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ORIGINAL ARTICLE

A comparative study of Essure® hysteroscopic sterilisation versus laparoscopic sterilisation

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Abstract The purpose of this study is to compare success rate, patient satisfaction, discomfort, procedure time and intraoperative adverse events of hysteroscopic (Essure®) versus laparoscopic sterilisation. This study includes a retrospective case–control comparative study of 70 patients who had laparoscopic or hysteroscopic sterilisation performed. Systematic chart review for the documentation of preoperative counselling, operative time, intraoperative complications, documentation of correct application of Essure® and Filshie® clips and duration of hospital stay was also done. Patient follow-up was arranged and a questionnaire completed including details of postoperative pain, satisfaction of procedure, recovery time and compliance with confirmatory hysterosalpingogram attendance and associated pain. The main outcome measures were pregnancy rate following attempted tubal blockage, return to normal activity and patient satisfaction. Secondary outcome measures include patient discomfort, procedure time, device placement, compliance with hysterosalpingogram, postoperative complications and recovery time. There is a statistical difference in favour of Essure® for postoperative pain, operative time, return to work/normal activity and hospital stay with no difference in complications or pregnancy. As a conclusion, Essure® is a safe and effective alternative to laparoscopic sterilisation with significantly less procedure-related pain.

Keywords Hysteroscopic sterilisation · Essure® · Efficacy · Patient satisfaction · Recovery time · Coil placement · Laparoscopic sterilisation · Filshie Clips®

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Introduction

The average woman in the UK spends over three decades of her life actively avoiding pregnancy [1]. Traditionally, laparoscopic sterilisation is the most accepted and widely used method of tubal sterilisation [2].

Approximately 50,000 laparoscopic sterilisations are performed annually in the UK; this number has remained surprisingly constant since the 1980s [3].

The purpose of this study is to compare well-established laparoscopic sterilisation with the newer hysteroscopic Essure® sterilisation. Primarily, we will analyse success in terms of pregnancy rate and patient satisfaction in terms of pain experienced, return to normal activity and acceptability. We will also compare device placement, patient demographics, appropriate preoperative counselling, use of general anaesthesia, intraoperative and postoperative complications, operative time, duration of hospital stay and compliance with postprocedure hysterosalpingogram.

Laparoscopic sterilisation is a well-established, relatively safe operation. Nevertheless, it does carry with it the risk of visceral damage, vascular injury, damage to retroperitoneal structures, risk of general anaesthesia and less serious complications such as postoperative wound infection and pain [4]. These risks are further increased in patients with large body mass index (BMI), patients with previous abdominal or pelvic surgery and patients with previous pelvic infection, conditions that gynaecologists are facing on an increasingly frequent basis.

In 2002, the Essure® hysteroscopic sterilisation system was approved by the US Food and Drug Administration [5]. It is a transcervical technique of tubal sterilisation. The Essure® system consists of two microinserts comprising a dynamic outer coil and an inner flexible coil which are placed hysteroscopically into the fallopian tubes under direct vision [5].

The Essure® system provokes a benign localised tissue response of inflammation and fibrosis leading to the obliteration and occlusion of the tubal lumen over a 3-month period [6].

Hysteroscopic sterilisation offers an alternative to traditional transabdominal approaches to tubal sterilisation; therefore, it is not associated with the same intraabdominal complications. It can also be performed successfully in the outpatient setting without the need for anaesthesia or sedation.

Methods

We retrospectively reviewed the charts of women who underwent sterilisation in the form of Essure® or laparoscopic sterilisation with Filshie Clips® between April 2008 and December 2011 in a district general hospital. The period of follow-up ranges from 6–50 months, mean follow-up of 19 months.

In this study, patients who underwent the Essure® procedure were placed in the lithotomy position; and where possible, the vaginoscopic technique was performed using a 30° hysteroscope 5 mm in diameter with continuous flow Bettocchi sheaths. Normal saline under low pressure was used to dilate the cervix and facilitate visualisation of the proximal portion of each fallopian tube lumen for the insertion of the microinserts. All procedures were performed by one of two trained minimal access consultant gynaecologists.

All patients who underwent Essure® sterilisation were identified from theatre database. Sixty patients were identified. Six charts were unable to be obtained from the records department and therefore not analysed. Nine charts had insufficient information to complete the study e.g. inaccurate patient contact details, no record of operative time.

