health care providers should support individuals who choose abstinence and assist them with negotiation and planning skills to use abstinence effectively. Health care providers can also ensure that individuals who are practising abstinence are aware of sexual health issues that may become relevant to them currently or in the future.

Adopting an “abstinence-only” approach to counselling in lieu of comprehensive sexual education may increase harm and does not delay coital début.\textsuperscript{34}

**Effectiveness**

Abstinence is 100% effective in terms of family planning, provided that semen is not introduced onto the vulva or into the vagina. Abstinence is not an effective STI protection strategy if individuals are engaging in other sexual activities.

**Indications**

Abstinence may be chosen by women or couples who prefer to abstain from certain sexual behaviours for personal reasons or whose cultural, moral, or religious beliefs restrict the use of other methods of family planning.

**Contraindications**

It may be difficult to maintain a relationship where there is strong discordance about the decision to abstain from sex. Conversely, delaying sex may give a couple time to get to know each other and may improve the quality of the relationship.\textsuperscript{35} The decision to become sexually active must be made individually and voluntarily without coercion by others.

**Non-contraceptive Benefits**

Abstinence does not cost anything unless barrier methods are used for other sexual acts. Individuals who practise abstinence have a decreased risk of STIs and HIV infection, and primary abstainers have a decreased risk of cervical cancer.\textsuperscript{36}

**Risks and Side Effects**

Abstinence may be too restrictive for some couples and may leave women and couples unprepared if sexual activity occurs they do not know how to reduce risks.

**Initiation**

What individuals define as abstinence is an important question with clinical implications. Couples and individuals practising abstinence deserve respect and non-judgemental support. They should be offered education about other methods of birth control and safer sex to help them if their sexual agendas change. Assisting with communication skills to transmit intentions to partners can be valuable, especially for young people. Those who practise abstinence should be informed about emergency contraception, STI screening, and post-exposure prophylaxis in their community.

Some women may discontinue other contraceptive methods when they are no longer in a relationship (secondary abstinence). However, secondary abstinence does not necessarily require that they take a “break” from their other contraceptive method.

**Troubleshooting**

Health care providers should determine with those choosing abstinence why they made this choice, what sexual activities they will say “yes” to, and whether they have discussed these with their partner. It is important to help them avoid high-pressure sexual situations and teach them techniques for saying “no.” It is also important to suggest that condoms be readily available in case they change their minds.

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26. Abstinence is a contraceptive choice that requires supportive counselling and information-sharing from health care providers. (III)

Recommendations

23. Health care providers should respect the choice of a natural family planning (NFP) method, be aware of options for NFP, and be able to provide appropriate resources/counselling on the correct use of a woman or couple’s chosen method. (II-B)

24. Natural family planning methods should not be proposed to women solely based on contraindications to another contraceptive method without a thorough review of other potentially safe and more effective methods. (II-B)

25. Couples using natural family planning methods, including withdrawal and abstinence, should be provided with information about effective methods of emergency contraception and screening for sexually transmitted diseases. (III-B)

26. All pregnant or postpartum women should receive clear instructions on the lactational amenorrhea method of birth control and the criteria that must be met to achieve reliable contraception. (III-B)

REFERENCES


Barrier Methods

Barrier methods of contraception use a mechanical or chemical barrier to prevent sperm from passing through the woman’s cervix into the uterus and fallopian tubes to fertilize an egg. Some barrier methods also protect against STIs. Many barrier methods such as male and female condoms, spermicides, sponges, certain cervical caps (FemCap), and diaphragms (Caya diaphragm) can be obtained without a prescription and do not require consultation with a health care provider before use. The silicone diaphragm (Milex wide-seal) requires an initial visit to a health care provider for fitting. For maximum effect, barrier contraceptive methods must be used correctly and consistently.

**MALE CONDOMS**

A male condom is a sheath that covers the penis during intercourse and acts as a physical barrier to prevent sperm from entering the vagina. Male condoms may be made of latex, polyurethane, polyisoprene, silicone, or lambskin. Condoms are a safe, effective, and inexpensive user-controlled method of contraception. In Canada, condoms are the most common method of contraception used by women of reproductive age.

Latex condoms provide protection against many STIs, although they are less effective in preventing STIs that are transmitted by skin-to-skin contact, such as herpes and HPV, than those that are transmitted by body fluids because they do not cover all of the infected skin area. The level of protection against each specific STI has not been quantified. Latex condoms are offered in a variety of shapes, sizes, textures, and colours. Novelty condoms, such as those offered in sex toy supply stores or catalogues, cannot be sold for the prevention of STIs or pregnancy and they should not be used concurrently with a latex condom because they are made of materials that may weaken the latex.

Latex condoms may have disadvantages such as decreased sensitivity during intercourse, difficulties putting on and removing, potential deterioration during storage or when exposed to oil-based lubricants, and risk of latex allergy. Non-latex condoms (polyisoprene, polyurethane, silicone, and lambskin) were developed as alternatives for people who had latex allergies, sensitivities, or preferences that prevented the consistent use of latex condoms. Non-latex condoms usually cost more than latex condoms. Polyurethane condoms transmit more body heat, which allows more sensitivity and a thinner feeling with a less constricting fit. They are more resistant to deterioration and can be used with oil-based lubricants. Lambskin (“natural membrane”) condoms prevent pregnancy but are not recommended for STI prevention. Laboratory tests have shown that viruses such as hepatitis B, herpes simplex virus (HSV), and HIV can pass through small pores on the surface of lambskin condoms.

In general, non-latex condoms do not perform as well as latex condoms due mainly to significantly higher odds of breakage or slippage. This may increase concerns regarding their ability to prevent pregnancy and STIs; however, the effect on contraceptive efficacy and STI prevention has not been well studied. Despite this, they may still be an acceptable alternative for those who cannot or are unwilling to use latex condoms.

**Efficacy and Effectiveness**

Condoms are very effective when used consistently and correctly. The estimated probability of failure with perfect use is 2%, whereas typical-use failure rates are approximately 18%. Randomized controlled trials have found significantly higher failure rates (breakage and slippage), typical-use pregnancy probabilities, and perfect use pregnancy probabilities with polyurethane condoms than with latex condoms. A systematic review also found significantly higher odds of breakage with non-latex condoms than with latex condoms, but no difference in typical-use failure rates between the Avanti polyurethane condom, the Standard Tactylon, and latex condoms. Polyisoprene condoms are made of synthetic latex, but do not have the allergenic component of natural rubber latex. There are no published data regarding their contraceptive effectiveness, but they are considered to be comparable to latex condoms due to similarity in manufacturing process and structural makeup.

