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Hysteroscopic Essure Inserts for Permanent Contraception: Extended Follow-Up Results of a Phase III Multicenter International Study

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problems occurred. A diagnostic hysteroscopy was performed on all patients at 5 years. The cavity was found to be open, and both tubal ostia could be visualized. The authors concluded that MTCER can successfully treat menorrhagia without causing intrauterine scarring, thereby avoiding long-term complications [10].

We are currently completing a long-term follow-up of patients who underwent PEA. Questionnaires have been sent to 247 patients who underwent partial rollerball endometrial ablation between 1991 and 2003. Preliminary results are encouraging. The mean follow-up is 17.5 years, with a patient satisfaction rate of 89%. No patient developed new-onset cyclic pelvic pain. Hysterectomy was required for recurrent AUB in 8%, and all were found to have deep adenomyosis. This confirms Zupi et al's suggestion that when deep adenomyosis is strongly suspected in preoperative imaging studies, a hysterectomy should be recommended over any type of ablation.

In conclusion, we agree with Zupi et al that the lower reintervention rate and the better physical and mental health scores make LSH a more suitable procedure than HEA for treating AUB that is resistant to medical therapy. However, if future studies confirm that PEA provides successful treatment of intractable AUB without long-term complications, it would be a less-invasive procedure than hysterectomy for the treatment of intractable AUB.

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Hysteroscopic Essure Inserts for Permanent Contraception: Extended Follow-Up Results of a Phase III Multicenter International Study

To the Editor:

We read the article by Drs. Chudnoff, Nichols, and Levie [1] with great interest and applaud their publication of Phase III data on 5-year follow-up after hysteroscopic sterilization. However, we are concerned about their focus on perfect use rather than real-world use. Specifically, their evaluation of effectiveness was based on "women with successful bilateral placement of Essure inserts," rather than women who attempted Essure. For example, the study excluded 4 women who became pregnant before undergoing hysterosalpingography (HSG), 15 women who underwent hysterectomy, 1 woman who missed her 6-month follow-up HSG, 1 woman who was incarcerated, 1 woman who had unsatisfactory device placement, and 1 woman with leukemia from the intention-to-treat analysis. Removing these participants from the study's denominator makes the proportion of successful procedures appear higher than it actually is. In addition, 30% of enrolled women did not complete the 5-year follow-up, and these women may have had more problems than the women who completed follow-up.

We agree with the authors' hypothesis that some women might not consider laparoscopic sterilization owing to the need to undergo the procedure in the operating room, receive general anesthesia, or miss work. Yet the authors do not report how many of the procedures they studied were done in the office versus the operating room, information on anesthesia used, or days of missed work.

Although we appreciate the authors' reference to our previous publications on the topic, we feel that our results were misrepresented, perhaps because of a misunderstanding of our methodology [2,3]. Our Markov models incorporated all relevant data available in the published literature, including data from the manufacturer of Essure. We also performed extensive sensitivity analyses in both studies to assess the impact on our findings when varying the value of key variables over plausible ranges, rather than relying on single parameter assumptions. Moreover, we disagree with the authors' statement that our models "accentuate poor HSG follow-up with hysteroscopic sterilization" [1]. Based on published data available at the time of publication on the proportion of women completing HSG follow-up while considering the study size, to ensure that findings from a small study do not "count" as much as

findings from larger studies, we estimated that on average, 79% (range, 13%–94%) of women returned for the recommended HSG at 3 months [3]. Similarly, our "projected pregnancy rates" are based on published data reported in the literature, including pregnancies reported by the manufacturer on their website [4]. Indeed, data reported by Chudnoff et al support the findings of our studies; for example, they report that 81% of women (421 of 518) were able to rely on the procedure at 3 months postprocedure [1]. This finding confirms our first Markov model, which predicted that approximately 85% of women undergoing attempted hysteroscopic sterilization would be able to rely on the procedure for contraception at 3 months postprocedure [2].

In addition, Chudnoff et al incorrectly state that our models do not include complication rates. Both major and minor complications related to hysteroscopic and laparoscopic sterilization were incorporated in the first Markov model [2], and we found no significant difference in complications between the 2 procedures based on the data available at that time [2]. In contrast, inherent in Chudnoff et al's discussion of complications is the assumption that there are fewer complications with hysteroscopic sterilizations than with laparoscopic sterilizations. Although Chudnoff et al discuss 457 adverse events related to hysteroscopic sterilization with Essure reported in the Manufacturer and User Facility Device Experience (MAUDE) database, the Food and Drug Administration recently updated this number to 5093 adverse events reported since the 2002 approval [5]. This increase in adverse events has prompted the Food and Drug Administration to convene a public meeting of its Obstetrics and Gynecology Devices Panel on September 24, 2015, to discuss data on the safety and effectiveness of Essure.

Given that 750 000 women worldwide have undergone hysteroscopic sterilization since 2001 [6], evaluating the safety and effectiveness of hysteroscopic sterilization is of great importance. We still lack data on the short-term and long-term side effects, safety, need for further surgery including hysterectomy, and risk of pregnancy in women who attempt Essure, not just a subset of those who experience successful placement and receive follow-up with confirmation of tubal blockage. Women and their physicians need this essential information to make truly informed decisions regarding the choice of sterilization procedure.

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Bariatric Surgery Improves Outcome in Obese Women With Endometrial Cancer

To the Editor:

We read a case report written by Benito et al [1] with interest. The authors reported a case of an obese woman with grade I endometrial cancer (EC) who did not respond to fertility-preserving treatment with a levonorgestrel-releasing intrauterine device. The patient underwent laparoscopic sleeve gastrectomy and had significant weight loss with a complete response to treatment of endometrial malignancy after surgery. The authors discussed the potential causes of treatment failure, which are abnormally high levels of circulating estrogens that persist in obesity. They also recommended rapid weight loss in obese patients with EC to improve outcome (remission and recurrence of cancer) in fertility-preserving treatment. However, the authors did not mention how bariatric surgery modifies EC outcome compared with a conventional weight loss method.

In a recently published meta-analysis [2], we found that bariatric surgery has potential benefits in reducing the risk of developing EC compared with nonsurgical management. The cancer protective effects of bariatric surgery are thought to be caused by a decreased level of estradiol, insulin resistance, and inflammation [3, 4]. In a prospective study of obese women who had a 10% baseline endometrial hyperplasia prevalence [4], bariatric surgery improved glucose homeostasis, insulin responsiveness, and inflammation. A reduction of hormone and inflammatory markers likely improves the EC response to progestin-based, fertility-sparing treatments. Bariatric surgery is also considered a potentially cost-effective intervention in women with low-risk, early-stage EC due to improving quality of life [5].

In conclusion, we agree with the authors that physicians should strongly consider bariatric surgery as an adjuvant treatment in obese women with EC.