The Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Excellence in Women's Health

Female sterilisation by Filshie clip tubal occlusion

This statement has been developed and reviewed by the Women's Health Committee and approved by the RANZCOG Board and Council.

First endorsed by RANZCOG: November 2007
Current: November 2014
Review due: November 2017

Objective: To provide advice on methods available for permanent female sterilisation, particularly on sterilisation by Filshie clip tubal occlusion.

Target audience: All health professionals providing gynaecological care, and patients.

Values: The evidence was reviewed by the Women's Health Committee (RANZCOG), and applied to local factors relating to Australia and New Zealand.

Background: This statement was first developed by Women's Health Committee in November 2007 and reviewed in November 2014.

Funding: The development and review of this statement was funded by RANZCOG.

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1. Introduction

There is a range of methods available for permanent female sterilisation that involve either occlusion or transection of the fallopian tubes. A tubal occlusion can be performed laparoscopically or at open abdominal surgery (usually caesarean section), or hysteroscopically (e.g. Essure procedure). The most common method of female tubal occlusion in Australia and New Zealand is the Filshie clip system which has been available since 1982. During this procedure non absorbable titanium and silicone rubber clips are applied by either a disposable single use applicator or a reusable applicator which requires regular recalibration.

Although this statement applies predominantly to laparoscopic Filshie clip tubal occlusion, it is recognised that in some instances Filshie clips will be applied at caesarean section. This statement does not relate directly to that technique. It must be recognised that Filshie clips applied at caesarean section have a higher rate of failure.

2. Discussion and Good Practice Points

2.1 What is the suggested technique for application of the Filshie clip to the tube?

- Uterine manipulator in position.
- Entry technique for laparoscopy, as per RANZCOG/AGES Consensus Guideline: Guidelines for performing advanced operative laparoscopy (C-Trg 2).
- Multiple puncture laparoscopy.
- Identify the ovarian and round ligaments and the fallopian tubes by visualising their fimbrial ends.
- Apply the clip to the tube, ensuring the jaws of the clip completely enclose the tube. The manufacturer's guidelines currently recommend placement of the clip on the isthmic portion of the tube.
- After releasing the clip, ensure the tube has not been transected, the upper arm of the clip is flat and locked under the nose of the lower jaw, and that the tube is still completely enclosed.
- Repeat the procedure on the other side.
- It may be useful to document correct application of the Filshie clip by image capture device if available.

2.2 What are the minimum equipment requirements?

The procedure may be performed by either a disposable/ single-use or reusable applicator. Poorly serviced applicators can result in a loss of calibration which can lead to incorrect closure of the Filshie clip and possible failed tubal occlusion.

If using a reusable applicator it is strongly recommended that:

- Filshie clip applicators be serviced and recalibrated by their manufacturer or their appointed agent in line with the manufacturer's guidelines.
- Prior to using a reusable applicator it is good practice to ensure that the applicator is assembled correctly and tested with the pressure gauge to ensure correct calibration.

2.3 What are the main reasons for legal claims against medical practitioners resulting from a failed tubal occlusion?

Failed tubal occlusion has historically been a frequent source of legal claims against medical practitioners. The basis for such claims has been due to an alleged failure by the medical practitioner to:

- Time the procedure so that the patient is not pregnant, or exclude a pregnancy prior to performing the procedure;
- Warn of possible sterilisation failure;
- Perform the appropriate technique;
- Diagnose a pregnancy that occurs after a failed sterilisation; and
- Diagnose an ectopic pregnancy.

Another basis for claims has been inadvertent injury at laparoscopy. Therefore, it is vital that practitioners are skilled in carrying out the procedure.

2.4 Good Practice Points

1. Ensure a detailed history is taken about previous gynaecological procedures.
2. Ensure other contraceptive alternatives are discussed with the patient, including other safe long term methods of contraception.
3. The risk of the development of some ovarian carcinomas from the Fallopian tubes left in situ should be discussed with the patient, as well as consideration of sterilisation by bilateral salpingectomy instead of tubal occlusion (see below).
4. Provide printed material such as the RANZCOG brochure on tubal occlusion.
5. Discuss the risk of failure (for Filshie clips it is generally considered about 1 in 300) and record this discussion in the patient's file.
6. Ensure the appropriate patient consent form/ is correctly completed. It is good practice to include reference to the various discussions in the patient's file and in a letter to the referring doctor.
7. Ensure that the patient is aware that should a pregnancy occur, there is an increased risk of ectopic pregnancy. If a pregnancy occurs, ectopic pregnancy should be excluded as early as possible using appropriate diagnostic tests.
8. The date of the patient's last menstrual period should be recorded. It is recommended that the procedure be performed in the early to mid-follicular phase of the cycle unless other contraception is being used. A pregnancy test should be performed prior to the procedure if necessary.
9. The surgical unit at which the procedure is done is responsible for ensuring that equipment is serviced and that calibration gauges are available. It is the unit's responsibility to ensure that equipment is correctly calibrated. Fellows should satisfy themselves that the unit has conducted appropriate servicing and calibration.
10. Note any intraoperative difficulties. If initial application is not ideal, a second clip may be applied. If image capture equipment is available take adequate photographs to show that the clip has been correctly applied.