There is no evidence that condoms lubricated with N-9 are more effective in preventing pregnancy or sexually transmitted infections than lubricated condoms that do
not contain N-9. Due to the potential adverse effects of N-9, including an increased risk of HIV transmission, the use of condoms lubricated with N-9 is not recommended.

**Mechanism of Action**
The condom acts as a mechanical barrier to prevent exchange of fluid and semen. Some condoms tend to fit better than others; optimal fitting requires trying a variety of condoms.

**Indications**
Condoms are indicated for the prevention of pregnancy and STIs. Ideally, condoms should be used in addition to another primary contraceptive method (dual protection), because condom use provides protection against STIs and additional backup contraception.

**Contraindications**
The only relative contraindication to latex condom use is an allergy or sensitivity to latex. Lanolin sensitivity is a contraindication to the use of lambskin condoms.

**Non-contraceptive Benefits**
Condoms provide protection against STIs. A recent review of the effectiveness of condoms against the most common STIs emphasizes both the overall positive level of protection provided by condoms as well as the limitations in study design in trying to quantify this effect. Latex condoms decrease the risk of transmission of STIs associated with cervical/vaginal discharge (chlamydia, gonorrhea, trichomoniasis). A Cochrane Review found consistent condom use can decrease AIDS/HIV transmission by 80%.

Regular and adequate use of condoms may also lower the risk of cervical neoplasia although there is no consistent evidence that it reduces the risk of HPV acquisition. Condoms can prolong ejaculatory latency in men who have rapid/premature ejaculatory difficulties.

**Side Effects**
Condoms may cause irritation. Spermicides used with condoms, including spermicide-coated condoms, increase the risk of E. coli urinary tract infections due to alterations in the normal vaginal flora. Alterations in vaginal flora, vaginal irritation, and superficial abrasions may actually enhance the risk of HIV transmission and hence spermicide-coated condoms are no longer recommended. Some men may complain of decreased sensation or loss of erection.

**Risks**
Technical problems with condom use (unrecognized leakage, slippage, breakage) are more common when men do not take enough time or care to properly apply the condom. Common errors in condom use include not using condoms throughout sex, applying the condom after penetration, removing it before ejaculation, not leaving space at the tip, not squeezing air from the tip, putting the condom on upside down, not using water-based lubricants (with latex and polyisoprene condoms), and incorrect withdrawal. Frequent problems with condom use included breakage, slippage, leakage, condom-associated erection problems, and concerns with fit and feel. Health care providers should be aware of these potential errors and problems when counselling patients on the use of condoms.

**Myths and Misconceptions**

- **“Everybody knows how to use a condom.”**
  *Fact:* Errors in condom use are common. Men and women require counselling on how to correctly and consistently use condoms in order to prevent condom “accidents” such as breakage or spillage.

- **“I can’t get an STI if I always use a condom.”**
  *Fact:* Condom use is a risk-reduction strategy. Consistent and correct use of latex condoms reduces the risk of transmission of many STIs and HIV but it does not provide absolute protection against any STI. Latex condoms decrease the risk of transmission of STIs associated with cervical/vaginal discharge such as chlamydia, gonorrhea, and trichomoniasis, and decrease the risk of HIV transmission. However, their protective effect against HPV is uncertain. Although one study showed a decrease in HSV-2 acquisition in consistent condom users whose partners were serodiscordant, skin-to-skin contact with an active lesion may still result in STI transmission. Novelty condoms are not approved for STI prevention.

**Initiation**
Condoms are available for purchase in pharmacies and in many sexual health clinics. Innovative programs have been developed to improve access to condoms for individuals who find them difficult or embarrassing to purchase. Condoms provided through school-based clinics or dispensing machines are innovative ways to improve uptake and use in young people. Condoms are covered under Health Canada’s NIHB program of.

**Proper Use and Precautions**
Packaged condoms can be kept for up to 5 years if they are stored in a dry place away from light and heat. Condoms should not be used after their expiry date. Condoms deteriorate more quickly when exposed to temperatures over 37°C, high humidity, and air pollution. Some condoms are pre-lubricated with silicone, jelly, or cream, which may help to prevent condom breakage during intercourse. Latex and polyisoprene condoms should only be used with water-based lubricants because oil-based
lubricants can weaken condom integrity, reducing tensile strength, elongation, burst pressure, and burst volume (Table 8). Condoms should not be disposed of in toilets.

Ideally, women and their partners should be educated on the correct use of condoms (Table 9), availability of emergency contraception, and STI screening. A new condom should be used with every act of intercourse. Condoms should not be reused. The condom must be put on after the penis is fully erect but before intimate contact.

In case of condom breakage or leakage, condom users should be aware of and consider emergency contraception as well as STI testing and PEP according to STI guidelines if necessary.

**Troubleshooting**

*I don’t have the same feeling with a condom.*

While condom use may reduce sensitivity, there is no objective evidence for this. Reduced sensitivity may be an advantage for some men by enhancing erection and preventing premature ejaculation. To increase sensation, the male partner may use a textured, ultra-thin, or polyisoprene condom; place a water-soluble lubricant inside the reservoir of the condom; use the condom while masturbating; or ask his partner to roll it up over his penis.

*I lose my erection when using a condom.*

Making the application of the condom by the partner a part of sex play, for example during oral sex or masturbation, or learning to use the condom while masturbating may help overcome this obstacle.

*I using a condom interferes with the spontaneity of sex.*

Condom use may interfere with, or interrupt, foreplay and impair erection. Encouraging the partner to put the condom on as a part of sex play; eroticizing condom use, and using a condom during sex play before intercourse may alleviate this problem.

*I am allergic to latex.*

Couples who have a latex allergy or sensitivity can consider using polyurethane or polyisoprene condoms for both contraception and STI prevention.

