Hysteroscopic sterilisation performed in the outpatient setting avoids the risks and discomfort associated with the laparoscopic procedure. A variety of techniques has been assessed and discarded, mainly because of poor efficacy. More recently, the Essure® procedure has been shown to be easy to perform, acceptable to women and highly effective at five-year follow-up. However, concerns remain about the absolute irreversibility of this method of sterilisation. Other devices in development may prove to be equally effective but reversible. When introducing any new therapy it is important to ensure that informed consent is taken and outcomes are prospectively audited.

Keywords Essure® / hysteroscopy / outpatient procedures / sterilisation
Introduction

The ideal sterilisation technique would be safe, easy to perform and 100% effective. It could be done in the outpatient department and it would be potentially reversible. Researchers have attempted unsuccessfully for more than a century to find a procedure that meets all these criteria.

Female sterilisation is the most widely used method of contraception in the world. In the UK, laparoscopic sterilisation under general anaesthetic is the standard practice: around 20,000 women underwent this procedure in 2004/2005.¹ RCOG guidelines² quote the lifetime failure rate of laparoscopic sterilisation overall as 1:200, with that of the Filshie clip, the commonest method used in the UK, as 2–3:1000. Possible complications of laparoscopic sterilisation are: uterine perforation, visceral or vascular injury (3:1000) or even death (1:12 000).³ Shoulder tip pain secondary to the pneumoperitoneum is common postoperatively and the skin incisions can bruise or become infected. Advantages of the laparoscopic route, however, are that the pelvis can be inspected at the time of sterilisation and reversal is possible in 50–90% of cases.

Transcervical sterilisation techniques have been sought because they avoid the risks of the laparoscopic route, they allow women a quicker return to normal activities and they are especially useful in women for whom laparoscopy is contraindicated.

Historically, researchers have based their efforts around one of the following strategies:

* mechanical occlusive devices or plugs
* injection of tissue sclerosants or adhesives
* diathermy.

Electrosurgery has been abandoned as it was found to have an unacceptable failure rate⁴ and carried risks of perforation and visceral damage. Chemical and mechanical methods are still being pursued.

Chemical methods

Quinacrine

Quinacrine is the best studied chemical agent and offers the most promise of any such agent to date. Introduced as a technique for female sterilisation in Chile in the 1970s,⁵ it has been used worldwide with different dosages and frequency of treatments. Quinacrine has been more widely adopted in the developing world, as it is cheap and inserted without expensive hysteroscopic equipment.

The technique involves the blind introduction of pellets of quinacrine into the uterine cavity via a modified intrauterine device inserter. The pellets dissolve near the cornua, with some of the solution entering the tubes and causing a fibrotic reaction. The, now standard, technique, which involves the insertion of 252 mg of quinacrine on two occasions one month apart, has a quoted efficacy of 98% at two years.² Initial concerns over potential teratogenicity and carcinogenicity of quinacrine have not been substantiated. The Food and Drug Administration (FDA) approved research into quinacrine in 1998 and a phase I trial commenced in October 2000. The full results are awaited.⁶

Mechanical devices

Ovabloc® intratubal device

The Ovabloc® (Fame Medical Products, Nijmegen, The Netherlands) method has been in use since 1978. Phase II and III studies were performed in the late 1970s and early 1980s in Belgium and the USA.⁷ However, its use since has mainly been confined to a few centres in the Netherlands.

Technique

Insertion is an outpatient procedure. As the cervical canal must be dilated to a Hegar size 8 to allow the passage of an operating hysteroscope with a 7 Fr operative channel, premedication and intracervical local anaesthesia are required.

The procedure involves high pressure injection of viscous silicone into the ostium via a catheter. The silicone conforms to the shape of the ampulla of the tube and cures in approximately five minutes. The silicone contains radio-opaque silver powder which enables a radiological check for correct placement at completion of the procedure. Bilateral placement takes around 30 minutes.

The woman is asked to use contraception for three months, at which point a further plain X-ray is performed to exclude migration and expulsion.

Results

Published data report a 17% insertion failure rate. In women with a successful insertion the plug was expelled in 5% of cases, and it was removed because of complications in a further 3% of cases.⁸

Although the plug can be removed there is no evidence that this procedure is reversible.

Essure® device

Essure® (Conceptus, Inc., San Carlos, CA, USA) was approved for use by the European Union in 2001 and the FDA in 2002. It is widely used in Australia, the USA and Europe. The National Institute for Clinical Excellence (NICE) reviewed the device in February 2004.⁷ Having analysed the early data then available, it stated that the procedure should only be used with full informed consent and audit of outcomes. Essure is the only licensed hysteroscopic sterilisation technique in the UK.
**Technique**

This procedure involves the hysteroscopic application of a micro-insert into the intramural portion of the fallopian tube. Each device consists of a 4 cm long nickel–titanium (Nitinol®, NDC, Fremont, CA, USA) alloy outer coil within which lie polyethylene terephthalate (PET) fibres (Figure 1).

The procedure is performed with a standard 5/5.5 mm hystroscope with a 5 Fr (1.7 mm) operating channel. Procedure times from insertion to removal of the hystroscope are reported to be around nine minutes\(^1\) and local anaesthesia is not required. Figure 2 shows the hysteroscopic view after correct placement.

