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RAPID COMMUNICATION

The Essure™ hysteroscopic sterilisation procedure: initial experience in Sheffield, UK

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Abstract Essure™ hysteroscopic sterilisation is a minimally invasive, outpatient approach to female sterilisation, which avoids the possible complications of laparoscopic sterilisation. We present our experience of the first 100 cases of the procedure performed in our unit. The successful placement rate overall was 87%. Insertion failure, more common with the older devices and in the earlier part of the series, was due to pre-existing tubal damage in the majority of cases. Our patient satisfaction survey revealed that the procedure was associated with low pain scores and high satisfaction levels.

Keywords Sterilisation · Outpatient hysteroscopic procedures · Permanent contraception

Introduction

A WHO survey [1] in 1992 estimated that about 100 million women rely on permanent sterilisation as a form of contraception. A 1995 survey of several thousand US women found that the most popular contraceptive methods for a couple were female surgical sterilisation (28%) and oral contraceptives (27%). Over 21,500 laparoscopic sterilisations were performed under the NHS in England [2]. The Royal College of Obstetricians and Gynaecologists survey in 1999 estimated that in approximately 30% of couples with at least one partner sterilised, female sterilisation was more popular than male sterilisation [3].

Laparoscopic sterilisation is an invasive abdominal procedure associated with recognised complications. A prospective study of the complications of diagnostic laparoscopy by Kane and Krejs [4] revealed rates of 5.1% for minor complications and 2.3% for major complications requiring surgery or transfusion. The US Collaborative Review of Sterilization (CREST) study [5] showed that the risk of laparotomy to complete the sterilisation procedure is greater if the woman has a history of previous abdominal or pelvic surgery or obesity greater than 12% of ideal body weight. CREST study reported 10-year cumulative failure rates for all types of tubal occlusion methods of 18 per 1,000. A lower failure rate has been obtained with the Filshie clip. A prospective 10-year follow up study using the Filshie Clip [6] was commenced at the Family Planning Association in Nottingham in 1982 and only one patient out of 434 became pregnant giving a lifetime risk of 2.5 per 1,000 procedures.

Transcervical sterilisation was initially attempted in the 19th century and a variety of techniques have been assessed in an attempt to provide an alternative to traditional sterilisation methods. Three modalities have been used: chemical agents, electrodiathermy and mechanical methods. Electrosurgical sterilisation was found to have a high morbidity and has been abandoned. Of the chemical agents, Quinacrine has shown the most promising results and is still under investigation. A variety of mechanical or occlusive plugs were poorly retained.

The worldwide introduction of Essure™ has made hysteroscopic sterilisation a real option for women requesting permanent contraception. Introduced in a clinical trial in Australia in 1998, Essure™ gained an EC mark in 2001 and FDA approval in 2002. A modified device, with higher insertion rates, was introduced in 2004.

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As minimal anaesthesia and analgesia is required, women now have the option of permanent contraception while avoiding the risks associated with laparoscopy and general anaesthesia. The procedure is well tolerated and liked by patients and women are able to resume their normal activities within a few hours. Essure™ hysteroscopic sterilisation is highly effective. Five year data accepted by the FDA in 2005 demonstrated a 99.74% success rate [7]. No pregnancies have been reported when the devices have been correctly sited and the follow-up check performed correctly. The few pregnancies that have been reported to date were either associated with failure of the patient to attend the three-month follow-up or due to misreading of the ultrasound or hysterosalpingogram (AAGL Nov 2004).

Over 50,000 procedures have been performed worldwide to date, with 12,000 of these in Europe. NICE guidance on the Essure™ procedure in 2004 concluded that units performing Essure™ hysteroscopic sterilisation must have special arrangements for audit or research due to lack of availability of long term data.

We have been performing Essure™ hysteroscopic sterilisation at the Jessop Wing of the Royal Hallamshire hospital since November 2002. We report on our experience with this new technique in terms of success rates, complications and patient acceptability.

Methods

One hundred patients underwent outpatient hysteroscopic sterilisation between November 2002 and November 2005. All procedures were performed in the outpatient hysteroscopy clinic of this teaching hospital by one of three consultant gynaecologists experienced in diagnostic and operative outpatient hysteroscopy. Patients referred to the outpatient gynaecology clinic with a request for permanent contraception were counselled and provided with verbal and written information on outpatient hysteroscopic sterilisation and inpatient day case laparoscopic sterilisation.

Women opting for the Essure™ were advised of the absolute irreversibility of the procedure, a 5–10% insertion failure rate, possible complications of uterine perforation, device migration and infection. It was emphasised that they would be required to continue to use contraception until a check abdominal X-ray was done at three months post-procedure. High vaginal and cervical swabs were taken routinely and cervical cytology when indicated.