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**Table 8. Lubricants and products that are safe or unsafe to use with latex condoms**

<table>
<thead>
<tr>
<th>Safe</th>
<th>Unsafe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water and silicone-based lubricants</td>
<td>Baby oil, mineral oil, suntan oil, fish oil, coconut oil/butter, palm oil</td>
</tr>
<tr>
<td>(check package insert for confirmation)</td>
<td></td>
</tr>
<tr>
<td>Contraceptive foam and film</td>
<td>Olive oil, peanut oil, or vegetable oil</td>
</tr>
<tr>
<td>Glycerin USP</td>
<td>Margarine, butter</td>
</tr>
<tr>
<td>Egg white</td>
<td>Hemorrhoid or burn ointments</td>
</tr>
<tr>
<td>Saliva</td>
<td>Petroleum jelly (e.g., Vaseline)</td>
</tr>
<tr>
<td>Water</td>
<td>Rubbing alcohol</td>
</tr>
<tr>
<td>Vaginal moisturizers</td>
<td>Vaginal creams (e.g., Monistat, Estrace, Femstat, Vagisil, Premarin)</td>
</tr>
<tr>
<td></td>
<td>Some sexual lubricants (e.g., Elbow Grease, Hot Elbow Grease, Shaft)</td>
</tr>
</tbody>
</table>

*Check product insert and condom package for confirmation

USP: United States Pharmacopeial grade

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**Table 9. Using a condom**

- Put a drop or two of water-based lubricant or saliva inside the condom.
- Place the rolled condom over the tip of the erect penis.
- Leave a half-inch space at the tip to collect semen.
- If not circumcised, pull back the foreskin before rolling on the condom.
- Pinch the air out of the tip with one hand (friction against air bubbles causes most condom breaks).
- Unroll the condom over the penis with the other hand.
- Roll it all the way down to the base of the penis.
- Smooth out any air bubbles.
- After ejaculation and while the penis is still erect, hold onto the rim of the condom at the base of the penis so that the condom does not slip off.
- Do not spill the semen.
- Throw the condom away (do not flush down the toilet).
- Wash the penis with soap and water before any further contact.
“The condom breaks or slips during intercourse.”
Condom breakage may be due to rough handling, too much friction during intercourse, use of oil-based lubricants, incorrect storage (heat or light exposure), or usage after the expiry date. Condoms rarely slip off completely during intercourse, but they may slide down the shaft of the penis without falling off. The condom must be held at the base of the penis during withdrawal. Frequent slippage may indicate that the condom is too large and use of a more “snug” condom may be preferred. Emergency contraception should be used as soon as possible after a condom accident and STI testing/PEP should be considered according to the Canadian Guidelines on STIs.40

“My partner does not want to use condoms during intercourse.”
Health care providers can rehearse specific scenarios with their patients, walk through the process of when and how to purchase condoms, where to carry them, and when and how to bring up the subject of condom use. Negotiating skills to address resistance to condom use may be helpful.

FEMALE CONDOMS

The female condom is a soft, loose-fitting, seamless nitrile polymer sheath containing 2 flexible rings, one at each end. It is sometimes called an “internal condom.” The external ring at the open end of the condom sits outside the vagina and provides some perineal protection. The internal ring lies within the closed end of the pouch, allowing the condom to be inserted into the vagina and kept in place (Figure 3). The sheath is coated on the inside with a silicone-based lubricant. It can be placed in the vagina up to 8 hours before intercourse.41 The female condom does not deteriorate with exposure to oil-based products and withstands storage better than latex.

The FC2 female condom is the only female condom available in Canada, replacing the FC1 polyurethane female condom (Reality). The female condom can be purchased in pharmacies without a prescription.

Efficacy and Effectiveness
The 12-month pregnancy rate for perfect (correct and consistent) use of the female condom is 5%, while the typical-use failure rate is 21%.12 One randomized trial reported that the polyurethane female condom was as effective as a synthetic latex condom (5.24% vs. 4.3%).42 Potential reasons for failure of the female condom include: breakage (during intercourse or when withdrawing the female condom from the vagina), slippage (the FC slips completely out of the vagina during sexual intercourse), misdirection (during vaginal penetration the penis is inserted between the female condom and the vaginal wall), and invagination (the external retention feature of the condom is partially/fully pushed into the vagina during sexual intercourse).43

Mechanism of Action
The female condom is an intravaginal barrier. It lines the vagina completely, preventing contact. The female condom is not intended for use with a male condom, because the 2 condoms may adhere to one another and slip or become displaced.

Indications
The female condom is the only method of dual protection (against both pregnancy and STIs) available specifically for women. A woman who does not like the other vaginal barrier methods may prefer to use the female condom.

The female condom has several advantages. A woman can place it autonomously. It does not require an erect penis for insertion. It is also safe to use for those with a latex sensitivity and can be used with oil-based lubricants. Male partners may find it more comfortable and less constricting than male condoms. The internal and external rings may make sex more enjoyable for the male or both partners by increasing stimulation.44
Contraindications
There is no absolute contraindication to the female condom. Relative contraindications include an allergy to nitrile polymer, abnormal vaginal anatomy that may interfere with a satisfactory fit or stable placement, and inability to learn the correct insertion technique.

Non-contraceptive Benefits
The FC1 was made of polyurethane, which is impenetrable in vitro to organisms the size of HIV. There are no data available on efficacy and STI prevention for the synthetic nitrile polymer FC2, although it was approved on the basis that its properties were comparable to the polyurethane female condom. There are no current data demonstrating that female condoms are equivalent to male condoms with respect to STI prevention. One study noted more mechanical problems with the female polyurethane condom than the male condom and thus semen exposure may be significantly higher with the FC compared to the male condom, particularly with the first few uses of the FC.

Side Effects, Risks, and Challenges
Slippage, breakage, misdirection, and invagination are possible challenges associated with use of the FC. FC users must practise inserting the device to become confident. Although the rings may make sex more enjoyable by providing greater stimulation, they may also cause discomfort during coitus. Female condoms cost more than male condoms (approx. $3 each in Canada) and are noisier during intercourse; however, the new nitrile polymer FC2 may be less expensive and less noisy than the previous polyurethane versions.

Initiation
Female condoms do not need to be fitted. For correct use the following instructions must be followed:

- The FC must be inserted before penile penetration occurs. It can be inserted up to 8 hours prior to intercourse.
- Use a new FC for each act of intercourse.
- Remove immediately after intercourse by squeezing and twisting the outer ring before standing up to keep semen inside the pouch.
- Throw the FC away (do not flush).

