Royal College of Obstetricians & Gynaecologists

Female Sterilisation

Consent Advice No. 3

February 2016

Female Sterilisation

This guidance replaces the previously published Royal College of Obstetricians and Gynaecologists (RCOG) Consent Advice No. 3 *Laparoscopic Tubal Occlusion*, published in October 2004.

This paper provides advice for clinicians in obtaining consent of women undergoing sterilisation by laparoscopy or hysteroscopy or at the time of caesarean section. It is intended to be appropriate for a number of procedures and combinations and the consent form should be carefully edited under the heading 'Name of proposed procedure or course of treatment' to accurately describe the exact procedure to be performed. If consent is required for additional procedures, further procedure specific consent should be obtained. The paper follows the structure of Consent Form 1 of the Department of Health, England[1]/Welsh Assembly Government[2]/Department of Health, Social Services and Public Safety, Northern Ireland.[3] It should be used in conjunction with RCOG Clinical Governance Advice No. 6 *Obtaining Valid Consent*.[4] Please also refer to the Faculty of Sexual and Reproductive Healthcare Clinical Guidance *Male and Female Sterilisation*.[5]

The aim of this advice is to ensure that all women are given consistent and adequate information for consent; it is intended to be used together with dedicated patient information. After discharge, women should have clear direction for obtaining help if there are unforeseen problems.

Clinicians should be prepared to discuss with the woman any of the points listed on the following pages.

Table 1. Presenting information on risk

Term	Equivalent numerical ratio	Colloquial equivalent
Very common	1/1 to 1/10	A person in family
Common	1/10 to 1/100	A person in street
Uncommon	1/100 to 1/1000	A person in village
Rare	1/1000 to 1/10 000	A person in small town
Very rare	Less than 1/10 000	A person in large town

The above descriptors are based on the RCOG Clinical Governance Advice No. 7 *Presenting Information on Risk*,[6] and are used throughout this document.

To assist clinicians at a local level, we have included in Appendix I a fully printable page 2 of the Department of Health, England/Welsh Assembly Government/Department of Health, Social Services and Public Safety, Northern Ireland, Consent Form 1 suitable for sterilisation. This form should be completed in addition to a consent document relating to the mode of sterilisation, e.g. laparoscopy, hysteroscopy or caesarean section. This page can be incorporated into local trust documents subject to local trust governance approval.

CONSENT FORM

1. Name of proposed procedure or course of treatment

Female sterilisation.

2. The proposed procedure

Describe the nature of female sterilisation. Explain the procedure as described in the patient information. It is crucial at this point to reiterate the permanent nature of the procedure the woman is about to undergo, and should ascertain that the patient does not wish to have any more children in the future. Discuss the potential of *not* removing intrauterine contraception (IUC) in case a blastocyst has already passed the site of tubal occlusion. Ensure the patient uses other forms of contraception/abstains to prevent pregnancy prior to the procedure, and this contraception should continue until the next menses.

If any other procedures are anticipated, these must be discussed and separate consents obtained.

3. Intended and potential benefits

To prevent pregnancy permanently.

Recent research[7] suggests a protective effect of tubal occlusion and salpingectomy on ovarian cancer, and this is therefore an opportunity to highlight this potential benefit.

4. Significant and frequently occurring risks[5,8]

It is recommended that clinicians make every effort to separate significant from frequently occurring risks. Women who are obese, women with significant pathology, those who have had previous surgery or who have a pre-existing medical condition must understand that the quoted risks for significant or frequent complications may increase.

4.1 Significant risks

These include:

- Failure resulting in unplanned pregnancy: the lifetime failure rate for laparoscopic tubal occlusion with clips is up to 2–5 in 1000 procedures at 10 years (uncommon).[9] The long-term failure rate of hysteroscopic sterilisation may be similar to other methods, but long-term data are limited. The failure rate of hysteroscopic sterilisation is quoted as 2 in 1000 (uncommon). These failure rates are higher than for the most effective long-acting reversible contraception methods; for example implant and intrauterine system (IUS).[10]
- Sterilisation failure that results in a greater risk of an ectopic pregnancy. (This is a recognised risk but there is no robust data to quantify the risk.)
- Visceral or blood vessel injury at the time of laparoscopy (2 in 1000; uncommon).
- Death as a result of the procedure (1 in 12 000; very rare).
- Regret, leading to a request for reversal of female sterilisation which is usually unavailable on the National Health Service. Regret is common, and more common if sterilisation is undertaken below 30 years of age, if the woman is childless, or if there is conflict between the woman and her partner. Regret is also more common when sterilisation is undertaken at the time of an abortion.[5]
- Failure to complete the procedure. (This is a recognised risk but there is no robust data to quantify the risk.)

4.2 Frequent risks

Changes in menstruation may occur following discontinuation of reversible hormonal contraception, especially with the combined oral contraceptive or levonorgestrel-releasing intrauterine system (LNG-IUS). Female sterilisation itself does not adversely affect menstrual function.

5. Any extra procedures which may become necessary during the procedure

The risk of laparotomy following laparoscopic tubal occlusion is up to 3 in 1000. Additional procedures are rare after hysteroscopic sterilisation.

6. What the procedure is likely to involve, the benefits and risks of any available alternative treatments, including no treatment[5,8]

6.1 Laparoscopic sterilisation

Insertion of a laparoscope through a small incision at the umbilicus. Through a second small incision a trocar is inserted and a titanium clip, or other suitable occluding device, is placed across each fallopian tube to completely obstruct it. It is important that you indicate the likely site of this second incision to the patient preoperatively.

