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60.1 Background

Female sterilisation was one of the commonest procedures carried out in the UK but there has been a decline over the past decade due to increased use of alternative contraceptives e.g. long acting reversible contraception (LARC). Female sterilisation is a permanent, non-reversible procedure. Therefore, patients need to be certain that they have been counselled appropriately before undergoing such a procedure. There is now only one main type of female sterilisation: Filshie clip laparoscopic sterilisation. The previous availability of the Essure hysteroscopic sterilisation procedure has now been withdrawn from the UK market as of September 2017.

60.2 Minimal Standards and Clinical Governance Issues

Guidance on standards for female sterilisation have been issued by the RCOG and Clinical Effectiveness Unit (CEU) of the Faculty of Sexual & Reproductive Healthcare (FSRH) [1–3].

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There should be clear, contemporaneous documentation within the medical records and a pre-operative check list should be completed with written consent obtained. This should include appropriate medical history and any clinical examination. The records should document the discussion that took place, requests made by the individual and any information provided. The reason for the sterilisation should be documented.

Legal advice should be sought if there is any doubt as to whether a person has the mental capacity to consent to a procedure that will permanently remove their fertility.

Counselling for the permanency of the procedure and lifetime failure rate of 1:200, with a possibly increased failure risk if the sterilisation is performed in the postpartum or post abortion period. In the postpartum period, the use of Filshie clip and modified Pomeroy technique are equally effective except that Filshie clip application is quicker to perform. Mechanical occlusion using the Filshie clip should be the method of choice for laparoscopic tubal occlusion.

Alternatives for permanent methods of sterilisation should be discussed e.g. Mirena coil and/or vasectomy. Women should be informed that some of these procedures have a lower failure rate (vasectomy), whereas others such as long-acting reversible contraceptives (which include injections, intrauterine devices (IUDs) and subdermal contraceptive implants) have a similar

failure rate and confer additional benefits related to menstrual cycles.

There are few situations which preclude a sterilisation but greater precautions are needed in women on anticoagulation therapy, cardiovascular disease, previous abdominal surgery and in those who are obese. For a hysteroscopic sterilisation, nickel allergy would be a contraindication. Higher regret rate are known to occur if sterilisation is performed in under 30 year olds, in nulliparous women, following a recent pregnancy or in women who have relationship issues. When sterilisation is performed during a Caesarean section, counselling and consent should be given at least 2 weeks in advance of the procedure.

It would be routine to provide a current valid written patient information leaflet, that includes operative risks from laparoscopy, that could lead to a laparotomy, particularly if there are co-existing risks e.g. obesity or prior abdominal surgery.

Assessment pre-operatively should include routine use of pregnancy test, record of last menstrual period, use of contraception during the cycle. Tubal occlusion can be performed at any time during the menstrual cycle as long as the woman has used an effective method of contraception up to the day of the procedure. However, a luteal phase pregnancy cannot be excluded with a negative pregnancy test hence the importance of emphasising the use of contraceptive in the cycle that the sterilisation is performed.

The procedure should be performed by an experienced surgeon undertaking at least 25 procedures per year.

The laparoscopic tubal occlusion should be with the use of a Filshie clip applied at the thinnest part of the fallopian tube i.e. at the isthmus level of the fallopian tube. It should be applied perpendicular to the fallopian tube and the clip should be applied to fully envelope the fallopian tube without leaving a knuckle of fallopian tube. This can be assured by having the ante-mesenteric border of the fallopian tube sit at the level of the hinge with no obvious gap between the hinge and

the fallopian tube. Steri-Shot™ disposable Filshie clip applicators should now be used in preference to the older applicators that required maintenance on a yearly basis or every 100 applications. The new disposable applicators have removed the need to ensure that correct pressure closes and locks the Filshie clip. The Filshie clip should only be applied after identification of the fimbrial end of the fallopian tube so that the correct structure is occluded. Filshie clip should be applied slowly without tearing the fallopian tubes, as this can result in a subsequent tubo-tubo fistula.

Common mistakes are applying the Filshie clip to the wrong structure i.e. the round ligament. Photographs should be taken post procedure for good clinical practice. The routine use of more than one Filshie clip on each fallopian tube is not recommended.

The use of other methods such as electrocautery, Hulka, fallope rings should not be used as the failure rates are much higher than the 2–3:1000 associated with the Filshie clip method.

Post procedure contraception should be continued preferably until the next menstrual period starts. Removing a coil during the sterilisation may inadvertently result in unintended pregnancy if ovulation has occurred prior to the procedure and a blastocyst has already passed the site of the tubal occlusion.

60.2.1 Specific Additional Aspects for Hysteroscopic Sterilisation

This procedure can be carried out without any anaesthesia. Local anaesthesia may be used if there is difficulty in passing the hysteroscope through the cervix.

Specific consent requires that contraception should be used for an additional 3 months until tubal occlusion has been confirmed by ultrasound scan or hysterosalpingogram. The latter is used if there was a difficulty in placing the Essure devices. Counselling should also include the failure of placement of the second device in up to 0–19% of cases, whereby an additional method

may be required i.e. a repeat attempt for hysteroscopic sterilisation or undergoing a laparoscopic sterilisation procedure.

Women who do not attend for confirmatory tubal occlusion testing should continue using a reliable form of contraception. Essure is as effective as laparoscopic tubal occlusion with a failure rate of approximately 1:200.