A control group of 25 consecutive laparoscopic sterilisations performed over the same time period and by the same operators were also identified from theatre database.

Laparoscopic sterilisation was performed using the Hasson technique for the insertion of a 12-mm umbilical trocar. One 5-mm peripheral trocar was used. The procedure was performed using an intraabdominal pressure of 15 mmHg. Filshie clips were placed perpendicular to the isthmic portion of the fallopian tube 1–2 cm from the cornua under direct visualisation.

A total of 70 patients from one centre were involved in this study, of which 45 underwent Essure® and 25 underwent laparoscopic sterilisation.

The notes were analysed for patient demographics including age, parity and BMI. Documentation of appropriate counselling was analysed in terms of the following:

- discussion of other options available including male sterilisation
- failure rate of chosen procedure
- documentation of permanency and irreversibility
- in the cases of Essure®, the requirement for alternative contraception for 3 months followed by imaging in the form of hysterosalpingogram

Intraoperatively, we analysed type of anaesthesia, intraoperative complications, documentation or pictures of correct Filshie Clip® and microinsert placement. Correct placement is taken as 3–8 coils visible in the uterine cavity following the placement of the Essure® devise. In the laparoscopic sterilisation group, it is the placement of the Filshie Clips® at the proximal isthmus at 90° to the long axis of the fallopian tube as described by Hulka and Reich [7].

Duration of hospital stay was recorded along with operative time as documented for both groups. As this was taken from the anaesthetic database, it is the time from the patient is positioned on the table to the end of the procedure. Following the procedure, in the cases of Essure®, the number of patients attending for hysterosalpingogram and the results were recorded.

All 70 patients were then contacted by the investigators and a survey completed. This was performed after a mean of 19 months (range 6–50).

This survey included the following details:

- patients' awareness of alternative options of sterilisation
- in the case of Essure® were patients given the opportunity to have the procedure performed awake
- if not would they have chosen to be awake
- satisfaction of the procedure using a three-point scale (very, somewhat, not at all)
- pain following the procedure on a 10-point scale (10 being the worst pain ever experienced, 0 being pain-free)
- postoperative complications
- time before return to normal activities
- awareness of the requirement for contraception for 3 months followed by hysterosalpingogram in the Essure® cases
- pain associated with hysterosalpingogram on a three-point scale (mild, moderate, severe)
- success of procedure in terms of pregnancies

Results were analysed using SPSS 15.0. Normally distributed continuous data was analysed using two-tailed t test. Mann–Whitney U test was used for non-normally distributed data. Risk ratios were calculated with 95 % confidence intervals. Significance level has been taken as $P<0.05$.

Results

Demographics

The demographic characteristics of the Essure® and laparoscopic sterilisation groups are summarised in Table 1.

Table 1 The demographic characteristics of the Essure® and laparoscopic sterilisation groups

	Essure	Lap Filshie	*P* value
Mean age (range)	36.5 (27–44)	35.1 (25–46)	0.22
Mean parity (range)	2.8 (1–6)	2.3 (1–5)	0.12
Mean BMI (range)	28.6 (19–56)	26 (16–32)	0.10

The mean age, parity and BMI in both groups were comparable with *P* values of 0.22, 0.12 and 1.0, respectively.

The mean BMI in patients who underwent Essure® was 28.6 compared with 26.0 in the laparoscopic sterilisation group. In the Essure® group, however, six patients (13 %) had a BMI >40.

Preoperative counselling

Twenty-seven out of 45 patients (60 %) attending for Essure® had documented evidence of appropriate counselling including as follows:

- documentation of alternative contraception options including vasectomy
- failure rate of procedure
- permanency
- irreversibility
- need for on-going contraception until hysterosalpingogram

Procedure

Initially, 50 of the 70 patients were due to have Essure®; however, five of these cases were converted to laparoscopic sterilisation. Reasons included cervical stenosis and tubal spasm. Therefore, placement of Essure® was achieved in 45 cases, 82 % of patients compared with 100 % of placement in the laparoscopic sterilisation group.

Correct coil placement bilaterally, defined as between three and eight coils visible on both sides was documented in 53 % of patients (36 % of patients had documented less than three coils visible on at least one side, and 11 % of patients had more than eight coils visible on at least one side).