11. If there is any doubt about either of the clip applications, or if one or both tubes can not be visualised, discuss the situation with the patient post-operatively.

12. If in doubt, advise the patient to use alternative contraception until tubal occlusion has been confirmed with hysterosalpingogram or hysterosalpingo contrast sonogram.

13. Uterine curettings are not required but if any have been obtained they should be submitted to pathology and the histology reviewed.

2.5 Salpingectomy versus tubal Occlusion

There is growing evidence that high-grade serous tumours of the ovary and peritoneal surface epithelium (the most common histologic sub-type of epithelial ovarian cancer) may originate in the fallopian tubes. Furthermore, there is no known benefit for retaining fallopian tubes in the post-reproductive period, and removal of the fallopian tubes does not appear impact on ovarian function (C-Gyn 25 Managing the adnexae at the time of hysterectomy for benign gynaecological disease). Hence, bilateral salpingectomy should be discussed with the patient during the informed consent process for Filshie clip tubal occlusion.

Although the removal of the fallopian tubes does not appear to increase surgical complications when performed with oophorectomy, there may be an increased risk of other complications when compared to tubal occlusive procedures. This, and the possible need for extra laparoscopy port sites when performing salpingectomy, should also be discussed with the patient.

3 Suggested reading

1. Lyneham R. A review of the Filshie system in Australia and New Zealand, O&G 2003; 5 (3): 194-195.

2. Filshie M G. Female sterilization, O&G 2000; 2 (1): 43-49.

3. Woodhouse D. Filshie clips safety alert update. O&G 1999;1 (1): 42-43.

4. RCOG Evidence-based clinical guideline number 4. Male and Female Sterilisation. 2004. Available at: http://www.rcog.org.uk/womens-health/clinical-guidance/sterilisation-women-and-men-what-you-need-know

4 Links to other College statements

Consent and the Provision of Information to Patients in Australia regarding Proposed Treatment (C-Gen 02a)

Consent and Provision of Information to Patients in New Zealand regarding Proposed Treatment (C-Gen 02b)

RANZCOG/AGES Guidelines for performing advanced operative laparoscopy (C-Trg 2)

(C-Gyn 25) Managing the adnexae at the time of hysterectomy for benign gynaecological disease.

(C-Gen 15) Evidence-based Medicine, Obstetrics and Gynaecology

5 Patient information

The pamphlet *Tubal Occlusion and Vasectomy - a Guide About Female and Male Sterilisation* and a range of other RANZCOG Patient Information Pamphlets can be ordered via:

https://www.ranzcog.edu.au/Womens-Health/Patient-Information-Guides/Patient-Information-Pamphlets

Appendices

Appendix A Women's Health Committee Membership

Name	Position on Committee
Associate Professor Stephen Robson	Chair and Board Member
Dr James Harvey	Deputy Chair and Councillor
Associate Professor Anusch Yazdani	Member and Councillor
Associate Professor Ian Pettigrew	Member and Councillor
Dr Ian Page	Member and Councillor
Professor Yee Leung	Member of EAC Committee
Professor Sue Walker	General Member
Dr Lisa Hui	General Member
Dr Joseph Sgroi	General Member
Dr Marilyn Clarke	General Member
Dr Donald Clark	General Member
Associate Professor Janet Vaughan	General Member
Dr Benjamin Bopp	General Member
Associate Professor Kirsten Black	General Member
Dr Jacqueline Boyle	Chair of the ATSIWHC
Dr Martin Byrne	GPOAC representative
Ms Catherine Whitby	Community representative
Ms Sherryn Elworthy	Midwifery representative
Dr Nicola Quirk	Trainee representative

Appendix B Overview of the development and review process for this statement

i. Steps in developing and updating this statement

This statement was originally developed in November 2007 and was most recently reviewed in November 2014. The Women's Health Committee carried out the following steps in reviewing this statement:

- Structured clinical questions were developed and agreed upon.
- An updated literature search to answer the clinical questions was undertaken.
- At the November 2014 face-to-face committee meeting, the existing consensus-based recommendations were reviewed and updated (where appropriate) based on the available body of evidence and clinical expertise.

Appendix C Full Disclaimer

This information is intended to provide general advice to practitioners, and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient.

This information has been prepared having regard to general circumstances. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual patient and the particular circumstances of each case.

This information has been prepared having regard to the information available at the time of its preparation, and each practitioner should have regard to relevant information, research or material which may have been published or become available subsequently.

Whilst the College endeavours to ensure that information is accurate and current at the time of preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available.