The PET fibres induce a fibrous reaction in the tube which peaks at around three weeks.\(^2\) Patients are instructed to use alternative contraception for three months after the procedure; a plain X-ray or hysterosalpingogram is done at this point to check continued correct device placement (Figure 3). Recent data suggest that in the majority of women a transvaginal scan can eliminate the need for X-ray follow-up.\(^3\)

**Results**

The first study of the safety and effectiveness of this procedure was published in 2001\(^4\) and showed that bilateral placement was achieved in 85% of cases. With increased experience, and following a slight modification to the device in 2003, insertion rates have risen to 98%.\(^5\) Satisfaction levels are generally high, with 96–97% of women reporting responses of ‘good’ to ‘excellent’ at up to two years.\(^6,7\)

Whenever the devices have been successfully inserted and a check X-ray at three months has indicated correct retention, no pregnancies have been reported.\(^8,9\) The pregnancies reported after Essure have been in cases where either the follow-up X-ray was misread or the woman failed to attend for her check-up at three months.

Over 50 000 procedures have now been performed worldwide (personal communication, Conceptus, Europe) with 12 000 of these in Europe, where 600 surgeons are trained in the technique. The FDA recently accepted data indicating 99.74% effectiveness with usage over five years.\(^10\)

Reported complications are: mild vaginal bleeding for up to one week in 57% of women; pain (69% reported no pain, 31% reported some pain, mostly mild, with 4% stating it to be as severe as their usual level of dysmenorrhea); and perforation (1%).\(^11\)

First generation ablative techniques are not possible after Essure because of the risk of transmission of electrical current along the device. However, thermal balloon ablation can be performed at the same time (R Valle, personal communication).

**Devices in development**

**Complete®**

Adiana’s Complete® transcervical sterilisation procedure (Adiana Inc., Redwood City, CA, USA) is a two-stage procedure. In the first stage, the epithelium of the intramural part of the tube is treated with radiofrequency energy. The second step is placement of a porous, silicone, nonbiodegradable matrix into the tubal lumen. The implant provokes a fibrous reaction that occludes the tube over a period of weeks. As with the Essure device, women are asked to continue using contraception for 12 weeks. A hysterosalpingogram at this time confirms tubal blockage.
New developments

The EASE trial (Evaluation of Adiana System) was completed in 2005. It was stated that 612 women were treated, with a 95% bilateral insertion rate and average treatment time of 12 minutes. In 6900 women–months of usage, there has been only one reported pregnancy with a properly placed device (T Vancaillie, personal communication). Twelve-month data are due for submission to the FDA towards the end of 2006.

Ovion Eclipse®

Ovion Eclipse® (American Medical Systems, Minnetonka, MN, USA) permanent contraceptive device consists of an expandable metal tube containing an inner matrix that induces fibrosis and blockage of the intramural part of the tube. At under 2 cm in length it is shorter than the Essure device. The procedure is at an early stage of development and FDA approval has not yet been sought.

Intratubal Ligation Device®

The Intratubal Ligation Device® (Invectus Biomedical, Salt Lake City, UT, USA) differs from those above in that occlusion is achieved by ligation of an invaginated portion of tubal epithelium by an elastomeric band. Subsequent scar formation creates a permanent tubal blockage. This procedure is currently in early development, awaiting phase I trials (personal communication, Invectus Biomedical).

Current situation in the UK

Uptake of Essure in the UK has been limited. The cost of the disposable devices and a lack of awareness of the technique among clinicians and public alike are possible reasons for this. Alternatively, clinicians here may simply be more cautious about the absolute irreversibility of the procedure and the relatively short-term data.

Perhaps surprisingly, in a recent patient preference study only 29% of a group of British women chose hysteroscopic over laparoscopic sterilisation. However, as the researchers pointed out, this may have partly been because of the relatively low level of pre-existing knowledge of the hysteroscopic operation compared with the laparoscopic.

The cost of the disposable devices can be offset by realising savings in the usage of inpatient beds and theatre time and the irreversibility of a sterilisation procedure remains only a relative drawback to many clinicians. It is likely that, with an ever-enlarging available volume of data on Essure and more surgeons receiving training, the technique will be adopted on a wider scale in the UK. However, as with any relatively new therapy, adequate patient counselling and prospective audit of outcomes are vital.

Summary

Hysteroscopic sterilisation has now become another option in permanent contraception and women should ideally be allowed to make an informed choice about which procedure they undergo. Insertion of the Essure device is a safe outpatient procedure with proven effectiveness at five-year follow-up. Further devices are being developed and it remains to be seen whether an equally effective, reversible technique will become available.

Declaration of interest

Andrew Baxter runs training sessions in the Essure technique. Course fees are paid into a hospital charitable account.

References

9 National Institute for Clinical Excellence. [www.nice.org.uk/ipcat.aspx?c=715232]
15 Conceptus. [www.conceptus.com].
17 Delphi Ventures – Adriana, Inc. Reports Completion of Treatment Phase of EASE Transcervical Sterilization Trial. [Press release 9 May 2005] [www.delphiventures.com].

© 2006 Royal College of Obstetricians and Gynaecologists