Troubleshooting
If the female condom slips or breaks, emergency contraception should be used as soon as possible if a pregnancy is not desired. Testing for STIs or obtaining PEP according to STI guidelines may also be appropriate.

DIAPHRAGM AND CERVICAL CAP

Diaphragm
The diaphragm is an intravaginal barrier method of contraception that is used in conjunction with a gel. It fits into the vagina from the posterior vaginal fornix to behind the upper part of the pubic bone to cover the cervix.

There are currently 3 types of diaphragm available in Canada: the Milex Wide-Seal Silicone Omniflex Diaphragm (Figure 4), the Milex Arcing Diaphragm (not pictured; the arcing diaphragm is very similar in appearance to the wide-seal), and the Caya SILCS Diaphragm (Figure 5). The Omniflex diaphragm has a distortion-free spring that provides arc no matter where the rim is compressed and the arcing diaphragm has a tension-adjusted spring that curves in one place. The arcing diaphragm is recommended for women who have less pelvic support. The omniflex and arcing diaphragms
(size 65 to 95 mm) are available by prescription in pharmacies and must be fitted by a health care provider. Yearly replacement is recommended.

The SILCS diaphragm was approved by Health Canada in December 2013\textsuperscript{50} and is made of silicone and nylon. It is available in one size and measures 67 mm in width and 75 mm in length. It fits most women (standard diaphragm size 65 to 80 mm for traditional diaphragm fitting). It has grip dimples at the side of the rim to provide a cue for where to hold the diaphragm during insertion and a removal dome to facilitate removal. It is available at pharmacies or online without a prescription and can last up to 2 years.

**Cervical Cap**

The only cervical cap available in Canada is the silicone FemCap which was approved by Health Canada in March 2009 (Figure 6).\textsuperscript{51} This can be purchased online or with a prescription. Replacement is recommended every year. The cap comes in 3 sizes based on pregnancy history.

**Efficacy**

Efficacy rates vary depending on the study and the methodology used. With perfect use, 6% of diaphragm users will experience an unintended pregnancy in the first year of use compared to 12% with typical use.\textsuperscript{12} These rates are based on diaphragm use in conjunction with a spermicidal jelly or gel, which is no longer available in Canada. These numbers are not based on use with the lactic acid-based buffering gel (Caya gel, Contragel) that is currently available in Canada for use with diaphragms. A study in couples using the SILCS diaphragm with either a nonoxynol-9 or an acid-buffering gel, reported a 6-month perfect use pregnancy rate of 7.9% (95% CI 11.7% to 14.0%).\textsuperscript{52} With typical use, the 6-month pregnancy rate was 10.4% (95% CI 6.9% to 14.0%) which extrapolated to 12-month typical-use failure rate of 18.8% (95% CI 12.0% to 23.6%).\textsuperscript{52}

There are no data on the efficacy/effectiveness of FemCap with the currently available acid-buffering gel (Caya gel or Contragel). In a randomized study comparing the first model FemCap to the Ortho All-Flex diaphragm using 2% nonoxynol-9 gel, the 6-month pregnancy rates were 13.5% and 7.9%, respectively.\textsuperscript{53} Therefore, a woman's willingness to accept a higher risk of an unintended pregnancy may be a determinant in her suitability for these barrier methods.

**Mechanism of Action for Diaphragm and Cervical Cap**

The diaphragm and cervical cap serve as a physical barrier between sperm and the cervix and should always be used in conjunction with a gel that immobilizes or kills sperm. Currently, there is no nonoxynol-9 based jelly or cream available in Canada. Diaphragm or cap users should use an acid-buffering lubricant such as the SILCS diaphragm gel or Contragel, which contain water, lactic acid, sodium lactate, cellulose, and sorbic acid. The gel forms a physical celluolose barrier in front of the cervix and lowers the pH of the vaginal fluid, thereby inhibiting sperm motility.

A diaphragm or cervical cap can be inserted up to 2 hours before intercourse. An additional application of an acid-buffering lubricant is required with each repeated act of intercourse or if it has been more than 2 hours since the device/gel was originally inserted and intercourse has not yet occurred. An applicator is necessary for this repeat insertion.

All devices should be left in place for at least 6 hours after intercourse. Diaphragms should not be left in longer than 24 hours after insertion in order to decrease the risk of TSS. If there has been sexual intercourse within the last 6 hours, the diaphragm can be kept in situ more than 24 hours (until at least 6 hours have passed since the last act of intercourse). The cervical cap can be left in place for up to 48 hours.

**Indications**

Diaphragms and cervical caps may be suitable for women who do not wish to use hormonal contraception or for whom hormonal contraception is contraindicated. Diaphragms and cervical caps can also be used by breastfeeding women, by woman with a latex allergy or latex sensitivity, and those who are willing to accept a higher risk of an unplanned pregnancy taking into consideration the frequency of intercourse and the decrease in fertility associated with increasing age. The patient or her partner must be able to remove the diaphragm or cap.
Contraindications and Cautions
A history of HIV infection or being at high risk of HIV were previously considered absolute contraindications to use of the diaphragm or cervical cap because they were used with nonoxynol-9 containing-spermicides which themselves were associated with an increased risk of genital lesions and potential HIV transmission to uninfected sex partners. Nonoxynol-9 spermicidal gels are no longer available in Canada, hence there are currently no absolute contraindication to the cervical cap or the diaphragm. Relative contraindications include latex allergy (does not apply to silicone diaphragms or caps), silicone allergy (for silicone diaphragms and caps), and history of TSS.

A large cystocele, rectocele, or marked uterine prolapse may reduce the efficacy of the method. The SILCS diaphragm is not recommended if a woman requires a diaphragm size ≥ 85 mm or < 60 mm. After delivery or second trimester abortion, women should wait approximately 6 weeks until uterine involution is complete, and be refitted for a diaphragm or cap before re-using any of them. Refitting of the omniflex or arcing silicone diaphragms is also recommended after genital surgery or if the woman gains or loses 10 or more pounds.

Non-contraceptive Benefits
While some studies have suggested a decrease in risk for developing some STIs and cervical intraepithelial neoplasia in diaphragm users, others have studies have not. This has not been studied for the combination of diaphragm or FemCap and Caya gel currently available in Canada.

