For heavy menstrual bleeding, are long-term outcomes similar for treatment with the LNG-IUS and radiofrequency endometrial ablation?

Both interventions led to a large decrease in menstrual blood loss with similar quality of life (QoL) and satisfaction scores at 2 years postintervention, according to a randomized clinical trial (RCT) from the Netherlands. The investigators evaluated bleeding reduction, need for reintervention, and QoL for women who received either the Mirena levonorgestrel intrauterine system (LNG-IUS) 52 mg or endometrial ablation with the NovaSure device for primary treatment of heavy menstrual bleeding (HMB).

FAST TRACK

Results of a long-term RCT may aid in counseling women with HMB on the risks and benefits of the LNG-IUS and endometrial ablation

Beelen P, van den Brink MJ, Herman MC, et al. Levonorgestrel-releasing intrauterine system versus endometrial ablation for heavy menstrual bleeding. Am J Obstet Gynecol. 2021;224:187.e1-187.e10.

EXPERT COMMENTARY

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Counseling patients regarding treatment of HMB requires a realistic discussion about the risks of intervention and the expected outcomes. In addition to decreasing menstrual blood loss, treatment benefits of the LNG-IUS include a reversible form of intervention, minimal discomfort with placement in an office environment with an awake patient, and a reliable form of contraception. Abnormal uterine bleeding (AUB) and progesterone-related adverse effects historically have been associated with LNG-IUS use and can lead to patient desires for device removal or additional intervention.

Similarly, in addition to endometrial ablation (EA) decreasing menstrual blood loss, its benefits include avoiding a hysterectomy with an outpatient procedure. Endometrial ablation does require a desire for no future pregnancies while using a reliable form of contraception. Risks of EA include failure to improve HMB or worsening pelvic pain that requires additional intervention, such as hysterectomy. Historically, clinical data suggest failure is more likely for women less than 40 years of age or with adenomyosis at the time of ablation.

Results of a long-term RCT by Beelen and colleagues may aid gynecologists in

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counseling patients on the risks and benefits of these 2 treatment options.

Details of the study

Performed between 2012 and 2016, this multicenter RCT evaluated primary intervention of the LNG-IUS in 132 women versus EA in 138 women. The women were older than age 34, did not want a future pregnancy, and had other etiologies of AUB eliminated.

The primary outcome was blood loss after 24 months as assessed with a Pictorial Blood Loss Assessment Chart (PBAC) score.

Secondary outcomes included controlled bleeding, defined as a PBAC score not exceeding 75 points; complications and reinterventions within 24 months; amenorrhea; spotting; dysmenorrhea; presence of clots; duration of blood loss; satisfaction with treatment; QoL; and sexual function.

The statistical null hypothesis of the trial was noninferiority of LNG-IUS treatment compared with EA treatment.

Results. Regarding the primary outcome, the mean PBAC score at 2 years was 64.8 for the LNG-IUS treatment group and 14.2 for the EA group. Importantly, however, the authors could not demonstrate noninferiority of the LNG-IUS compared with EA as a primary intervention for HMB.

For the secondary outcomes, there was no significant difference between groups, with both groups having a significant decrease in HMB at 3 months with PBAC scores that did not exceed 75 points: 60% in the LNG-IUS group and 83% in the EA group. In the LNG-IUS group, 35% of women received additional medical or surgical intervention versus 20% in the EA group.

Study strengths and limitations

Strengths of this study include its multicenter design, with 26 hospitals, and the long-term follow-up of 24 months. During the follow-up period, women were allowed to receive a reintervention as clinically indicated; thus, outcomes reflect results that are not from only a single designated intervention. For example, of the women in the LNG-IUS group, 34 received a surgical intervention, 31 (24%) underwent EA, and 9 (7%) underwent a hysterectomy. However, 6 of the 9 who underwent hysterectomy had a preceding EA, and these 6 women are not reported as surgical intervention of EA since the original designation for intervention was the LNG-IUS.

Notably, the patients and physicians were not blinded to the intervention, and the study excluded patients who wanted a future pregnancy. ●

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Counseling patients regarding the LNG-IUS and EA for management of HMB requires a discussion balanced by information regarding the risks and the foreseeable benefits of these interventions. This study suggests that long-term primary and secondary outcomes are similar. Therefore, in choosing between the 2, a patient may rely more on her values, her age, and her consideration of future pregnancy and uterine preservation.

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FAST TRACK

The study authors could not demonstrate noninferiority of the LNG-IUS compared with EA as a primary intervention for HMB