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Review Article

Essure Hysteroscopic Sterilization Versus Interval Laparoscopic Bilateral Tubal Ligation: A Comparative Effectiveness Review

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ABSTRACT A comparative effectiveness analysis was performed to examine the risks and benefits of laparoscopic bilateral tubal ligation compared with hysteroscopic sterilization using the Essure Permanent Birth Control System (Bayer HealthCare AG, Whippany, NJ). Existing evidence shows that both LBTL and Essure are safe and effective methods of female sterilization. Both have high rates of efficacy and low rates of complications although when complications do occur, those related to the Essure procedure are more likely to be minor in nature. The analysis was limited by the restricted number of studies involving head-to-head comparisons of the 2 approaches. Journal of Minimally Invasive Gynecology (2015) 22, 342–352 © 2015 AAGL. All rights reserved.

Keywords: Essure; Hysteroscopic sterilization; Laparoscopic; Tubal ligation

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Unintended pregnancies remain a serious public health issue worldwide, and it is estimated that in the United States about 50 unintended pregnancies per 1000 women of reproductive age occur per year [1]. Twenty-seven percent of the estimated 38.2 million women using contraception in the United States rely on bilateral tubal sterilization [2,3], with the proportion of contraceptors choosing female sterilization increasing with age, reaching 50% among contraceptors aged 40 to 44 years [4]. It is estimated that approximately 700 000 female sterilization procedures are performed in the United States annually [2,5,6].

Tubal sterilization can be implemented either postpartum or as an interval procedure unrelated to the time of pregnancy. Approximately one half of tubal sterilizations are performed as interval procedures [7]. By the mid-1990s, the majority of interval tubal sterilizations were performed laparoscopically, mostly under general anesthesia [7]. These procedures are commonly referred to as laparoscopic bilateral tubal ligations (LBTLs), and they involve a variety of occlusion techniques, including bipolar coagulation, ligation, or mechanical occlusion techniques using spring clips or silastic rings. Interval laparoscopic sterilization is typically performed in an outpatient facility under general anesthesia [8]. In 2002, the US Food and Drug Administration approved the Essure Permanent Birth Control System (Bayer HealthCare AG, Whippany, NJ) [9], which can be placed in an outpatient facility or physician office setting without the need for general anesthesia. The Essure Permanent Birth Control System consists of 2 microinserts that are placed hysteroscopically in the proximal fallopian tubes where they induce a fibrotic reaction that causes complete tubal occlusion in approximately 3 months. Verification using imaging techniques such as a modified hysterosalpingogram (HSG) in the United States, transvaginal ultrasound, or x-ray is essential at the end of this period to ensure that the inserts are in the correct position. The modified HSG can also determine if occlusion has occurred. Women undergoing the Essure procedure are counseled to use alternative methods of contraception for 3 months after the procedure and until microinsert location and occlusion (in the case of HSG) are confirmed with imaging. The manufacturer's instructions for use recommend the administration of a nonsteroidal anti-inflammatory drug 1 to 2 hours before the microinsert placement procedure along with a local anesthetic. Intravenous short-acting benzodiazepine or a similar agent may also be administered to prevent or reduce

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discomfort if needed; 497 305 Essure kits were distributed worldwide from 2001 to 2010 [10].

The aim of the present analysis was to compare interval LBTL versus hysteroscopic sterilization using the Essure device in terms of procedure completion rates, reliance, procedure efficacy, pain, and complication rates.

