

Contraception with a novel “frameless” intrauterine levonorgestrel-releasing drug delivery system: A pilot study

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Abstract

Objective

To evaluate the contraceptive performance, acceptability, side-effects and adverse events 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. Fifty-four insertions were performed in fertile women between 16 and 51 years of age for contraception by the first author. From these, 18 women were fitted with the FibroPlant-LNG IUS for the treatment of excessive bleeding as well as for contraceptive purposes. Twelve of these women had medium to large size uterine fibroids in addition to heavy menstrual flow. The trial covers a period from a minimum of 6 months up to 16 months.

Results

At the time of study analysis the total number of women-months was 464. Twentyone women having the FibroPlant-LNG IUS in place for periods in excess of one year. No pregnancies occurred. All women reported greatly reduced bleeding, however no cases of amenorrhea resulting from endometrial suppression were encountered. Significant spotting was rare after the first three months following insertion. No complications (e.g., infection, expulsion or perforation) occurred. The FibroPlant-LNG IUS was well tolerated by all women involved in the study and no systemic hormonal side-effects were reported.

Conclusion

Although the average age of women included was 40, this preliminary study suggests that FibroPlant-LNG IUS is an effective contraceptive. The FibroPlant-LNG IUS is also highly efficacious in controlling bleeding in women presenting with excessive menstrual flow. Effective endometrial suppression is the principal mechanism underlying both the contraceptive effect and its effect on menstrual blood loss. The low release rate of levonorgestrel results in an absence of hormonal side-effects. The unique “frameless” design characteristics of the IUS facilitates insertion and minimises reports of pain and discomfort. These factors, together with the low incidence of amenorrhea appear to be a significant step forward from the ‘framed’ Nova-T LNG-IUS (Mirena®).