Risks and Side Effects
Diaphragm use is associated with an increased risk of persistent or recurrent UTIs, possibly because of pressure from the diaphragm's rim on the urethra and the concurrent use of spermicides. In a 6-month study comparing a 2% nonoxynol-9 based gel with the Ortho All-Flex diaphragm and the FemCap, there were significantly more UTIs in diaphragm users (12.4% vs. 7.5%), but the percentages of women who discontinued the study because they had 2 or more infections were around 1% in both groups.

The risk of TSS is increased slightly in women who use vaginal barrier methods of contraception. The annual incidence is 2 to 3 cases per 100 000 women. These TSS cases would result in less than 1 death per year (0.18) for every 100 000 vaginal barrier users.

Myths and Misconceptions
“All barrier methods protect against HIV infection.”
Fact: While male latex condoms protect against HIV infection, other barrier methods such as diaphragms and the cervical cap provide limited HIV protection because the vaginal mucosa is still exposed.

“Using a diaphragm or cervical cap alone, without a gel that immobilizes or kills sperm, is as effective as using it with the gel.”
Fact: There are no conclusive studies indicating that a diaphragm or cervical cap is equally effective at preventing pregnancy if used with or without an acid-buffering gel or spermicide. Manufacturers continue to recommend that a gel that immobilizes or kills sperm be used with barrier methods such as the diaphragm and cervical cap.

Initiation
Omniflex or arcing silicone diaphragm
A pelvic examination by a qualified health care provider is required for fitting the Omniflex or Arcing Silicone diaphragms. Fitting ring sets are available from the manufacturer. Fitting rings are produced in 5 mm increments (65–85 mm in diameter), but Milex Wide-Seal Silicone Omniflex diaphragms are available in sizes ranging from 60 to 95 mm. The woman should be fitted with the rim type (Omniflex or Arcing) type that she will ultimately use and may practice with it under the supervision of her health care provider.

Cervical Cap
The cervical cap should fit comfortably over the cervix with the brim adhering to the vaginal fornices.

Before a woman can successfully use the diaphragm or cervical cap, she will require detailed instructions for insertion, the opportunity to practice, and assistance/reassurance from her health care provider. Online videos can help to demonstrate how to insert the device. Providing information about the availability of, and indications for, emergency contraception, STI screening, and PEP is also important.

Troubleshooting
If a diaphragm user is experiencing recurrent UTIs, a refit or change of rim type may help, or she may wish to try the cervical cap which has been associated with lower odds of UTIs than diaphragms. Post-coital voiding or antibiotic use may help.

CONTRACEPTIVE SPONGE AND SPERMICIDES

Contraceptive Sponge
The sponge is a small, disposable, polyurethane foam device that is used intravaginally. The Today sponge, a pillow-shaped sponge containing nonoxynol-9, is the only contraceptive sponge available in Canada. It comes in one size only and is
available in pharmacies without a prescription. The concave dimple on one side fits over the cervix to provide a physical barrier to sperm and a woven polyester loop on the other side facilitates removal (Figure 8).

### Spermicides

Spermicides are composed of a spermicidal agent in a carrier that allows dispersion and retention of the agent in the vagina. Nonoxynol-9 (N-9) is available in Canada as a vaginal contraceptive film or as foam. Spermicides are available without a prescription. The use of a spermicide alone provides less effective contraception than using it in combination with a barrier method.

**Vaginal contraceptive film** is a 2-by-2 in. sheet of film containing 28% nonoxynol-9 (Figure 9). It must be inserted at least 15 minutes before intercourse in order to melt and disperse. If more than 3 hours have elapsed before intercourse, another film must be inserted.

### Effectiveness

The Today sponge has a perfect use failure rate of 9% in nulliparous women and 20% in parous women.12 Typical failure rates are 24% in parous users and 12% in nulliparous women.68 Effectiveness can be increased by using the sponge in combination with a male condom.68 A review of clinical trials found that the sponge was less effective than the diaphragm in preventing pregnancy, and discontinuation rates were higher.69

Vaginal spermicides are among the least effective of all modern family planning methods.70 Studies are difficult to compare and vary widely in size, focus, and quality.71 A recent review concluded that the currently available studies are of insufficient quality to predict pregnancy rates with spermicide use.70 Failure rates in the first year of use vary from 18% with perfect use to 28% with typical use.12

### Mechanism of Action

The contraceptive action of the sponge is primarily provided by the action of the impregnated spermicide, augmented by its ability to absorb and trap sperm. The sponge acts as a sustained release spermicidal reservoir for a period of 24 hours. Spermicides are composed of a spermicidal agent in a carrier that allows dispersal and retention of the agent in the vagina. Nonoxynol-9 is a surfactant that destroys the...
sperm cell membrane. It is not a microbicide, and should only be used for contraceptive purposes, not as a lubricant or for STI prevention.

**Indications**
The sponge or the spermicide may be suitable for women who wish to avoid pregnancy but who also wish to and/or must avoid hormonal contraception, intrauterine contraceptives, or other barrier methods. Women who use the sponge or the spermicide alone should be aware of its higher failure rate compared to other methods of contraception. Some women choose the sponge because of its prolonged 24 hours of protection. The sponge or the spermicide may be used with other barrier methods to increase its effectiveness.

**Contraindications**
The only absolute contraindication to the sponge or the spermicide is being at high risk for HIV because nonoxynol-9 increases the risk of vaginal and cervical irritation or abrasions and thus, the transmission of HIV. Relative contraindications include:
- an allergy to nonoxynol-9,
- being HIV-positive or having AIDS due to increased risk of HIV transmission to uninfected sex partners,
- use of antiretroviral therapy and a history of TSS.

The following conditions may not be compatible with the use of the sponge or spermicides:
- abnormal vaginal anatomy that interferes with satisfactory insertion of the spermicide or stable placement of the sponge,
- inability to use correct insertion technique,
- repeated UTIs, or
- full-term delivery within the past 6 weeks, a recent spontaneous or induced abortion, or vaginal bleeding, including menstrual flow (for sponges only). If there is a personal or medical need for highly effective.

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**Table 12. Instructions for diaphragm use**

**PRIOR TO INSERTION**
1. Wash hands. Check the diaphragm for holes, cracks, or tears by holding it up to the light
2. Check the expiration date of the Caya gel/Contragel
3. Insert the diaphragm no more than 2 hours before having sex
4. Prior to insertion of a diaphragm, put a teaspoon of acid-buffering gel into the bowl of the diaphragm and around the rim.

