

Treatment of primary and secondary dysmenorrhea with a novel “frameless” intrauterine levonorgestrel-releasing drug delivery system: a pilot study

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Abstract

Objective

To evaluate the effect on menstrual pain in women with primary and secondary dysmenorrhea of a novel “frameless” intrauterine drug delivery system (IUS), FibroPlantlevonorgestrel (LNG), releasing 14µg of LNG/d. An ancillary objective being to evaluate the effect of the new IUS on menstrual blood loss.

Study design

An open label, non-comparative ongoing pilot study. Eighteen insertions were performed in women between 16 and 52 years of age by the first author. Four insertions were done in nulligravid women. Eight women were categorized as having primary dysmenorrhea and 12 as having secondary dysmenorrhea. Twelve women complained of heavy bleeding. Three women had significant fibroids and 3 were suspected to have adenomyosis.

Results

The trial covers a period from a minimum of 3 months up to 33 months. By the end of August 2001, 12 recruited women had at least 12 months follow-up and 6 between 3 months and one year. All women reported much reduced pain, or no pain at all, and strongly reduced bleeding which started as soon as one month after insertion of the FibroPlant-LNG IUS. There was one exception. The latter woman had significant fibroids. She reported much reduced bleeding but this was not as pronounced as in the other women in the study. All women are continuing to use the method.

Conclusion

The results of this preliminary study suggest that the FibroPlant-LNG IUS, releasing 14 µg of LNG per day, is a safe and effective method for the treatment of primary and secondary dysmenorrhea. The absence of a frame is particularly advantageous in these women. Of significant added importance of this LNG IUS is its high effectiveness in reducing menstrual bleeding, a symptom often present in women with menstrual pain complaints, and the fact that the system provides effective contraception. The low daily release rate of levonorgestrel from the FibroPlant-LNG IUS results in a virtual absence of hormonal side effects.