Effect of Levonorgestrel releasing Intrauterine system in Women with Heavy Menstrual Bleeding

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Abstract

The objective of this study was to evaluate the efficacy for up to 1 year, of levonorgestrel releasing intrauterine system (LNG-IUS, Mirena) in the treatment of women with menorrhagia. It was a prospective, non-comparative, observational study. A 20 microg/day LNG-releasing-IUS was inserted postmenstrually to 35 women (between 35 and 50 years of age) who suffered from heavy menstrual bleeding (HMB). Menstrual patterns were assessed, before LNG-IUS was inserted and at 3, 6, and 12 months of use. The most common bleeding pattern at 3 months after insertion was spotting, and after 6 and 12 months, the majority of women presented with oligomenorrhea with hypomenorrhea. Two women expelled the device spontaneously. At 12 months 88.5% of women continued the use of LNG-IUS. In conclusion, LNG-IUS was a safe and effective treatment for women with menorrhagia and it should first be considered as an appropriate non surgical treatment for HMB before embarking on hysterectomy.

Key words : levonorgestrel releasing intrauterine system, menorrhagia

Introduction

Menstrual problems are one of the most common gynaecological complaints among the reproductive age women worldwide. Menorrhagia is one of the most common gynaecological complaints in contemporary gynaecology affecting 10-15% of women. Medical treatment for benign lesions include nonhormonal or hormonal oral medications for prolonged period of time. When medical treatment is ineffective or unacceptable to the patient, surgical treatment like hysterectomy or endometrial ablation is the choice. Hysterectomy was for many years the most common solution & even today half of all hysterectomies performed worldwide are for the purpose of treating HMB.

The levonorgestrel releasing intrauterine system is a nonsurgical, long acting, alternative to the medical and surgical treatments for heavy menstrual bleeding. This prospective, non comparative observational study has been conducted to find out the efficacy of LNG-IUS in women with heavy menstrual bleeding.

Materials and methods

This is a prospective, non comparative, observational study done at ESICMC-PGIMSR, Bangalore for a period of one year from August 2011-July 2012. Thirty five patients were included in the study. Patients attending the gynaecological OPD complaining of heavy menstrual bleeding between the age group 35-50 years were included in the study. Pregnant females, post menopausal women, patients of leiomyoma & adenomyosis were excluded from the study. An informed consent was taken from all the women included in the study. A detailed history of the patient's complaints regarding the regularity of cycle, duration of the flow, number of pads changed, amount of the blood loss as per pictorial blood loss assessment chart was taken. Local examination & internal examination were done to rule out other causes of heavy bleeding. Transvaginal USG was done to know the endometrial thickness & to rule out other causes of bleeding. The patients were further subjected to Pap smear and endometrial biopsy. The LNG-IUS was inserted in the postmenstrual phase in the minor operation theatre.

The patients were followed up after 3 months, 6 months and 1 year after the insertion of LNG-IUS. All the women were informed of the possibility of occurrence of spotting, scanty or infrequent menstruation and amenorrhoea.

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Results

Out of the 35 women who had LNG-IUS inserted,8 were between 35-39 years of age, 25 were between 40-45 years and 2 were between 46 – 50 years of age (Table 1).

