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REVIEW

Efficacy, safety, and patient acceptability of the Essure™ procedure

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Abstract: The Essure™ system for permanent contraception was developed as a less invasive method of female sterilization. Placement of the Essure™ coil involves a hysteroscopic transcervical technique. This procedure can be done in a variety of settings and with a range of anesthetic options. More than eight years have passed since the US Food and Drug Administration approval of Essure™. Much research has been done to evaluate placement success, adverse outcomes, satisfaction, pain, and the contraceptive efficacy of the Essure™. The purpose of this review is to summarize the available literature regarding the efficacy, safety, and patient satisfaction with this new sterilization technique.

Keywords: hysteroscopic sterilization, Essure™, safety, efficacy, acceptability

Introduction

On the spectrum of women's health issues, contraception is a leading topic of discussion. According to data gathered by the National Surveys of Family Growth in 2006–2008, the Centers for Disease Control reports that more than 99% of sexually experienced women have used at least one contraceptive method.[1] Of all the contraceptive options, tubal sterilization was utilized by 10.3 million women.[1] Tubal sterilization was second only to oral contraceptive pills, which were used by 10.7 million women.[1] The history of tubal sterilization has evolved dramatically since its introduction in the nineteenth century. Most recently, transcervical tubal sterilization techniques have offered women less invasive approaches for permanent contraception.

Developing reliable methods of hysteroscopic sterilization has proven an elusive goal. Since its first description in the mid 1800s, various substances have been used for tubal occlusion, including heat, mechanical plugs, and other chemical agents.[1–3] In 2002, Essure™ (Conceptus Inc, San Carlos, CA) became the first permanent contraceptive system to be approved by the US Food and Drug Administration (FDA).[1,3] Since that time, there has been a growing body of literature describing its safety, efficacy, and acceptability.

Description

The Essure™ system is a minimally invasive alternative for permanent female sterilization.[4–6] Essure™ utilizes a transcervical hysteroscopic approach to place permanent microinserts into the fallopian tube ostia bilaterally. The microinserts comprise an inner coil composed of stainless steel/polyethylene terephthalate fibers and an outer coil of nitinol, a nickel-titanium alloy.[3] The nitinol coil deploys and expands

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to anchor into the proximal fallopian tube.[3] The inner coil is composed of polyethylene terephthalate fibers which induce local tissue ingrowth and fibrosis, resulting in eventual occlusion of the fallopian tube.[3,7] This is a benign tissue response that takes several weeks for the desired result of complete tubal lumen occlusion to occur.[6] Therefore, a confirmatory test is required three months after Essure™ placement to confirm bilateral tubal occlusion. In the US, this test is a hysterosalpingogram.[6] Until this imaging study has been completed, patients must be properly educated on the need for another form of reliable contraception, such as oral contraceptive pills, Depo-Provera®, transdermal or transvaginal contraceptive patches or rings, barrier methods, or abstinence. Absolute contraindications to use of the Essure™ include allergies to nickel, titanium, or contrast dye.[2]

Efficacy

The indicator of efficacy of the Essure™ device is the ability to prevent conception from occurring. The US Collaborative Review of Sterilization investigated the efficacy of various tubal sterilization techniques in 1996, prior to the development of the Essure™. These procedures included clip sterilization, unipolar coagulation, bipolar coagulation, and postpartum partial salpingectomy. Cumulative 10-year probability of pregnancy was determined to be about 18.5 per 1000 female sterilization procedures.[8,9] The failure rate range was 7.5–36.5 per 1000. This included tubal sterilization methods, such as postpartum partial salpingectomy, laparoscopic unipolar coagulation, Falope rings, interval partial salpingectomy, bipolar coagulation, and spring clips.[8,9] The manufacturer of Essure™ reports effectiveness rates of 99.95%, 99.90%, 99.84%, 99.80%, and 99.74% at years 1, 2, 3, 4, and 5, respectively.[10]

