CLINICAL PRACTICE GUIDELINE

Contraception: Sterilisation

This document should be read in conjunction with the Disclaimer

Contents

Aim

- To provide staff with information on tubal occlusion sterilisation methods in Australia.

Key points

1. Laparoscopic sterilisation with Filshie clips is currently the most common method of sterilisation in Australia[1], is the most appropriate method for mechanic occlusion[2], and can be used provided there are no contraindications.
2. Application of Filshie clips is recommended in the early to mid-follicular phase of the cycle unless other contraception is being used.[1] Perform a same-day pre-procedure pregnancy test.[1, 2] A negative test does not exclude luteal phase conceptions.[2]
3. The Essure® procedure has a 0-19% risk of micro-insert placement being unsuccessful, after up to 2 attempts,[2] due to one or both tubal ostia being inaccessible. To increase success, the Essure® procedure is recommended to be performed between day 7 and 14 (proliferative stage) of the menstrual cycle.[2] Additional contraception should be used for 7 days before the procedure and for the following 3 months, and imaging (hysteroscopy or abdominal x-ray) is required to confirm correct placement of the inserts.[2, 3] Health professionals inserting Essure® should have supervised training to become proficient in insertion, and adequate training in performing and interpretation of confirmatory imaging.[2]
4. Inform the woman that if pregnancy occurs following a sterilisation procedure, risk for ectopic pregnancy is increased.[1, 2]

Background

Female sterilisation is performed via laparoscopy, at open abdominal surgery (e.g. caesarean section), hysteroscopy (e.g. Essure®) or mini-laparotomy[1, 2] to prevent the passage of sperm and fertilised ova down the fallopian tube. The Filshie clip system is the most common method of tubal occlusion in Australia and New Zealand.[1] A relatively recent development is the Essure® procedure, performed via hysteroscopy using local anaesthetic/light sedation.[3] A small (40mm long/ 0.8mm diameter)[2] soft device called a micro-insert, micro-coil or micro-spiral is placed into each fallopian tube.[3] The micro-inserts consist of a stainless steel inner coil, an expanding nickel-titanium outer coil, and a polyethylene fibre core, which provokes a local tissue response over the next 3 months leading to occlusion of the lumen.[2]

Efficacy

Laparoscopic and laparotomy sterilisation:

- >99.5% with laparoscopic and laparotomy sterilisation[3]
- >99.8% with Filshie clips (cumulative pregnancy rate 1.7/1000 procedures)[2]

Hysteroscopic sterilisation:

- >99.8%* with Essure®[2] (In 1 large study: 64 pregnancies from ~50,000 procedures)[3]

*Note: There is limited research beyond the 3 month confirmation review available.[2] Using an intention to treat model estimates a 5.7% annual risk of pregnancy after hysteroscopic sterilisation.[4] Further rigorous research required.[4, 5]

Precautions/ contraindications

Essure® specific: Hysteroscopic sterilisation with Essure® is contraindicated if the woman has a proven patch test allergy to nickel, uncertainty about ending fertility, suspected pregnancy, birth/abortion <6weeks prior, active/recent pelvic infection, untreated acute cervicitis, unexplained or severe vaginal bleeding, suspected gynaecological malignancy, abnormal uterine cavity / fallopian tubes that impacts visualisation of tubal ostia or makes cannulation difficult, allergy to contrast media used for hysterosalpingogram, or use of corticosteroids.[2]

Surgical sterilisation has no conditions that permanently restrict eligibility from voluntary use. The risks of sterilisation are weighed against risk of pregnancy. The significant UK Medical Eligibility Criteria (UKMEC) for female sterilisation are summarised below[3]:

Caution (Category C)[3]:

Procedure conducted in routine setting with extra preparation & precaution if:

- Young age (particularly <30); obesity (≥30 BMI- increased surgical & anaesthetic risk); nulliparous; post-partum (at time of caesarean); sterilisation concurrent with elective abdominal surgery.
- Hypertension (adequate control); consistently elevated blood pressure (BP) (systolic 140-159mmHg or diastolic >90-94mmHg); history of ischaemic heart disease (IHD); stroke (history of cerebrovascular accident, including transient ischaemic attack); uncomplicated valvular heart disease & congenital heart disease.
- Uncomplicated systemic lupus erythematosus (SLE); epilepsy; depressive disorders; breast cancer (current); uterine fibroids; diabetes (type1 and 2 without vascular disease); hypothyroidism; cirrhosis(mild- compensated without complications); liver tumours (benign & malignant); thalassemia; sickle cell disease; iron deficiency anaemia (Hb >7 to <10g/dl); kidney disease.