Ninety eight percent of Essure® patients had their procedure performed under general anaesthesia. This compared to 100 % of patients on the laparoscopic sterilisation group. This was the units' first experience with the Essure® technique; therefore, general anaesthesia was largely employed initially.

Operative time was recorded from the anaesthetic record. This was significantly less in the Essure® group, mean time of 15.6 mins, compared to the laparoscopic sterilisation group, mean time 35.2 mins, with a *P* value of <0.001. Procedure details for both groups are summarised in Table 2.

Postoperative tubal patency

Forty women (89 %) attended for hysterosalpingogram 3 months following their procedure. Correct placement and bilateral occlusion was confirmed in 100 % of hysterosalpingograms including cases where microinsert placement was suboptimal (i.e. not the desired 3–8 coils visible in the uterine cavity following device placement).

Patient reported outcome measures

Results of the retrospective follow-up survey are summarised in Table 3.

On a three-point scale of satisfaction, 42 patients (93 %) were "very" satisfied with the procedure, and the remaining three patients were "somewhat" satisfied.

In the laparoscopic sterilisation group, 92 % were "very" satisfied and 8 % "somewhat" satisfied.

The mean postoperative pain score in the Essure® group on a 10-point scale was 3.2 (range 0–9), this compared to 6.5 in the laparoscopic sterilisation group (range 1–10), making this difference statistically significant with a *P* value of <0.001. Mean return to normal activities also showed statistical significance, *P* value 0.02.

In patients undergoing hysterosalpingogram, 15 out of 40 (37.5 %) described the pain as severe on a scale of mild, moderate and severe. This resulted in three women claiming they would reconsider Essure® hysteroscopic sterilisation on the experience of hysterosalpingogram alone.

Complications in the Essure® group consisted of one patient (2 %) who required a course of oral antibiotics for a presumed case of endometritis. In the laparoscopic sterilisation group, three patients (12 %) reported complications. One patient required readmission for analgesia (this patient has been included in the overnight stay group), and two required oral antibiotics for wound infections.

Pregnancy

There have been no pregnancies in either group patients accounting for 104 woman years. Follow-up in the Essure® group ranged from 3–47 months (mean 18 months). This time has been taken from the time of confirmatory test (or 3 months postprocedure in patients who did not attend for hysterosalpingogram) to the completion of questionnaire. In the laparoscopic sterilisation group, follow-up ranged from 6–44 months (mean 20 months) and is taken from the date of the operation.

Discussion

This study evaluated multiple aspects of a new surgical technique from a clinician and, more importantly, patient

Table 2 Procedure details for both groups

	Essure	Lap Filshie	*P* value
Operative time	15.6(6–35)	35.2 (20–65)	*P*<0.001
Bilateral placement (%)	82	100	RR 0.83 CI 0.72–0.96 *P*=0.009
Overnight stay (%)	2	24	RR 0.09 [95 % CI 0.01–0.73] *P*=0.02

perspective. The majority of permanent sterilisations in the UK remain laparoscopic sterilisations.

Laparoscopic procedures require general anaesthesia, which increases the overall risk to the procedure. They are also associated with increased postoperative pain and prolonged hospital stay. Laparoscopic sterilisation requires instrumentation of the abdominal cavity; although it is generally safe, it does carry a risk of vascular and visceral injury ranging from 4.5 per 1,000 laparoscopies [8].

One of the major advantages of laparoscopic sterilisation is the opportunity it provides to inspect the pelvis and abdomen to exclude pathology. Patients enjoy the advantage of being able to rely on laparoscopic sterilisation as contraception immediately after the procedure without a need for a confirmation test. It also provides essential laparoscopic training opportunities to trainees in the specialty.

Similarly, the Essure® procedure offers gynaecologists skills in operative hysteroscopy and the patient the opportunity to have a diagnostic hysteroscopy performed.

Obesity is an ever-growing epidemic challenging the health service at present. It adds to the complexity of procedures and increases the associated risks.

Essure® is not suitable for every patient. Contraindications include patients with previous ablation procedures performed, certain gynaecological malignancies, abnormal uterine cavity and patients less than 10 weeks postpartum. It is particularly useful in patients with an increased BMI, previous pelvic and abdominal surgery and previous pelvic infection. Where intraoperative hurdles present during hysteroscopic sterilisation such as tubal spasm or cervical stenosis, laparoscopic sterilisation is a reasonable alternative. Although according to Bettocchi, these problems can often be overcome by improved training in hysteroscopy [9] and equipment such as fluid management systems to ensure optimal intrauterine pressure. As our study was carried out following the introduction of Essure® into our unit, the conversion rate to laparoscopic sterilisation of 10 % may partially be attributed to operator inexperience.