The procedure was timed, if possible, for the first half of the menstrual cycle. When appropriate, women were advised to take two packets of the combined oral contraceptive pill without a break to avoid bleeding at the time of the procedure. Women took a premedication of diclofenac sodium 100 mg and paracetamol 1 g orally two hours prior to their appointment. If non-steroidal inflammatory agents were contraindicated, 30 mg of codeine phosphate was substituted. A urine pregnancy test was performed prior to the procedure.

Initially the hysteroscopy was performed using a Cusco's speculum for visualisation and tenaculum to hold the cervix, with an intracervical block of 3 ampoules of Citanest (prilocaine hydrochloride 30 mg/ml and felypressin 0.03 IU/ml). Latterly a vaginosocopic approach without the use of local anaesthetic has been used. Three litre bags of normal saline in a pressure bag set at 60–100 mmHg were used for irrigation. All the procedures were performed using a standard Olympus 5.5 mm hysteroscope with a 5Fr operating channel. 'Rescue' analgesia, by way of 'Entonox', was available if required. Women could watch the procedure on the monitor if they wished and were allowed home within 30 min of the procedure. Two nurses were required in the clinic: one to attend to the patient and the other to assist the surgeon and monitor the irrigation fluid.

An audit nurse has recently been employed to contact the women by telephone 48 hours after the procedure. Patients were asked to assess their satisfaction and pain levels and detail their requirement for analgesia and ability to resume normal activities.

The standard follow-up check of device placement was a plain abdominal X-ray three months after the procedure. A hysterosalpingogram (HSG) was arranged if the X-ray was inconclusive, if less than three or more than eight coils were seen in the uterine cavity at the end of the procedure or if the women had experienced undue pain during the insertion (suggesting an increased risk of possible perforation).

Results

One hundred Essure™ hysteroscopic sterilisation procedures were performed between November 2002 and November 2005. The modified Essure™ devices were introduced in April 2004: 37 procedures were performed with the old devices and 63 procedures with the modified devices. Two patients had uterine anomalies (one subseptate and one bicornuate uterus); the Essure™ devices were successfully placed in these cases. Two patients had a Thermachoice™ endometrial ablation performed immediately after the Essure procedure. Five patients had repeat procedures following the first failed attempt.

Bilateral insertion of the devices was possible in 85 (85%) women at the first attempt and 87 (87%) with two attempts. The causes of insertion failure are detailed in Table 1. The patient with severe pain could not tolerate the initial hysteroscopy; in the 'obese' woman it was not

Table 1 Reasons for failed Essure™ device placement (n=13)

Reason for failure	Number of cases
Pain	1
Obesity	1
Failed cannulation	11
Tubal investigations in failed cannulation (n=11)	
Blocked tubes	8
Declined HSG and opted for different contraception	2
Failed to attend tests	1

possible to reach the uterine fundus with the standard length hysteroscope.

Of the five patients who had repeat procedures, two were successful, while the remaining three patients were confirmed to have tubal blockage on subsequent assessment. Insertion rates compared with the number of procedures performed is shown in the Fig. 1. Our successful placement rate with the old devices was 76%, which increased to 94% with the modified devices. Whilst the overall insertion rate was 87%, it is notable that in our last 40 cases, we did not encounter any failures.