It is recommended that clinicians use this document alongside RCOG Consent Advice No. 2 *Diagnostic Laparoscopy*.[11]

6.2 Sterilisation at caesarean section

After delivery of the baby and closure of the uterus, the fallopian tubes are divided and tied. Specimens of fallopian tube are sent for histopathological confirmation. If sterilisation is to be performed with caesarean section, counselling should be given well in advance of the procedure. Sterilisation at caesarean section is less likely to be amenable to successful future reversal of female sterilisation.

A number of studies have reported that the incidence of regret and dissatisfaction is increased when sterilisation has been performed concomitantly with caesarean section. Tubal occlusion should ideally be performed at an appropriate interval after pregnancy wherever possible. Should tubal occlusion be requested postpartum, women should be made aware of the increased rate of regret and the possible increased failure rate.[5]

It is recommended that clinicians use this document alongside RCOG Consent Advice No. 7 *Caesarean Section*.[12]

6.3 Sterilisation at abortion

Laparoscopic sterilisation is technically possible at the time of an abortion. However, tubal occlusion should ideally be performed at an appropriate interval after pregnancy wherever possible. Should tubal occlusion be requested at the time of abortion, women should be made aware of the increased rate of regret and the possible increased failure rate.

6.4 Hysteroscopic sterilisation

A hysteroscope is passed through the vagina and cervix to view the tubal ostia in the uterine cavity. A pellet or nickel/titanium coil is placed within the lumen of each fallopian tube to completely obstruct it. Postoperative imaging is necessary by ultrasound, X-ray or hysterosalpingography to confirm correct tubal placement or blockage 3 months after this procedure. Continued contraception is necessary prior to this confirmatory investigation.

Reversal of female sterilisation following this procedure cannot be achieved via fallopian reanastomosis, therefore consideration should be given to in vitro fertilisation.

It is recommended that clinicians use this document alongside RCOG Consent Advice No. 1 *Diagnostic Hysteroscopy Under General Anaesthesia*.[13]

6.5 Long-acting fertility control

Long-acting methods of fertility control, such as the LNG-IUS and the progestogen subdermal implant, offer at least the same degree of protection with lower risks and disadvantages.

6.6 Male sterilisation

Sterilisation by vasectomy has a lower failure rate in the order of 1 in 2000 and less risk as a procedure. It is often undertaken under local anaesthesia.

7. Statement of patient: procedures that should not be carried out without further discussion

Other procedures which may be appropriate but not essential at the time of treatment should be discussed and the woman's wishes recorded.

8. Preoperative information

A record should be made of any sources of information (such as RCOG or locally produced information materials) given to the woman prior to surgery. Please refer to the RCOG patient information leaflet *Laparoscopy.*[14]

9. Anaesthesia

Where relevant, the woman must be made aware of the form of anaesthesia planned and be given an opportunity to discuss this in detail with the anaesthetist before surgery. It should be noted that for woman that are obese, there are increased surgical and anaesthetic risks associated with laparoscopic tubal occlusion which must be disclosed.

References

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10. Heinemann K, Reed S, Moehner S, Minh TD. Comparative contraceptive effectiveness of levonorgestrel-releasing and copper intrauterine devices: the European Active Surveillance Study for Intrauterine Devices. *Contraception* 2015;91:280–3.
11. Royal College of Obstetricians and Gynaecologists. *Diagnostic Laparoscopy*. Consent Advice No. 2. London: RCOG; 2008.
12. Royal College of Obstetricians and Gynaecologists. *Caesarean Section*. Consent Advice No. 7. London: RCOG; 2009.
13. Royal College of Obstetricians and Gynaecologists. *Diagnostic Hysteroscopy Under General Anaesthesia*. Consent Advice No. 1. London: RCOG; 2008.
14. Royal College of Obstetricians and Gynaecologists. *Laparoscopy*. London: RCOG; 2010.

Appendix I: Female sterilisation consent to treatment form

Patient identifier/label .....

Name of proposed procedure or course of treatment *(include brief explanation if medical term not clear)*

Female sterilisation

Statement of health professional *(to be filled in by health professional with appropriate knowledge of the proposed procedure, as specified in the consent policy, and preferably capable of performing the procedure themselves)*

I have explained the procedure to the patient with other possible alternatives. In particular, I have explained:

The intended benefits

To prevent pregnancy permanently.

Serious and frequent risks

- Failure of the procedure resulting in unplanned pregnancy: the lifetime failure rate is 2–5 per 1000 at 10 years (uncommon).
- If future pregnancy occurs, there is a greater chance that it may be ectopic (pregnancy outside the womb) than may occur naturally.
- Regret, leading to request for reversal.
- Failure to complete the procedure by the chosen method
- Absolute irreversibility of hysteroscopic sterilisation may lead to request for IVF.

Any extra procedures which may become necessary during the procedure

- Laparotomy (open surgery) for repair of damage to bowel, bladder, uterus or blood vessels.
- Other procedure *(please specify)* .....

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient. I have discussed the permanent nature of the procedure.

The following information has been provided .....

The procedure will involve

☐ General and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation

Signed ..... Date .....

Name *(print)* ..... Position .....

Contact details *(if patient wishes to discuss options later)*

.....

Statement of interpreter *(where appropriate)*

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe she can understand.

Signed ..... Date .....

Name *(print)* .....

Top copy accepted by patient Yes / No *(please circle as appropriate)*

This Consent Advice was produced on behalf of the Royal College of Obstetricians and Gynaecologists by:
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All RCOG guidance developers are asked to declare any conflicts of interest. A statement summarising any conflicts of interest for this Consent Advice is available from: https://www.rcog.org.uk/en/guidelines-research-services/guidelines/consent-advice-3/.

The final version is the responsibility of the Women's Health Patient Safety Expert Group of the RCOG.

The review process will commence in 2019, unless otherwise indicated.