Delay (Category D)[3]:

Delay until condition evaluated and/or corrected:

- Pregnancy; post-partum or post-abortion (<6 weeks)
- Venous thromboembolism (VTE) (current on anticoagulation; major surgery with prolonged immobilisation; immobility unrelated to surgery e.g. Wheelchair use)
- Unexplained vaginal bleeding (before evaluation), suspicious for serious condition; Pelvic inflammatory disease (current); purulent cervicitis or gonorrhoea (current); chlamydia; gestational trophoblastic neoplasia with abnormal level of beta hCG; cervical cancer awaiting treatment or endometrial or ovarian cancers

- IHD (current); gall bladder disease (current); viral hepatitis (acute or flare); anaemia (iron deficiency <7g/dl); local abdominal skin infection; acute bronchitis or pneumonia, systemic infection or gastroenteritis.

Special (Category S)[3]:

These conditions require a setting with an experienced surgeon and staff, with equipment for general anaesthesia and back up medical support:

- Cardiovascular disease (multiple risk factors); BP raised (systolic ≥160 or diastolic ≥95mmHg); vascular disease (coronary heart disease, peripheral vascular disease, transient ischaemic attacks or hypertensive retinopathy); valvular disease, congenital heart disease (complicated);
- endometriosis; fixed uterus due to previous surgery or infection; known pelvic tuberculosis; previous abdominal or pelvic surgery
- Diabetes (type 2 with nephropathy/retinopathy/neuropathy or with any other vascular disease); SLE (positive or unknown antiphospholipid antibodies; severe thrombocytopenia; or immune-suppressive treatment); hyperthyroidism; coagulation disorders; cirrhosis (severe decompensated); chronic asthma, bronchitis, emphysema or lung infection; inflammatory bowel disease (e.g. Crohn's, ulcerative colitis); abdominal wall or umbilical hernia; AIDS & using anti-retrovirals.[3]

Complications

Laparoscopic and mini-laparotomy sterilisation[3]

- Complications with the procedure: Injuries to bowel, bladder or blood vessels[2] and ureter; diaphragmatic or shoulder pain; risks of general anaesthesia; excessive bleeding or infection. Mortality rates are low (~4 in 100,000 procedures)[3]
- Complications long term: possibility of pregnancy (of these 40% are ectopic); if ceasing hormonal contraception, menstrual cycles may be irregular or heavier without hormonal control.[3]
- See also RANZCOG patient information pamphlet: "Laparoscopy".

Hysteroscopic transcervical occlusion methods (e.g. Essure®)

- Complications with the procedure: Perforation of the uterus or fallopian tubes, causing release of the device into the abdominal cavity; Unsatisfactory placement of the device; pelvic pain, excessing bleeding and infection;[3] nausea, dyspareunia, urinary tract infection, vaginal discharge, nickel allergy[2]
- Complications long term: Pregnancy (particularly ectopic) due to unsatisfactory placement or poor occlusion;[3] PID, micro-insert migration& expulsions[2]
- There is limited long-term information on complications, efficacy& safety of Essure®.[5] Many studies only followed women until the 3month confirmation review.[2]
- See also RANZCOG patient information pamphlet: "Hysteroscopy".

Regret

Regret is more common if sterilisation is performed with a caesarean section, when stress in the woman's personal relationships, in younger or nulliparous women,[3] if coercion from health professional or partner, or if psychosexual issues present.[2] More care is required when counselling women under 30 years old, and those without children.[2] If sterilisation is to occur at caesarean section, counsel at least 2 weeks in advance.[2]

Medical history, examination & investigations

Medical history[3]

Include:

- past & present illnesses, allergies & risk factors for surgery (see also precautions)
- previous relevant operations, including gynaecological procedures[1], previous anaesthetic problems, limitations on activity, substance abuse, social situation.[3]
- detailed menstrual obstetric history, history of pelvic disease, current contraception & medications
- discussion regarding the decision for sterilisation (see also counselling below)[3]

Examination

No routine requirements in primary care settings.[3] If required, or history indicates, perform:

- a blood pressure; weight and height to calculate BMI (obesity increases risks[2])
- auscultation of heart and lungs; abdominal/ bimanual pelvic palpation[2]; examination of the skin at the operative site

(IUD) left insitu may need to be removed at procedure, so women using this method should use another form of contraception for 7 days prior to the procedure[2] where abstinence cannot be guaranteed. If an IUD is present pre-sterilisation, leave insitu and remove at least 7 days after tubal occlusion.[2]

Investigations

No routine requirements in the primary care setting.[3] If required:

- Exclude the possibility of pregnancy at the time of procedure[3]
- Investigate for sexually transmitted infections (STI)& attend Pap Smear if indicated.
- Order additional tests as required prior to Pre-admission Clinic or hospital admission e.g. cardiac assessment, X-rays.