**INSERTION**
Press the rim together and push the diaphragm into the vagina as far as it will go. Feel the diaphragm to ensure that it covers the cervix. If uncomfortable, take it out and insert again.

**AFTER INTERCOURSE**
Keep in place for at least 6 hours after sex. It should not be kept in longer than 24 hours.
For multiple acts of sex, ensure the diaphragm is in the correct position and insert additional gel into the vagina before each act of sex.

**REMOVAL**
Wash hands. Insert a finger into the vagina, under the rim of the diaphragm, pull it down and out. The diaphragm should be washed with mild soap and clean water and dried after each use.

**Table 13. Instructions for cervical cap use**

**INSERTION**
1. Place 1/2 teaspoon of Caya gel in the groove between the dome and brim of the cervical cap. Place 1/4 teaspoon in the bowl of the device with a small amount over the brim.
2. Flatten the device by squeezing it. Place in the vagina with the bowl facing upward and the long brim directed toward the woman’s back until it covers the cervix.

**REMOVAL**
1. Must be left in place for at least 6 hours after intercourse (no more than 48 h)
2. To remove the device, the woman should squat and bear down to bring the device closer to the fingers. The device should be rotated and removed by breaking the suction using the finger strap.
contraception, the sponge or the spermicide should not be the first contraceptive choice. The sponge and spermicides with nonoxynol-9 should also not be recommended to sex workers or to women with at increased risk of HIV infection.\textsuperscript{72}

**Non-contraceptive Benefits**
There is currently no evidence that the sponge or spermicides reduce the risk of acquiring STIs such as gonorrhea, chlamydia, or trichomoniasis.\textsuperscript{72}

**Risks and Side Effects**
The risk of TSS that is present with vaginal barrier use also applies to sponge use.\textsuperscript{62} Sponge users must be aware of the symptoms and signs of TSS and recommended precautions.

Genital irritation associated with nonoxynol-9 can lead to easier transmission of HIV.\textsuperscript{16,72} In a randomized study of sex workers in HIV endemic countries, there was a statistically increased risk of developing HIV in women who used spermicide more than 3.5 times daily and no reduction of HIV in those who used it less frequently.\textsuperscript{26} The use of spermicides has also been associated with an increased risk of urinary tract infection.\textsuperscript{73,74}

**Myths and Misconceptions**

**“Sponges and spermicides offer protection against STIs.”**
*Fact:* Sponges are not microbicides. Nonoxynol-9 is not an effective microbicide; it may potentially damage vaginal mucosa and thus may enhance HIV transmission.\textsuperscript{16,72,75,76} Spermicides have no protective effect against chlamydia, gonorrhea, or trichomonas infections.\textsuperscript{73} Condoms should always be used for STI prevention. Although nonoxynol-9 increases the risk of HIV infection when used frequently by women at high risk of infection, it remains a contraceptive option for women at low risk.

**“Use of a spermicide alone provides contraceptive that is as reliable as the use of a barrier method.”**
*Fact:* Spermicides used alone have a substantially higher failure rate than other contraceptive methods\textsuperscript{12} and quality studies of efficacy are lacking.\textsuperscript{70}

**“Nonoxynol-9 lubricated condoms are more effective than regular condoms.”**
*Fact:* Condoms lubricated with or without nonoxynol-9 are similarly effective in preventing pregnancy.\textsuperscript{76} The use of condoms lubricated with nonoxynol-9 is associated with an increased risk of UTIs.\textsuperscript{24}

**Initiation of the Sponge**
The contraceptive sponge (Today sponge) can be inserted up to 24 hours before intercourse. Protection begins immediately and lasts for 24 hours even with repeated acts
Table 14. How to use spermicides

- Read and follow the package instructions
- Insert spermicide high in the vagina to cover the cervix
- Use the appropriate amount of spermicide
- Wait the recommended time between insertion and intercourse
- Insert an additional application of spermicide with every act of intercourse
- Do not douche for at least 6 hours after intercourse
- Always have additional supply of spermicides

of intercourse. It must be left in the vagina for at least 6 hours after the last act of intercourse but should not remain in the vagina for more than 30 hours total.

Prior to using the sponge, women should wash their hands. The sponge should be moistened with 2 tablespoons of water and squeezed once in order to activate the spermicide. With the dimpled side of the sponge facing the cervix, the sponge is folded upward and inserted deep into the vagina. The sponge must cover the cervix and the loop should be on the bottom to facilitate removal. The sponge must be inserted before the penis enters the vagina. The sponge must be left in place for at least 6 hours after the last act of intercourse, and then can be removed by pulling on the loop.

Initiation of Spermicides

It is important to read and follow the instructions carefully, especially the length of time from insertion of the spermicide to intercourse, and the duration of effectiveness (See Table 14).

Spermicide users should be counselled about the use of emergency contraception in the event that they fail to use the spermicide or it was not used correctly.

Troubleshooting

Inserting a contraceptive sponge or a spermicide should be practised before coitus takes place, in order to increase comfort with use. If genital irritation or unpleasant odour occurs, infections such as STIs, vaginal moniliasis, and bacterial vaginosis should be ruled out.

Summary Statements

27. Latex condoms, used consistently and correctly, will provide protection against pregnancy (II-2) and sexually transmitted infection (STIs), including human immunodeficiency virus infection (II-1). However, no barrier contraceptive method can provide 100% protection from all STIs. (III)
28. Polyurethane and other non-latex male condoms have a higher incidence of breakage and slippage than latex condoms; hence, the protection they provide against sexually transmitted infections (STIs) and human immunodeficiency virus (HIV) infection is inferior to that of latex condoms (I). Polyurethane and polyisoprene condoms remain important options for contraception and reduction of STIs in the presence of latex allergies. Lambskin condoms do not protect against HIV infection. (III)
29. The effectiveness of barrier methods can be complemented by the use of emergency contraception. (III)
30. The contraceptive sponge and spermicides used alone are not highly effective contraceptive methods; their effectiveness may be enhanced when used in combination with another contraceptive method. (II-2)
31. Contraceptive products containing nonoxynol-9 may cause vaginal epithelial damage and increase the risk of human immunodeficiency virus infection. (I)