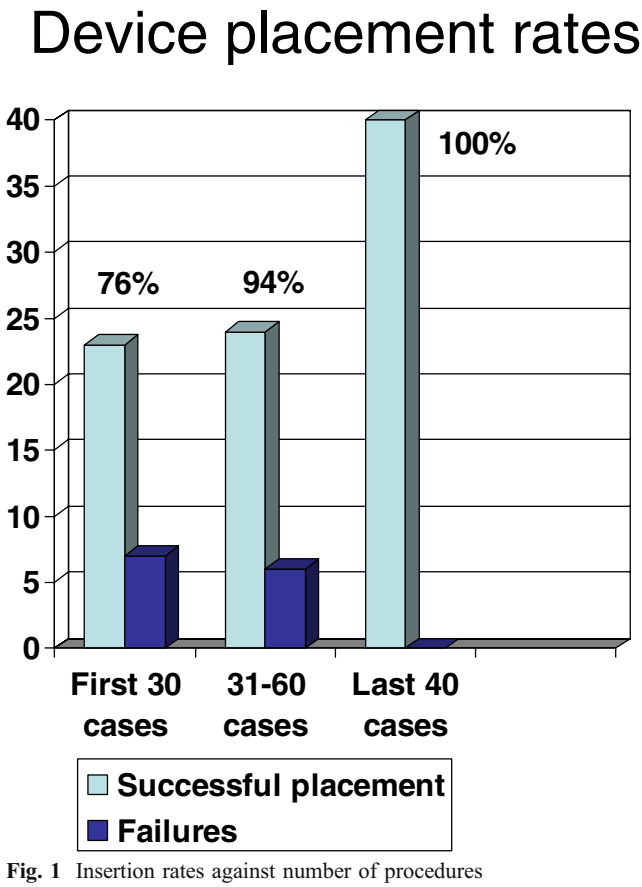

Fig. 1 Insertion rates against number of procedures

Three incorrect device placements occurred in our initial cases using the old devices. One device, that was known to be too shallow, was passed vaginally. This woman had a successful second procedure.

In another patient, where the ostia were very lateral, one of the devices was eventually found to have migrated distally and the other to have perforated the tube near the cornua. Although the correct number of coils was seen in the cavity at the end of the initial procedure, the woman did experience pain at the time of insertion, which settled spontaneously. She was well enough to go home, but subsequently presented six days later with pain on the left side. An ultrasound scan revealed bright echoes of the devices within the myometrium and no other pathology was noted. She was treated with antibiotics for a possible infection and allowed home the same day. The abdominal X-ray at three months suggested that the left device was inappropriately sited; this was confirmed by outpatient hysteroscopy, which revealed an absent device on the left side. The patient was therefore offered a diagnostic laparoscopy and tubal sterilisation. At laparoscopy the cornual perforation was apparent on the right side and the left device was located free on the omentum. Both devices were removed without difficulty.

In the third patient, a normally sited device migrated in a woman who did not experience pain at the time of the procedure. A hysterosalpingogram at three months revealed in fact absent filling of either tube, with a correctly sited device on the right, but a more distal placement on the left side. An outpatient hysteroscopy and transvaginal scan confirmed the absence of a correctly sited device on the left side and at a subsequent laparoscopy, the migrated device was again located on the omentum and easily removed.

Two other patients presented with pain after device insertion within two weeks of the procedure. They were managed conservatively. Ultrasound scans in both cases were normal and repeat hysteroscopy confirmed correct device placement. Both patients settled without further treatment.

Of the 83 patients who had uncomplicated bilateral placements to date, 79 patients have had either an abdominal X-ray or HSG to confirm device positions. Two patients have failed on several occasions to attend for assessment; two patients still await their 3-month review. Only two patients, as described above, have been shown so far to have incorrect device placement. In both these patients' the device migrated distally into the peritoneal cavity.

Thus far, 37 patients have been followed-up with a 48-hour telephone questionnaire to assess their well being, identify possible complications and monitor patient satisfaction. Our survey revealed that 24 (65%) patients experienced no pain or mild pain during the procedure,

eight (20%) moderate pain and six (15%) severe pain. Only three (8%) patients felt that they would have preferred to have more pain relief. One patient felt that she would have preferred to have a general anaesthetic. Most patients (36 out of 37) said that they would recommend this procedure to a friend and all patients were satisfied with the care that they received.

Discussion

Our successful insertion rate has increased with time, which reflects the experience from other centres. A multi-centre pivotal trial [8] was performed in mid-2000 in the USA, Australia and Europe involving 518 patients. Bilateral placement was obtained in 86% patients in the first attempt and 90% by the second attempt. The Essure™ device was modified and improved in 2003 and has been in use in our unit since April 2004. Our latest figures (see Fig. 1) now correspond with those from other reported case series: data from Kerin et al. [9] in 2004 demonstrated successful placement rates of 98% in 102 cases.

Our results have improved over time for several reasons. As with any other operative procedure, Essure™ hysteroscopic sterilisation is associated with a learning curve. This curve could have been steeper were it not for the fact that three clinicians were dividing the cases between them. Funding issues restricted the number of cases we were initially able to perform. Introduction of the modified newer devices made the devices smoother and slightly more rigid, making insertion easier.

By adopting the vaginoscopic technique and not using a speculum or instrumenting the cervix, women are less likely to experience discomfort. Despite this one woman could not tolerate insertion of the hysteroscope further than the internal os, a recognised complication of any hysteroscopy, with or without local anaesthetic. Indeed it has been shown that the use of local anaesthetic does not improve the outcomes in Essure procedures [10].

Early in our series, we did not routinely re-attempt the procedure in cases of failed cannulation due to the cost of the device. However, we have since successfully repeated the procedure in two out of five cases. This reflects the experience from other units where successful second attempts are possible in 50% of patients. Presumably the initial failure in these women is due to temporary tubal spasm. Such spasm may be reduced by the usage of warmed irrigation fluid and we have recently started using a warming cabinet. The use of antispasmodics has not been shown to reduce the incidence of tubal spasm. However, in a recent study from Singapore a significant increase in placement rates and decreased mean operation time were seen when patients were pre-medicated with spasmolytics (hyoscine) [11].