Methods

We searched PubMed and the Cochrane Database of Systematic Reviews. PubMed was searched for randomized controlled trials, reviews, systematic reviews, meta-analyses, clinical trials, and comparative or longitudinal observational studies published between January 1, 2003, and October 31, 2013, using the following terms: "([Essure® OR tubal ligation OR tubal sterilization OR tubal coagulation OR tubal occlusion OR laparoscopic sterilization OR hysteroscopic sterilization] AND [contracepti* OR sterilization OR pregnancy prevention])," "([laparoscopy OR laparoscopic] AND [tubal ligation OR sterilization] AND trocar AND [injuries OR injury OR complications])," "([tubal clip OR bipolar coagulation OR unipolar coagulation OR tubal silicone ring OR silicone rubber band OR falope ring OR spring clip OR spring-loaded clip OR Hulka$ clip OR Filshie clip] AND [sterilization OR sterilisation])," and "(anaesthe* OR anesthe* AND laparoscop* AND [gynecol* OR gynaecol* OR women OR sterilisation OR sterilization OR ligation])." Search results were filtered for "humans," "English language," and "abstract available." The Cochrane Database of Systematic Reviews was searched for Cochrane reviews, other reviews, trials, technology assessments, and economic evaluations published between January 1, 2003, and October 31, 2013, using the following search terms: ([Essure® OR tubal ligation OR tubal sterilization OR tubal coagulation OR tubal occlusion] AND [contraception OR sterilization OR pregnancy prevention]). In addition, we conducted a general Internet search for instructions for use (IFUs) for medical devices involved in tubal ligation and for recent government publications with statistics and demographic data related to unplanned pregnancies and sterilization procedures. Original studies with less than 50 subjects were removed from the analysis. The PubMed, Cochrane, and general Internet searches resulted in the selection of 48 clinical articles, 2 IFUs, and 1 government publication. Reference lists from all selected articles were reviewed by 2 independent reviewers to find additional publications. Nine additional articles were selected from reference lists for a total of 58 publications and 2 IFUs (Fig. 1). In addition, after a comprehensive review of the included/excluded studies, we elected to include a particular foundational publication specific to laparoscopic tubal ligations, the 1996 US Collaborative Review of Sterilization (CREST) [11]. The CREST study is a large, prospective, multicenter observational study of 10 685 women conducted by the US Centers for Disease Control and Prevention. It is the largest single study conducted on the outcomes of female sterilization procedures in the United States and the most frequently cited source of method-specific rates of unplanned pregnancy. Because the CREST study is the most encompassing study of the procedure to date and its results are frequently cited in more recently published studies, it seemed appropriate to include it despite its earlier publication date.

All studies were reviewed independently by 2 reviewers and assessed for their risk of bias (quality assessment, grading studies as "good," "fair," or "poor" based on guidance documents from the US Agency for Healthcare Research and Quality). Conflicts were resolved by consensus. Data from included studies were extracted and entered into an electronic database using Excel software (Microsoft, Redmond, WA). The extracted data included study design; US study versus outside of the US study; setting of care; study population description; number of study subjects; patient ages; intervention characteristics; incidence/prevalence data of interest; and outcome measures including procedure completion rate, reliance for contraception, HSG compliance rates, efficacy, pain during and/or after the procedure, complications, and associations with hormonal changes and cancer risk (Table 1). Although we used a 10-year period for selecting the published literature, we used a more extended time frame in treating information from cited, earlier studies. Specifically, for cited data, we used a cutoff point of January 1, 1993. Data were analyzed qualitatively; because of the lack of comparable study designs and outcomes, pooled analyses were not conducted.

Results

Procedure Completion Rate

Because of inherent differences in the nature of the sterilization procedures, successful completion rates are a more relevant metric for Essure than LBTL. We found no studies for which successful completion of laparoscopic tubal ligations was a specified end point; however, Mackenzie et al [12] found that laparoscopic Filshie clip (CooperSurgical, Inc., Trumbull, CT) sterilization procedures were terminated before completion in 0.5% of women because of pain or nonnegotiable pelvic adhesions encountered during the procedure. In another prospective cohort-controlled study, all women undergoing laparoscopic sterilization had successful completion [13]. However, the number of women in the laparoscopic sterilization study arm was very limited (n = 22).

Essure procedures present a more complicated situation for determining procedure completions because not all procedures result in successful bilateral placement. Furthermore, a percentage of women with successful bilateral placement may be found to have inadequate placement or a patent fallopian tube at 3-month confirmation testing. In Essure's phase II trial, successful bilateral placement occurred in 98% of the study population (100/102) during the initial placement attempt [14]. In Essure's phase III trial, 92% of women (464/507) had successful bilateral placements at the first attempt [15]. Eighteen of the 43 women with initially unsuccessful placement in the phase III trial had successful bilateral placement at the second attempt. The reasons for unsuccessful placement were varied, but tubal obstruction and stenosis or difficult access to the proximal tubal lumen were the most common reasons for placement failure [15]. Notably, both trials used first-generation Essure devices that are no longer on the market. In postmarketing trials, bilateral placement rates have shown improvement with updated delivery catheters. Several studies using Essure's third-generation catheter show bilateral placement rates ranging from 92% to 99% [16–26]. Duffy et al [13] reported lower bilateral placement rates of 81%; however, 3 of