Recommendations

27. Health care providers should promote the consistent and correct use of latex condoms to improve protection against pregnancy, human immunodeficiency virus infection, and other sexually transmitted infections. (II-2A)
28. Health care providers should educate women and men about the correct use of barrier methods. They should emphasize the need for dual protection against pregnancy and infections. (II-2B)
29. Women who use barrier methods of contraception should be counselled about emergency contraception. (III-B)
30. The use of spermicide-coated condoms should no longer be promoted. (I-A)
31. Diaphragms and cervical caps should continue to be available in Canada and appropriate training should be available for health care providers to become proficient in fitting diaphragms. (III-C)
32. Nonoxynol-9 products should not be used to reduce the risk of sexually transmitted infections and human immunodeficiency virus (HIV) infection and should not be used by women at high risk for HIV transmission. (I-A)

REFERENCES


27. Fennell J. “And isn’t that the point?”: pleasure and contraceptive decisions. Contraception 2014;89:264–70.


CHAPTER 5


Permanent Contraception

**FEMALE CONTRACEPTION**

Female permanent contraception methods are the most popular contraceptive methods worldwide, and are the fourth most commonly used method of contraception in Canada. 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. 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. A single anaesthetic can be used for both the abortion and the permanent contraceptive procedures.

**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% (Table 15). A Canadian study found a 20-year cumulative failure rate of 0.9%. The risk of pregnancy varies by the occlusion technique used and by the age of the woman at the time of the procedure.

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. 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. 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%). 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.

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. 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. 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. 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%). Similarly, a large 10-year retrospective study reported a failure rate of 0.15%. 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. 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
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). 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%.

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). A pregnancy test should be done on the day of the procedure. 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. 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. The titanium Filshie clip is significantly less effective than partial salpingectomy when used in the postpartum period and is not recommended immediately postpartum or at the time of Caesarean section.

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. 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
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. 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. 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.

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The choice for permanent contraception has personal, social, and medical implications. It is important to provide adequate counselling and ensure informed consent. 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; 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. 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. 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.

**Table 15. Pregnancy rates by sterilization method**

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

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

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. 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. 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, BRCA status, use of oral contraceptives, and parity. This protective effect is likely attained by altering ovarian function, or by providing a barrier to ascending cancer cells or carcinogens. 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. Most serious ovarian cancers appear to originate from precursor lesions at the fimbriated end of the fallopian tube, whereas most endometrioid and clear cell cancers seem to originate from exfoliated endometrial cells and are associated with endometriosis. Excisional methods may confer greater risk reduction than other tubal ligation methods; 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.

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. 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.

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. 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. Current data on the effect of hysteroscopic transcervical tubal occlusion on menstrual patterns are conflicting.

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%. 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). Thermal bowel injuries during tubal electrocoagulation may result in delayed bowel perforation and peritonitis. Independent risk factors for complications include diabetes, general anaesthesia, previous abdominal or pelvic surgery, and obesity. Postoperative complications include fever, wound infection, and bruising.

The overall complication rate with hysteroscopic transcervical tubal occlusion is approximately 2.7%. 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. Potential complications of hysteroscopic tubal occlusion include:

- tubal perforation (1–5%),
- uterine perforation,
- hypervolemia from uterine distension medium,
- 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%).

Rates of unsuccessful bilateral coil placement at one session vary from 1.5% to 11.6%, 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-Procedural Regret
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%. Other recent studies among various countries have shown probabilities of regret varying from 2% to 5.5% in the years following permanent contraceptive procedures. 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.

Younger age is a major risk factor for regret. 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. 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.

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.

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%. 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. 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.

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. 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.

“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 amounts of nickel and that an adverse event secondary to nickel hypersensitivity is possible but very unlikely (<0.01%).

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). 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 salpingectomy (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.

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), pelvic X-ray, or HSG should be performed 3 months after insertion of intra-fallopian microinserts. This confirmatory test must be performed by a gynaecologist or radiologist who is trained in the assessment of microinsert position. Although pelvic ultrasound or HSG can be used as a confirmatory test in Canada, HSG is recommended in the following circumstances:

- 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);

Some experts are of the opinion that given the equivalent complication rates seen with tubal interruption and salpingectomy, 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.

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.

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- 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. 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. 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. 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. 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. 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 ≥ 37 years of age had higher success rates with IVF compared to reversal (51.4% vs. 36.6%). After hysteroscopic tubal occlusion procedure, one small study showed implantation and successful pregnancy outcomes after IVF in 2 patients. 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.

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, 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, 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.

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.

Summary Statements

<table>
<thead>
<tr>
<th>Number</th>
<th>Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>32.</td>
<td>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)</td>
</tr>
<tr>
<td>33.</td>
<td>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)</td>
</tr>
<tr>
<td>34.</td>
<td>The 10-year cumulative failure rate of female permanent contraceptive procedures is less than 2%. (II-2)</td>
</tr>
<tr>
<td>35.</td>
<td>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)</td>
</tr>
<tr>
<td>36.</td>
<td>Tubal ligation is associated with a decreased risk of ovarian cancer. (II-2)</td>
</tr>
<tr>
<td>37.</td>
<td>Regret is one of the most common complications following a permanent contraceptive procedure with young age being a major risk factor. (II-2)</td>
</tr>
<tr>
<td>38.</td>
<td>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)</td>
</tr>
<tr>
<td>39.</td>
<td>Salpingectomy may provide women, who are absolute in their decision, the additional benefit of risk reduction against ovarian cancer. (II-2)</td>
</tr>
</tbody>
</table>

Recommendations

<table>
<thead>
<tr>
<th>Number</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>33.</td>
<td>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)</td>
</tr>
<tr>
<td>34.</td>
<td>In a well-informed woman who understands her contraceptive options and the permanency of the procedure and who is capable of consent, age...</td>
</tr>
</tbody>
</table>
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. Compared to tubal ligation, vasectomy is safer, more effective, less expensive, and less invasive. It can be performed under local anaesthetic. Canada is one of only 8 countries in which vasectomy use is equal to or more frequent than tubal ligation for contraception.

