

Drug Monitor

ONLINE EDITION

When Endometrial Surgery Isn't Enough

Surgery for endometriosis isn't always curative, and often other measures, such as aromatase inhibitors and progestins, are needed postoperatively to prevent recurrence. However, drug adverse effects can make it difficult for patients to adhere to longterm treatment. One solution may be a levonorgestrel-releasing intrauterine system (IUS), suggest researchers from Mahidol University, Bangkok, Thailand. These researchers suggest the IUS would release the drug more slowly, potentially reducing adverse effects, and would render the compliance issue moot for at least 5 years.

In a double-blind controlled trial of 54 patients with endometriosis and moderate-to-severe dysmenorrhea, researchers compared a levonorgestrel-releasing IUS with expectant management. The IUS was inserted immediately after surgery, while the patient was still under anesthesia. Patients in both groups were given structured diaries to record pelvic pain, vaginal bleeding, and type and number of analgesic medications. At follow-up visits (every 3 months after surgery), nurses assessed the patients for subjective outcomes, and a gynecologist performed a clinical examination.

Both groups showed significant improvement from baseline in dysmenorrhea score and noncyclic pelvic pain score (P < .001). The proportions of patients with moderate-to-severe dysmenorrhea or dyspareunia were significantly lower in the treatment group (P = .031). These benefits were observed for at least 12 months, although at 12 months, 25 of 27 women in the treatment group had amenorrhea, spotting, or light bleeding.

Two patients in the treatment group and 9 in the expectant management group had recurrent moderate-to-severe pain within 1 year after surgery; pain started at 8 months in the expectant group, compared with 9 and 10 months in the treatment group.

In the treatment group, 20 of 27 patients reported 1 or more adverse effects, compared with 18 of 23 patients in the expectant management group. The researchers say the adverse effects were probably related to progestogen. Bloating was more common in the expectant management patients; acne, oily skin, breast tenderness, and weight gain were more common among the treatment patients.

At 12 months, 4 patients in the treatment group asked to have the IUS

removed as a result of frequent spotting. Two patients were switched to combined oral contraceptive pills, 1 patient received depomedroxyprogesterone acetate, and 1 patient did not receive hormonal treatment. The patients rated the substituted hormonal treatments as acceptable and effective for at least 24 months after the change.

The researchers note that the accepted outcome measurement for treatment of endometriosis is evaluation of symptom recurrence and quality of life; their study provides evidence for the success of the IUS on both counts. More patients in the treatment group reported being very satisfied. Their Short Form-36 (SF-36) scores improved from baseline, particularly in the physical health subscale. The expectant management patients' SF-36 scores didn't change.

Moreover, the IUS may prevent the formation of endometriotic cysts. In the study, 2 patients in the expectant management group had recurrent endometriotic cysts at 6 and 9 months, whereas no patient in the treatment group had recurrent cysts.

Source: Tanmahasamut P, Rattanachaiyanont M, Angsuwathana S, Techatraisak K, Indhavivadhana S, Leerasiri P. *Obstet Gynecol.* 2012;119(3):519-526. doi: 10.1097/A0G.0b013e31824264c3.