There is evidence that there is a 6–10 times more likely increased risk of operative intervention within one year of Essure sterilisation procedures [4–6]. Around 2% of women within one year require alternative methods of sterilisation because of the inability to place the devices, have the devices removed because of incorrect placement or due to symptoms causing pelvic pain (<https://www.fsrh.org/documents/fsrh-statementessurebmj/fsrhstatementessurebmj.pdf>).

As a result of the continued debate regarding the safety of the Essure method [7], the Essure method has now been withdrawn from the UK market. However, patients who have already had these devices fitted may present to clinicians in the coming years and request them to be removed.

Late failures resulting in a pregnancy can occur at any time after tubal occlusion with both methods. There is a higher risk of ectopic pregnancy when failures occur. When a pregnancy occurs while an individual is on a waiting list for sterilisation they should be offered further counselling about future contraceptive choices due to change in their circumstances.

60.3 Reasons for Litigation

The main reasons for litigation in cases of female sterilisation relate to:

- Counselling
- Patient pregnant at the time of sterilisation (luteal phase pregnancy)
- Procedure related complications
- Post-operative care
- Failure

- Litigation occurs when the wrong structure has been occluded e.g. round ligament rather than the fallopian tube. There is evidence that failure that occurs within 12 months of laparoscopic tubal occlusion this is likely to be due to operator error rather than a non-negligent tubo-tubo fistula [8].

60.4 Avoidance of Litigation

It is important to follow the principles set out in the checklists given above for each type of sterilisation method.

Adequate documentation of the reasons for the sterilisation as well as the permanency of the procedure, its alternatives, failure, ectopic pregnancy and risks associated with the actual procedure need to be clearly documented. Contraceptive advice leading up to and following the procedure must be given. Due care and diligence when performing the procedure should be taken to avoid failure. When a laparoscopic procedure is undertaken the fimbrial end of the tube should be identified before application of the Filshie clip which should be placed over the isthmic (thinnest) portion of the tube to ensure complete tubal occlusion. When a hysteroscopic procedure is performed additional counselling should include the need for contraception following the procedure and until confirmation of tubal occlusion as well as the higher re-operation rate in the first year.

Female sterilisation still represents a good method for permanent contraception but patient counselling and up to date written information is important to avoid litigation in the future.

60.5 Case Study

A 27-year-old woman with 3 normal vaginal deliveries was sterilised with placement of two Filshie clips on the right fallopian tube and one on the left. She had been appropriately counselled and the appropriate consent was taken. During the application of the first Filshie clip

application to the right fallopian tube, the pneumoperitoneum was not maintained and therefore a second Filshie clip was applied. She was found to be pregnant 14 months later and delivered a healthy baby. The photographs taken at the time of sterilisation indicated that both of the right fallopian tube Filshie clips were applied distal to the isthmus i.e. beyond the thinnest part of the fallopian tube. It is likely that the occlusion was not complete with an obvious gap between the fallopian tube and the hinge of the Filshie clip indicating that there was likely to be a knuckle of tube left unoccluded. The left Filshie clip was appropriately applied.

Ultimately identification of the failure can only be determined by removal of both fallopian tubes to assess histologically for the reasons of failure and to complete the sterilisation effect.

Key Points: Sterilisation

- There are two main methods for female sterilisation: laparoscopic by Filshie clips (usually by general anaesthesia) and hysteroscopic using Essure (outpatient under local anaesthesia). The latter is now withdrawn from the UK market as of September 2017.
- Essure hysteroscopic methods are associated with a higher re-operation rate in the first year.
- Clear, contemporaneous documentation and a valid consent should be obtained.

- Counselling of permanency, failure, alternatives, risks, complications and regret.
- Contraceptive advice before and after the procedure depending on the procedure undertaken.
- Due diligence when performing the procedure to avoid failure.

References

1. Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Unit guideline. Male and female sterilisation; 2014. <http://www.fsrh.org/pdfs/MaleFemaleSterilisationSummary.pdf>.
2. NICE Clinical Knowledge Summaries. Contraception – sterilisation. <https://cks.nice.org.uk/contraception-sterilization#!scenario:1>.
3. Varma R, Gupta JK. Failed sterilisation - evidence-based review and medico-legal ramifications. *BJOG*. 2004;111:1322–32.
4. Antoun L, Smith P, Gupta JK, Clark TJ. The feasibility, safety, and effectiveness of hysteroscopic sterilization compared with laparoscopic sterilization. *Am J Obstet Gynecol*. 2017;217(5):570.e1–6. <https://doi.org/10.1016/j.ajog.2017.07.011>. pii: S0002-9378(17)30853-0.
5. Mao J, Pfeifer S, Schlegel P, Sedrakyan A. Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study. *BMJ*. 2015;351:h5162.
6. Perkins RB, Morgan JR, Awosogba TP, Ramanadhan S, Paasche-Orlow MK. Gynecologic Outcomes After Hysteroscopic and Laparoscopic Sterilization Procedures. *Obstet Gynecol*. 2016;128(4):843–52.
7. Dhruva SS, Ross JS, Garipey AM. Revisiting essure - toward safe and effective sterilization. *N Engl J Med*. 2015;373:e17.
8. Varma R, Gupta JK. Predicting negligence in female sterilization failure using time interval to sterilization failure: analysis of 131 cases. *Hum Reprod*. 2007;22:2437–244.