Success of the Essure™ is largely dependent on correct placement. Manufacturer data using the Essure™ system model ESS205 reports the bilateral placement rate to be 94.6% after the first placement attempt.[11] Various studies have reported initial placement success at a rate of 84%–98%.[2] The results of a prospective Phase III clinical trial funded by Conceptus Inc were reported in July 2003. This study demonstrated that bilateral placement of the Essure™ device was achieved in 90% (464) of the 518 women participating in their study.[4] In these 464 women, bilateral placement was successful with only one procedure in 96%.[4] The remaining 18 women required a second placement procedure that was ultimately successful. Other studies, between the years 2004 and 2010, have reported rates of initial Essure™ insertion ranging between 88% and 98%.[7,12–16] These cases include both office and operating room settings, although some studies did not specify this.

When the initial attempt at Essure™ placement was not successful, the majority of patients were offered a second placement procedure. Many of these have been successful, raising the overall success rate for bilateral Essure™ placement to 92%–96%.[4,16] Panel and Grosdemouge reported success with the Essure™ among 96.7% of the 492 patients included in their prospective multicenter study in 2006.[14] Success was defined as bilateral placement of the Essure™ (on the first or second attempt) or unilateral placement with a history of a unilateral salpingectomy or confirmation of occlusion of the second fallopian tube via hysterosalpingogram.

Factors impeding bilateral placement from being possible include uterine anomalies and proximal tubal occlusion, tortuosity, spasm, or stenosis.[3,4,15] In the Cooper et al study of 518 patients, placement of the Essure™ was not attempted in 2% because of uterine, cervical, or fallopian tube pathology preventing exposure of the tubal ostia.[4] Anatomic factors, such as lateral tubes, endometrial polyps, uterine adhesions, stenotic tubes, obesity, and no visible tubal ostium, accounted for 77% of cases of failed bilateral placement in this 2003 study.

Hysteroscopy revealed 0.6% of patients with intrauterine pathology in another study, preventing physicians from proceeding with Essure™ placement.[14] In an office-based hysteroscopy analysis by Levie et al, 3% of patients were unable to have the Essure™ placed due to uterine pathology found at the time of hysteroscopy.[12] Some of these clinical situations included cervical stenosis, laterally-placed fallopian tubes, bicornuate uterus, and endometrial polyps or endometrium blocking view of the ostia.

The use of nonsteroidal inflammatory agents prior to the procedure appeared to increase the success of Essure™ placement.[3,13] In one study, women received an anti-inflammatory agent 30–60 minutes before the procedure, along with a paracervical block. The patients also received intravenous sedation if needed. Anti-inflammatory agents have been suggested to work by decreasing tubal spasm during the procedure.[17] However, this finding has not been replicated in all studies.[14]

Clinicians may encounter situations in which a patient has had a previous unilateral salpingectomy. A few studies have included these patients in their analyses, and shown successful placement and confirmation of tubal occlusion on hysterosalpingogram.[14] This suggests that a previous unilateral

salpingectomy is not a contraindication to an Essure™ procedure for occlusion of the remaining fallopian tube. Some research has included women with a previous history of a salpingectomy and previous hysterosalpingographic documentation of unilateral tubal occlusion. Documentation of unilateral salpingectomy and subsequent postprocedure tubal occlusion are important parts of the counseling in these cases.

Since the development of the Essure™ system, Conceptus Inc has attempted to address these issues by continually updating and improving the coil catheter delivery system. The new coil catheter system was designed to carry the Essure™ coil past areas of higher tubal resistance. Kerin et al investigated this new version of the Essure™ in 2004 and demonstrated a higher initial bilateral placement rate of 98%.[15] Such improvements in the device have been attributed to higher success with the initial procedure compared with the Phase II and Phase III trial data reported by Cooper et al[4] and Kerin et al in 2003[24].