Hysteroscopic sterilisation offers advantages to patients in terms of pain, hospital stay and recovery. In our study, there were less complications documented in the Essure® group; however, these were not statistically significant. From our study, the review of pregnancy rates has demonstrated that both procedures are comparable and reliable. Although the small number of cases prevents definitive conclusions, the follow-up period does provide reassurance that this new service is a safe alternative to laparoscopic sterilisation. Existing literature would further suggest that pregnancy rates are favourable for Essure® compared to laparoscopic sterilisation.

Hysterosalpingogram might be a source of considerable pain for some women. Thankfully, due to updated protocols, it is only indicated as a secondary confirmation test in special cases. Alternative modalities such as transvaginal ultrasound scan and plain x-ray have been recommended to be the best primary screening tests to demonstrate correct device placement and therefore increase the acceptability of Essure® [10].

A prospective multicentre cohort study carried out in the Netherlands in 2011 evaluating the use of transvaginal ultrasound in 1,145 women who underwent uncomplicated Essure® hysteroscopic sterilisation demonstrated that transvaginal ultrasound scanning was comparable to hysterosalpingogram in terms of diagnosing the adequacy of the procedure. As ultrasound is minimally invasive and avoids exposure to ionising radiation, the recommendation was that it should be considered as a first-line diagnostic test [11].

As with any retrospective study, there are obvious limitations. Firstly, six patients were unable to be included due to difficulties in the record department. Secondly, the operative time for Essure® patients should be documented as scope into vagina to scope out of vagina; however, as our time was

Table 3 Results of the retrospective follow-up survey

	Essure	Lap Filshie	
Return to work (days)	4.5 (1–17)	9.0 (1–35)	*P*=0.02
Postop pain score	3.2 (0–9)	6.5 (1–10)	*P*<0.001
Complications (%)	2	12	RR 0.19 [95 % CI 0.02–1.69] *p*=0.13
Pregnancy rate (%)	0	0	

recorded on the anaesthetic chart, this was not possible. However, by using times recorded by the anaesthetic staff, this does remove operator bias with regard to operative time. Thirdly, it is well-documented that patient recall of pain and satisfaction is less accurate and reliable with longer follow-up times.

The Crest Study previously demonstrated that one of the common beliefs regarding tubal sterilisation, that pregnancies were most common in the first year following the procedure, is in fact inaccurate. It demonstrated tubal sterilisation failures up to 10 years postprocedure [7]. This highlights the need for a longer follow-up period. The FDA recommends a 10 year follow-up postprocedure to monitor for additional pregnancies [10].

Several retrospective studies exist for pregnancy rates following hysteroscopic sterilisation such as "Hysteroscopic Sterilization: 10-Year Retrospective Analysis of Worldwide Pregnancy Reports" by Munro et al [12] which suggests that hysteroscopic sterilisation is 99.74 % effective against pregnancy at 5 years and smaller prospective studies such as "Hysteroscopic Sterilization Using a Microinsert Device: Results from a Multicentre Phase II Study" by Kerin et al [13] which reported no pregnancies after 6,015 woman months in 227 women. However, a large prospective study would be useful to further assess the reliability of Essure® such as exists for laparoscopic sterilisation in the Crest Study where >10,000 patients were followed up over 8–14 years for pregnancies [7].

Reviewing the outcome of Essure® in our unit has led to the introduction of this procedure being offered in our ambulatory outpatient hysteroscopy department using a vaginoscopic technique without anaesthesia or sedation. It is likely that by adopting the ambulatory approach to Essure®, outcome measures may become more favourable.

Conclusion

Essure® is a safe and effective alternative to laparoscopic sterilisation with significantly less procedure-related postoperative pain. Significantly shorter operative time, shorter hospital stay and faster return to normal activities make Essure® a superior procedure in many ways for women and health trusts. This study has reinforced the need to thoroughly counsel women and document informed consent appropriately.

Declaration of interest Kathy Niblock, Katie Connor, David Morgan and Keith Johnston declare that they have no conflict of interest.

Consent All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation. Informed consent was obtained from all patients included in this study

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