Table 1. Age wise distribution of patients

Age(yrs)	Number of patients	%
35-39	8	22.9
40-45	25	71.4
46-50	2	5.7

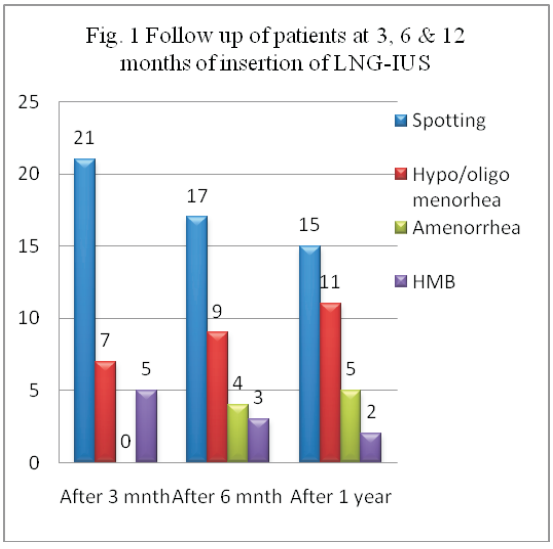
Histopathological examination of endometium showed proliferative endometrium in 5 women, 27 women had secretory endometrium and 3 women had simple hyperplasia (Table 2). At 3 months follow-up after LNG-IUS insertion, 21 women had spotting, 7 had oligomenorrhoea with hypomenorrhoea, and 5 continued to have heavy menstrual bleeding. 2 women expelled the LNG-IUS spontaneously, one 20 days after insertion and the second during the next menstrual cycle. At 6 months follow-up after LNG-IUS insertion, 17 women had spotting, 9 had oligomenorrhoea with

Table 2. Endometrial histopathology

Endometrial Histopathology	Number of patients	%
Proliferative endometrium	5	14.3
Secretory endometrium	27	77.1
Simple hyperplasia	3	8.6

hypomenorrhoea, and 4 had amenorrhoea. Three women continued to have heavy bleeding. At 1 year follow-up after LNG-IUS insertion, 15 women had spotting, 11 had oligomenorrhoea with hypomenorrhoea and 5 had amenorrhoea. 2 women continued to have heavy bleeding(Figure1). Thirty one women are continuing to use LNG-IUS after 1 year. 2 patients who expelled the device are on hormonal oral medication and 2 patients who said that they continued to bleed heavily and were not satisfied wit the device underwent hysterectomy.

Table 1. Age wise distribution of patients



Discussion

The World Health Organizations reports that 18 million women aged 30-55 years perceive their menstrual bleeding to be exorbitant[1]. It has been reported that only 10% of these women experience blood loss severe enough to cause anaemia or be clinically defined as menorrhagia[1,2]. National Institute for Health and Clinical Excellence(NICE), which defines HMB as 'excessive menstrual blood loss which interferes with the woman's physical, emotional, social and material quality of life) [3]. The levonorgestrel releasing intrauterine system (LNG-IUS;Mirena) was first introduced & tested in Egypt at Assiut University Hospital in order to assess its acceptability & safety in breast fed babies as well as its effectiveness as a contraceptive method in postpartum breast feeding women. One of the non contraceptive benefit of the LNG-IUS is the well documented reduction in menstrual blood loss[4].

The LNG-IUS is a nova T-shaped device composed of a cylinder containing 52mg of levonorgestrel covered by a rate controlling polydimethyl siloxane capsule which serves to regulate the rate of hormonal release. The entire length of the system is 32mm, and the T-shaped plastic frame is impregnated with barium sulphate which makes the device radio opaque. Two threads

are attached to the loop at the base of the IUS to aid removal. Initially 20mcg of levonorgestrel is released every 24 hours & is associated with very few systemic side effects. Levonorgestrel can be detected in the circulation within a few hours. At the end of five years, the initial release rate of levonorgestrel decreases to 11mcg every 24 hours. There is strong suppression & atrophy of the endometrium, with the stroma becoming swollen and decidual, the mucosa thinning & the epithelium becoming inactive[5].

In recent years a large number of Cochrane reviews and randomised controlled trials have compared different treatment modalities for idiopathic HMB. Progestogens can be highly effective but should be restricted to short term use[6]. In a randomised study published in 2010, LNG-IUS was compared with Medroxyprogesterone acetate(MPA).The results confirmed those of the earlier Cochrane study, showing an 85% success rate with LNG compared with a 22% success rate with MPA [7]. A prospective randomised study performed at nine Canadian centres found that LNG-IUS was significantly better than combined oral contraceptives at treating HMB. Treatment was considered successful in 80% of the LNG-IUS group verses 36.8% of the oral contraceptives group [8]. Of all the products reviewed, the LNG-IUS is the most effective at reducing HMB.

Conclusion

The LNG-IUS is a safe and effective treatment for women with menorrhagia and it should first be considered as an appropriate non surgical treatment for HMB before embarking on hysterectomy.

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