Appropriate follow-up is necessary to determine the efficacy of this product. Patients must understand the importance of confirming tubal blockage and proper device placement with a subsequent imaging study. Without this objective evidence of tubal occlusion and/or device placement, they cannot rely on the Essure™ for contraception.[10] Until this confirmatory test, another reliable form of contraception must be used. The type of imaging study used for the Essure™ confirmation test varies according to location. The hysterosalpingogram is the method utilized in the US, but other countries rely on plain x-ray or transvaginal ultrasound to document placement.[18,19]

As discussed, three months following initial placement of the Essure™ coils, patients must undergo a hysterosalpingogram to confirm bilateral tubal occlusion. Unfortunately, not all studies included this aspect in their analysis of success of the Essure™ procedure.[7,12,14] Of the patients with successful bilateral placement of the Essure™, tubal occlusion rates are high, in the 92%–96% range.[4,17,20] Loss of patients at the three-month follow-up interval was a limitation in these studies. Compliance with follow-up has been documented to be as low as 12.7%.[7,21] This differs drastically from the 98% compliance with a three-month hysterosalpingogram reported elsewhere.[4] Savage et al reported that 13% of their study population was lost to follow-up prior to obtaining a hysterosalpingogram.[20] Factors accounting for these differences may include patient education, cultural and economic barriers, and physician compliance. Lack of a follow-up hysterosalpingogram was the singlemost important factor contributing to pregnancies reported to the manufacturer worldwide between 1997 and 2005.[3,5,6]

Physician experience does not appear to have a significant impact on efficacy. The Phase III clinical trial by Cooper et al included 20 physicians having a wide range of experience with hysteroscopy and the Essure™. Seventy percent of the physicians had no previous experience with the Essure™ system. Despite this, the physicians still had a high (>95%) success in placement with one procedure.[4] Length of time for the procedure improved with experience, and bilateral placement rates did not change significantly.[4] A larger retrospective study involving 884 women and 118 physicians at 30 different facilities had primary successful placement in 96.2% of these patients.[20]

Over the past few years, various patient characteristics have been investigated to determine if they have any effect on efficacy of the Essure™. Nulliparity, obesity, body mass index, previous abdominal surgery, and age have been evaluated in many studies, and have not been demonstrated to have an effect on success.[4,13,14,20] One study did show higher successful placement in an outpatient versus inpatient setting, despite similar patient characteristics.[20] Various uterine anatomy anomalies and pathology have been known to prevent placement of the Essure™ device.

Efficacy of the Essure™ device is ultimately determined by its contraceptive efficacy. Effectiveness in previous clinical trials has been defined as "a lack of pregnancies in women who have achieved bilateral placement, and have had a confirmatory hysterosalpingogram showing proper micro-coil location and occluded tubes".[17] Based on this criterion, there have been no reported pregnancies in the clinical trials.[17] This includes data from a prospective, international, multicenter Phase II trial that reported no pregnancies after 9620 woman-months of exposure to intercourse.[4] In a retrospective review of tubal occlusion and risk factors for failure conducted at Kaiser Permanente in Northern California, three of 884 women who underwent hysteroscopic Essure™ sterilization conceived after the hysterosalpingogram was interpreted as bilateral tubal occlusion. However, subsequent internal review of these three cases determined that the Essure™ devices were not properly placed.[20] Placement of the device during the follicular phase of the menstrual cycle is recommended by the device manufacturer. The two main reasons for this recommendation are ease of device placement with a thinner endometrial lining and to exclude the possibility of an early luteal phase pregnancy.[11] The only four pregnancies encountered in the pivotal trial were in women who were pregnant at the time of Essure™ placement.[11]

In 2007, Levy et al reviewed the reported pregnancies after Essure™ sterilization to date.[5] Of the estimated 50,000 Essure™ procedures performed worldwide between 1997 and 2005, there were 64 unintended pregnancies reported to the manufacturer. The causes of the pregnancies were evaluated by the reporting physician and manufacturer staff. Patient or physician noncompliance accounted for 47% of cases, followed by misinterpreted x-ray or hysterosalpingogram (28%), and then pregnancy at time of Essure™ placement (12.5%). One pregnancy was the result of Essure™ placement using a previous device design that is not available anymore. The other seven cases did not have sufficient information available to determine the cause or area of miscommunication. Examples of patient compliance issues included failure to return for three-month hysterosalpingogram and failure to use alternative methods of contraception before the hysterosalpingogram or after hysterosalpingogram confirmed tubal patency.[5] These are areas in which patient education and follow-up reminders may substantially reduce the failure rate. Also, pregnancy tests within 24 hours of Essure™ placement and placement during the follicular phase of a woman's menstrual cycle may avoid situations in which a patient is already pregnant at the time of Essure™ placement.