Appropriate patient selection can also help to reduce the rate of failed tubal cannulations. We initially performed the Essure procedure on all women requesting it, irrespective of possible complicating factors such as a history of ectopic pregnancy. This may have contributed to the high number of ‘failed’ cases subsequently found to have pre-existing tubal damage. We now perform pre-operative hysterosalpingogram on women at increased risk of having tubal damage. It remains to be seen whether the high incidence of tubal damage early in our series was a statistical glitch or a true reflection of our population.

Further improvements in our success rates may be possible with the use of longer hysteroscopes. In our series, one of our failures was related to an obese patient, where it was impossible to reach the ostia. Hysteroscopes with a greater length from the outflow port to the distal tip are available and are vital in certain cases.

Better successful placement rates can also be obtained by timing all procedures to the first half of the menstrual cycle. The thinner endometrium at this point in the cycle facilitates visualisation of the ostia and ensures correct depth of insertion. It was impossible to time all the cases in this way in our series as we only had one Essure session a month.

Follow-up has been by plain X-ray in most cases. HSG was used in cases of suspected perforation or incorrect placement. It has been shown that ultrasound can assess device placement [12]. This would have the advantage of avoiding exposure to radiation and could allow an earlier check-up of women with suspected incorrect placement.

Complications following hysteroscopic sterilization with Essure are rare with uterine perforation and device migration occurring in less than 1% of patients. The perforation in our series happened in a laterally sited ostia, which makes this complication more likely. It also occurred early in the learning phase, when perhaps too much force was applied.

In our series, postoperative pain was either none or mild in 65% of cases, moderate in 20% and severe in 15%. Only four patients had to be seen post procedure due to pain; of these two patients had a migrated device, the other two patients settled with conservative management.

Our patient satisfaction survey performed after 48 hours showed very high satisfaction rates of 97%. Similar results were obtained by Kerin in 2001 [13] at 2-year follow up.

Essure hysteroscopic sterilisation is being performed in increasing numbers throughout the world; however, the uptake in this country has been slow. There are a number of possible reasons for this. A recent study [14] on women’s attitudes in the UK towards sterilisation options showed that 77% preferred laparoscopic sterilisation rather than

hysteroscopic sterilisation despite its obvious advantages. This may be a reflection of a lack of awareness of hysteroscopic sterilisation by health workers in primary care and by the public, as very few centres in the UK offer the procedure.

In a recent cohort controlled comparative study of Essure versus laparoscopic sterilisation Duffy et al. [15] showed that Essure hysteroscopic sterilisation is associated with greater patient satisfaction than laparoscopic sterilisation. This agrees with a pilot study (unpublished data) conducted in our centre. We assessed patient well being after laparoscopic and hysteroscopic sterilisation by a questionnaire at 48 hours and 14 days. Our study showed that Essure hysteroscopic sterilisation was associated with a significant reduction in time spent in hospital, time spent recovering and time taken to resume normal activities. On average, patients returned to normal work 48 hours after the Essure procedure as opposed to 7 days with laparoscopic sterilisation.

A possible reason for the slow uptake of Essure is the cost of the devices; a pair of Essure devices costs around £550, whereas two Filshie clips cost £140. When staff, theatre time, in-patient costs, administration and other hospital charges [16] are taken into account, the costs per treatment are rather closer with laparoscopic sterilisation with Filshie clips costing £714.64 per treatment and Essure hysteroscopic sterilisation £816.46. An American cost-analysis study [17] found office hysteroscopic placement of the Essure device to be a more cost-effective method than laparoscopic tubal ligation.

Finally, clinicians in the UK may be more wary of the complete irreversibility of the procedure. It is of course vital that patients are fully counselled prior to any sterilisation operation, but some women may still regret the decision at a later date. Successful IVF pregnancies have now been reported after Essure (AAGL Nov. 2004) when microinserts were used to obstruct tubes distally obstructed by a hydrosalpinx prior to assisted fertility treatment [18].

Conclusion

Essure hysteroscopic sterilisation is a simple, reproducible procedure that, after appropriate training, can be performed by any gynaecologist with experience in outpatient hysteroscopy. Women requesting permanent contraception should now have the choice of this outpatient procedure. It avoids the risks of laparoscopic sterilisation and the 5-year results are promising. Our data indicates that the best figures seen around the world can be reproduced in the UK.

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