Counselling

1. Provide women with printed information, such as the RANZCOG pamphlet 'Tubal Occlusion and Vasectomy'[1] & 'Laparoscopy' / 'Hysteroscopy' if required. Inform that vasectomy is safer and quicker, with less morbidity than laparotomy/ laparoscopy.[2]
2. Discussion should include:

- Decision making: Alternative contraceptive methods[1], including long acting options[2]; what & who influenced the sterilisation choice & any ambivalence or coercion by partner or others; how long considered sterilisation; what role fertility plays in the woman's and/ or partner's concept of sexuality.[3]
- information about the procedure, preparation required, and complications[2, 3] (including risk for some ovarian carcinomas from the fallopian tubes left insitu and consideration of bilateral salpingectomy)[1]
- any medical issues that can affect the procedure[3]
- the use of contraception until sterilisation occurs; and that sterilisation provides no protection from STI[3]
- Irreversible nature of sterilisation and poor reversal success rates.[3] Successful reversal is most likely if clips are used on the mid-isthmus portion of tube.[3] Note: Hysteroscopic transcervical sterilisation is considered irreversible, however IVF pregnancies have been documented after using Essure®.[3]
- post-procedure signs of ectopic pregnancy[2], infection and complications
- failure rates,[3] and if pregnancy occurs after the procedure, there is increased risk of ectopic pregnancy[1, 2]
- risk of future regret[2], if situation changes (e.g. death of children/partner, breakup of relationship/marriage)[3]

3. The decision to perform tubal occlusion at the time of caesarean section should be discussed and consented in advance, in the antenatal period.[3] Women should be informed that intrapartum, postpartum and post-abortion requests by women for sterilisation have an increased regret rate and possible increased failure rate.[2, 3]
4. Women should be advised that alternative contraception should be used for 3 months after insertion of Essure® devices[2, 3] and ideally 7 days after laparoscopic sterilisation (see 'Follow-up' below).[2] If a diaphragm is the preferred option then this should be fitted prior to the procedure. IUDs are not recommended for use in the presence of Essure® microinserts as entanglement and inadvertent removal of microinserts at the time of IUD removal or insertion is a risk.

Consent

- Obtain written consent for the procedure on the MR295 Generic Consent Form. RANZCOG suggest it is good practice to record discussions in the medical file and in a letter to the referring doctor.[1]
- The woman's decision for sterilisation does not require consent from a partner.[3]
- If the woman lacks capacity to consent, the decision can only be made under direction of appropriate state authority.[3] See also RANZCOG Sterilisation Procedures for Women with an Intellectual Disability (C-Gyn 10).

- The operating health practitioner should ensure they are satisfied that a complete history, information exchange and examination have occurred, and that the woman does not have any concurrent conditions needing extra precautions/consideration.[2]

Pre admission clinic

Women should attend a Pre-admission Clinic (PAC) outpatient appointment within one week of the booked date for the procedure to allow anaesthetic and medical review. If attending Day Surgery her medical history will determine if she needs to attend the PAC. The woman will be advised of any preparation required prior to the procedure and timing of surgery at this appointment.

Post-procedural care

Women should be provided information on their surgery, any complications that occurred, recovery information and any follow-up care required.[2] See also relevant RANZCOG patient information pamphlets.

Follow-up[3]

Theoretically, laparotomy and mini-laparotomy have immediate contraceptive coverage and no other contraception is required (barrier STI protection may be used).[3] However, it is advised that if the woman was using combined hormonal contraceptives (CHC) (e.g. vaginal ring, combined oral contraception), progestogen only pill or non-hormonal contraception, that these continue for 7 days after laparoscopic tubal occlusion.[2] If a woman using CHC is due to have a hormone-free interval when the sterilisation is due, the woman should restart active CHC and continue until >7days after laparoscopic tubal occlusion.[2] If using the progestogen only implant, this can be removed at the time of procedure or any time afterwards.[2]

Hysteroscopic transcervical occlusive sterilisation with Essure® requires follow up after 12 weeks for radiological confirmation of complete tubal occlusion. Alternate contraception is required from the procedure until this confirmation.[3] Women should be advised that if they miss this appointment, they need to continue using alternative contraception until the tubal occlusion can be confirmed.[2]

Method failure:

Assess gestation, exclude ectopic pregnancy, discuss pregnancy choices, and consider future contraception as there may be increased risk of further failure.[3]

References

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Related legislation, policies and guidelines

Legislation – Guardianship and Administration Act 1990 (part 5, division 3: Limitations on sterilisation of persons under guardianship or where application for guardianship made)

Related Policies –

- DoH OD 0657/16 WA Health Consent to Treatment Policy (2016)

Other related documents –

- RANZCOG (2013): Sterilisation Procedures for Women with an Intellectual Disability (C-Gyn 10)
- Sexual Health Quarters (SHQ) (Information sheets): Contraception Choices; Male and Female Sterilisation
  (Note: Refer to SHQ website for multicultural contraception/ sexual health resources)
- SHQ (Health Professionals): Contraception Essentials (2013)

WNHS policies & guidelines

KEMH Clinical Guidelines: Contraception

See KEMH Policy Manual Consent to Treatment/ Surgery/ Intervention Policy (2014)

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