

The effect on menstrual blood loss in women with uterine fibroids of a novel “frameless” intrauterine levonorgestrel-releasing drug delivery system: a pilot study

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Abstract

Objective

To evaluate the effect on menstrual blood loss, in women with uterine fibroids, of a novel “frameless” intrauterine drug delivery system (IUS), FibroPlant-levonorgestrel (LNG), releasing 14µg of LNG/day.

Study design

An open label, non-comparative ongoing pilot study. Fourteen insertions were performed in premenopausal women between 39 and 48 years of age for the treatment of menorrhagia. The effect on menstrual blood loss was evaluated using a simple visual assessment technique. Women were followed-up for at least 12 months (range 12-30 months).

Results

At the time of study analysis the total number of women-months was 283. All women, except one reported greatly reduced bleeding. In two women, the treatment failed although both reported reduced bleeding. One failure (patient n° 4) was due to the presence of a large endometrial polyp. This patient underwent hysterectomy. The other women (patient n° 1) had submucosal fibroids. She refused hysterectomy and is continuing treatment. In the other 12 patients, reduction of bleeding was appreciable after one month of treatment and tended to decrease further over the next months to stabilize afterwards. The mean bleeding score before treatment was 465 (185-960) and dropped to a mean score of 100 (range 5-300) after a minimum of 12 months of treatment which is highly statistically significant ($p < 0.001$). In 8 women, the bleeding reduced to very low scores. An effect on the size of the uterine fibroids could not be demonstrated. Significant spotting was rare after the first three months following insertion. Neither complications (e.g., infection, expulsion or perforation) nor pregnancies occurred. The FibroPlant-LNG IUS was well tolerated by all women involved in the study and no systemic hormonal side effects were reported.

Conclusion

This study suggests that FibroPlant-LNG IUS is effective to significantly reduce the amount of menstrual blood loss in women with menorrhagia in the presence of intramural and subserosal fibroids and can avoid surgery. The strong endometrial suppression is the principal mechanism explaining the effect on menstrual blood loss of the IUS. The two failures probably explain that a successful treatment in women with endometrial abnormalities (e.g. polyps, submucous fibroids) is unlikely with the IUS.

The low daily release rate of levonorgestrel from the FibroPlant-LNG IUS results in a low incidence of hormonal side effects.

The simple design characteristics and revolutionary anchoring system account for minimising the occurrence of complaints of pain and expulsion. The flexible fibrous delivery system adapts to cavities of every size even when severely distorted.