Safety

The American College of Obstetricians and Gynecologists has summarized the safety of traditional, nonhysteroscopic female sterilization techniques. Death from tubal sterilization is rare, with mortality rates in the US reported as 1–4 deaths per 100,000 procedures.[22] Traditional nonhysteroscopic female sterilization techniques carry an overall complication rate of 0.9%–1.6%.[22] The data regarding safety of the Essure™ device has been reassuring. The incidence of adverse events on the procedure day has been in the range of 0%–3.1%.[4,7,23] These have included vasovagal response, hypervolemia from uterine distention media, and severe emesis secondary to pain medication.[4] There were no major adverse events in the Phase II and pivotal trial data between 1998 and 2001.[6,24] The investigators classified "major adverse events" as death, bowel injury, and major vascular injury. "Perforation" is a potential complication of Essure™ placement. This has been reported in 0%–2.8% of patients in the literature.[6,23] As a hysteroscopic-dependent procedure, the basic inherent risks of hysteroscopy are risks of the procedure itself. Hysteroscopy has proven to be a safe and well tolerated procedure which can be performed in a variety of settings.[25] The safety of the procedure has been further confirmed by its successful use in high risk patient populations such as those with severe cardiac disease.[26]

Various side effects of Essure™ placement are discussed on the manufacturer's website. These include symptoms during or immediately after placement, such as mild to moderate cramping, nausea or vomiting, dizziness or lightheadedness, and bleeding or spotting.[10] Additional adverse events can be explored by review of the Manufacturer and User Facility Device Experience database. This database is organized through the US FDA. Its utility is to represent reports of adverse events pertaining to various medical devices. The link to this website is http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

For some patients and physicians, another appealing aspect of the Essure™ procedure is the possibility of performing the procedure in the office, rather than in the operating room. To date, research has supported the safety and efficacy of performing Essure™ procedure in both settings.[12–14,16,20] The procedure can also be performed with a variety of anesthetic agents. However, these options will vary at each institution, based on available resources and preference of the surgeon, anesthesiologist, and patient.

A prospective, multicenter study in France did not find any differences in success rates between centers, despite each center determining its own location (operating room versus hysteroscopy room) of Essure™ placement.[14] This group did not find any differences in success when they compared the types of anesthesia used. Their patient population utilized a variety of anesthetic options, including general, regional, intravenous sedation, local, and no anesthesia.

Nichols et al designed a multicenter, prospective study to compare Essure™ sterilization in the operating room versus the office.[13] The location of the procedure was determined on an individual basis by physician and patient preference. Of the 320 women enrolled in this study, 252 procedures were completed in the operating room versus 68 in the office. There was no difference between procedure time, bilateral placement rate, or complications between the two groups. However, the office population did have higher gravidity, more use of preprocedure nonsteroidal anti-inflammatory agents, and more use of oral contraceptives prior to Essure™ placement. A criticism of this study is the lack of randomization, which more accurately reflects the probable scenario practitioners will encounter. Patient preference will be a contributing factor when determining the location of Essure™ placement. Anesthesia choices varied between the operating room and office groups. The operating room group most frequently utilized a combination of paracervical block and

intravenous sedation, compared with the office group in which a paracervical block and an oral sedative combination was most common.

A recent publication in 2010 described the results of a randomized, blinded clinical trial investigating the effects of paracervical block with lidocaine on procedure pain compared with a saline placebo. There was no difference in successful placement or complications in either group.[27]

Another prospective study investigating the placement of Essure™ in the office setting had promising results.[16] The average procedure time was 12.4 minutes, and 96% of patients had successful bilateral placement of the Essure™ coils. They also had a 98% tubal occlusion rate at the three-month postprocedure hysterosalpingogram.