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% and the risk of pregnancy once post-vasectomy azoospermia or rare non-motile sperm has been confirmed is 1 in 2000. Vasectomy is not effective immediately and couples must continue to use another effective method of contraception until one fresh PVSA shows azoospermia or ≤ 100 000 RNMS. The time from vasectomy to azoospermia or RNMS varies and may take weeks to months to occur, although most men are azoospermic by 3 months post-vasectomy and 98–99% are azoospermic by 6 months. Spermatozoa persist in the seminal vesicles, and thus in the ejaculate, for 2 to 3 months or between 10 and 30 ejaculations after vasectomy; recanalization cannot be assessed before such time or number of ejaculations have passed. 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. When vas occlusion techniques associated with low occlusive failure rates have been used, repeat vasectomy is necessary in 1% of vasectomies.

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, and the use of electrocautery and fascial interposition. 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. Reported failure rates with intraluminal cautery and/or fascial interposition are less than 1%. Suture ligation of the vas without fascial interposition is not recommended because of higher failure rates (up to 11.5%).

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 perivasal tissues with special instruments. Due to shorter operating times and decreased rates of hematomas, infections, and intraoperative pain, MIV techniques should be performed to isolate the vas deferens. The ends of the vas should be occluded by any one of 4 techniques that are associated with occlusive failure rates consistently below 1%. 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.

Alternatively, non-divisional extended electrocautery can be used.

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. The goal of facial 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.
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 descended 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 descended 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 ≤ 100 000 non-motile sperm), and no interference with intercourse. At 5 years post-procedure, it is the most cost-effective method of contraception.103,106

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.\textsuperscript{92} The risk of complications is also affected by surgeon experience.\textsuperscript{107} Rare complications include Fournier's gangrene, vasocutaneous and vaso-urinary fistula, and trauma to neighbouring structures (i.e. perforated small hydrocele).\textsuperscript{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%.*\textsuperscript{91,92} Non-steroidal anti-inflammatory medications may be used for symptom relief.\textsuperscript{19} Few of these patients will require additional surgery (i.e. vasectomy reversal).\textsuperscript{19,92}

*Rates of regret* following a vasectomy procedure range from 2 to 6%\textsuperscript{7,109,110} although a large American cohort found that 19.6% of men who had undergone vasectomy desired more children in the future.\textsuperscript{109} One American study found that 2% of men who had a vasectomy had a subsequent reversal procedure,\textsuperscript{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).\textsuperscript{7} Risk factors for regret include younger age,\textsuperscript{7,108,110} belonging to a religious group,\textsuperscript{109} and having no children.\textsuperscript{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).\textsuperscript{60} The likelihood of obtaining a reversal generally increases over the years following sterilization.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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).\textsuperscript{92} There does not appear to be an association between prostate cancer and age at vasectomy, time from vasectomy, or calendar year of vasectomy.\textsuperscript{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).\textsuperscript{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).\textsuperscript{115} There is no evidence of an association between vasectomy and testicular cancer.\textsuperscript{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.\textsuperscript{19,92,116,117}

*Vasectomy affects sexual function.*

*Fact:* Vasectomy does not affect sexual function.\textsuperscript{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.\textsuperscript{19,91,92,109} 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.\textsuperscript{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.\textsuperscript{19,92,109} 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.\textsuperscript{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...
CHAPTER 6: Permanent Contraception

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

Vasectomy should be offered with local anaesthesia with or without oral sedation.\textsuperscript{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.\textsuperscript{92}

A minimally invasive approach should be used for vas isolation because it is associated with less pain and fewer early complications than CV.\textsuperscript{19,92,101,103} A technique for vas occlusion with a failure rate of \( \leq 1\% \) should be used.\textsuperscript{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).\textsuperscript{19,91,92} Routine histological examination of the excised parts of the vas deferens is not required.\textsuperscript{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.\textsuperscript{91,92} The PVSA should be performed on a fresh uncentrifuged specimen\textsuperscript{120} 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).\textsuperscript{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).\textsuperscript{91,92} A routine second PVSA is not required.\textsuperscript{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.\textsuperscript{121} If motile sperm are seen on PVSA at 6 to 12 weeks, this indicates either recanalization or a technical failure.\textsuperscript{92} Repeat testing should be performed every 4 to 6 weeks until azoospermia or RNMS is seen.\textsuperscript{91} Delayed vasectomy success has been shown to occur in more than 50\% of men with a first PVSA showing motile sperm.\textsuperscript{94} However, motile sperm at 6 months indicates a vasectomy failure and a repeat vasectomy should be considered.\textsuperscript{19,92}

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

Non-motile sperm concentrations \( \leq 100 000 \) sperm/mL on PVSA have a risk of pregnancy similar to a PVSA with azoospermia.\textsuperscript{122} Patients can discontinue other contraception after one PVSA shows either azoospermia or rare non-motile sperm (\( \leq 100 000 \) sperm/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 17. Category of recommendations for permanent contraception procedures

<table>
<thead>
<tr>
<th>Category</th>
<th>Accept</th>
<th>No medical reason exists to deny permanent contraception to a person with this condition.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category C</td>
<td>Caution</td>
<td>The procedure is normally conducted in a routine setting but with extra preparation and precautions.</td>
</tr>
<tr>
<td>Category D</td>
<td>Delay</td>
<td>The procedure is delayed until the condition is evaluated and/or corrected. Alternative temporary methods should be provided.</td>
</tr>
<tr>
<td>Category S</td>
<td>Special</td>
<td>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.</td>
</tr>
</tbody>
</table>
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

### Table 18. Probability of pregnancy following vasectomy reversal125,127

<table>
<thead>
<tr>
<th>Time since vasectomy</th>
<th>Sperm in the semen, %</th>
<th>Pregnancy, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5 years</td>
<td>91.0–98.6</td>
<td>63.3–88.0</td>
</tr>
<tr>
<td>5 to 10 years</td>
<td>88.0–97.6</td>
<td>68.8–82.0</td>
</tr>
<tr>
<td>10 to 15 years</td>
<td>91.0–95.3</td>
<td>55.1–86.0</td>
</tr>
<tr>
<td>More than 15 years</td>
<td>89.0–97.1</td>
<td>56.5–44.0</td>
</tr>
</tbody>
</table>

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 ≤ 100 000 non-motile sperm, the risk of contraceptive failure is 1 in 2000 (0.05%). Repeat vasectomy is necessary in ≤ 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 ≤ 100 000 non-motile sperm/mL. (III-B)

### REFERENCES


122. Korthorst RA, Consten D, van Roijen JH. Clearance after vasectomy with a single semen sample containing < than 100 000 immotile sperm/mL: analysis of 1073 patients. BJU Int 2010;105:1572–5.