Overall, the safety profile of the Essure™ device appears to be excellent. There has been no difference in safety between operating room and office procedures. Ongoing research will need to continue to address the safety profile in the long-term, such as 10 and 20 years from insertion. Another question that may arise is that regarding tubal sterilization and its protective effects on ovarian cancer. Does the Essure™ female sterilization provide the same protective benefits in reducing ovarian cancer risk as traditional sterilization techniques?

Patient acceptability

Overall, studies have demonstrated high satisfaction with the Essure™. In a six-year review of the Essure™, the literature has reported satisfaction and comfort rated as good to excellent in 96%–99% of women at follow-up visits.[3] As part of their Phase III study investigating the Essure™ device, Cooper et al evaluated satisfaction in a cohort of 464 women with successful bilateral Essure™ microinsert placement. Comfort was rated as good to excellent by 99% at all follow-up visits. Another favorable aspect of this study was a shorter total procedure time compared with laparoscopy. The average time from procedure room entry to discharge from the facility was 80 minutes. As discussed in the previous section, the Essure™ has the appeal to many women of being a safe office procedure, if the medical facility has the necessary resources. Hysteroscopy time has been reported to be less than 15 minutes, on average, in both operating room and office settings.[4,13,14,16]

A study by Duffy et al compared laparoscopic tubal ligation with Essure™ hysteroscopic sterilization.[28] The results showed that 82% of Essure™ patients reported procedure tolerance as "excellent to good" compared with 41% of patients who underwent laparoscopic tubal ligation. This study evaluated patient satisfaction after a 90-day interval as well. Of the Essure™ patients, 100% were satisfied with their recovery, compared with 80% of the laparoscopic tubal ligation patients.

A 2010 publication by Levie et al specifically addressed the question of patient satisfaction with office-based Essure™ sterilization.[12] The majority of these patients (70%) rated procedure-associated pain as equal to or less than their typical menstrual pain. Their follow-up surveys were very positive in regard to patient satisfaction. Follow-up surveys were collected for 84% of the study patients. Of these, 92% preferred having the procedure done in the office, 98% would recommend the procedure to a friend, and 93% would undergo the procedure again if necessary. It is not surprising that higher satisfaction was significantly correlated with lower average pain scores.

Only a few studies have evaluated postoperative recovery and patient symptoms. In the prospective Phase III trial published in 2003, the majority of the participants (58%) reported an uneventful recovery period.[4] Of the 228 women who reported symptoms, the three most common ones were cramping (30%), pain (13%), and nausea (9%). These resolved in 56% of the women before discharge.

When addressing patient acceptability one must also consider cost. Essure™ has been shown to be a more cost effective option when compared to traditional laparoscopic sterilization.[29] This is true even if both procedures are performed in the operating room.[30]

We do not yet have data describing the outcomes of Essure™ placement in women with a history of chronic pelvic pain, severe dysmenorrhea, or severe dyspareunia. Therefore, we do not have the ability to counsel these patients adequately on postoperative satisfaction. Whether the Essure™ device will have any effect on their symptomatology is unknown.

There is limited literature investigating patient acceptability of the Essure™ hysteroscopic sterilization option. Patient preference for tubal sterilization options has not been investigated since the addition of the latest hysteroscopic sterilization techniques. Understanding potential barriers, patient awareness, and misconceptions about tubal sterilization options would improve women's health and physicians' ability to educate patients on permanent female sterilization. As with all sterilization procedures, the patient should understand the permanent nature of the procedure. The patient should have no desire for future pregnancies.

Conclusion

When structured protocols are followed, Essure™ hysteroscopic sterilization is an effective, safe, and well accepted

method of permanent sterilization. This review serves the purpose of providing information for practitioners to utilize when counseling their patients regarding the Essure™ permanent contraception option.

Disclosure

The authors report no conflicts of interest in this work.

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