

Efficacy of levonorgestrel releasing intrauterine system for the treatment of menorrhagia due to benign uterine lesions in perimenopausal women

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ABSTRACT

Aims: To evaluate the efficacy of levonorgestrel-releasing intrauterine system (LNG-IUS, Mirena, Bayer Healthcare) in the treatment of menorrhagia caused by benign lesions of the uterus in perimenopausal women.

Settings and Design: A prospective observational study was conducted to study the efficacy of levonorgestrel intrauterine device in the treatment of menorrhagia due to benign lesions of the uterus in perimenopausal women.

Materials and Methods: Forty women with menorrhagia, due to benign conditions like idiopathic menorrhagia, fibroid (not more than 12 weeks size) or adenomyosis, attending our out-patient department were included in the study. All the women underwent a PAP smear, transvaginal sonography and endometrial biopsy. Endometrial carcinoma and cervical carcinoma were excluded. LNG-IUS was inserted in the postmenstrual phase. Blood loss was assessed by pictorial blood loss assessment chart (PBAC). They were followed up after 3 months, 6 months, and after 1 year.

Results: Majority of the women had menstrual spotting for 3–4 months followed by infrequent menstruation, scanty menstruation or amenorrhoea. LNG-IUS was removed because of continued bleeding in two cases and was removed because of displacement in one case. It was expelled spontaneously in four cases. Thirty-three women continued to use LNG-IUS.

Conclusion: LNG-IUS is a safe and effective option for women with menorrhagia due to benign lesions of the uterus in perimenopausal women.

Key Words: Levonorgestrel intrauterine system, menorrhagia, mirena, perimenopause

INTRODUCTION

Abnormal uterine bleeding (AUB) is the commonest symptom for which women seek gynecologist's consultation. AUB increases with advancing age. Heavy menstrual bleeding (HMB) is an important cause for anemia in perimenopausal women. Generally HMB is a symptom of ovulatory disorders, primary endometrial disorders, fibroid, adenomyosis, endometriosis or genital malignancies.^[1] 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. The levonorgestrel releasing intrauterine system is a nonsurgical, long acting, alternative to the traditional medical and surgical treatments

for heavy menstrual bleeding.^[2]

This prospective observational study has been conducted to find out the efficacy and patient satisfaction of LNG-IUS in perimenopausal women with heavy menstrual bleeding.

MATERIALS AND METHODS

Forty women who attended our hospital outpatient department with history of heavy menstrual bleeding due to benign lesions were included in the study. The study was approved by the institution's ethical committee. An

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informed consent was taken from all the subjects of the study.

All these women underwent a pap smear, a transvaginal sonography, and an endometrial biopsy. Women with fibroids (more than 12 weeks size) or malignancy were excluded. The subjects were counselled for the insertion of LNG-IUS. All the subjects were informed regarding the initial few months of spotting, infrequent menstruation and amenorrhoea. The LNG-IUS was inserted in the postmenstrual phase in the outpatient department. All the women were asked to maintain a pictorial blood loss assessment chart (PBAC).

The patients were followed up after 1 month, 3 months, 6 months, and at the end of 1 year.

RESULTS

Of the forty women who had LNG-IUS inserted 23 were between 41 and 45 years of age and 17 were between 46 and 50 years of age [Table 1].

Of the 40 women who had HMB, 30 women had ovulatory disorders or endometrial dysfunction, and 10 women had structural abnormalities. The structural abnormalities included five cases of fibroid, four cases of adenomyosis and one woman had endometrial hyperplasia due to Tamoxifen therapy [Table 2].

After 3 months follow-up after the LNG-IUS insertion, 3 (7.5%) had regular cycles, 24 (60%) women had spotting for 3 months, 5 (12.5%) women had infrequent cycles with scanty menstruation, and 8 (20%) women continued to have HMB [Table 3].

After 6 months of insertion of LNG-IUS none of the women had regular cycles, 13 (32.5%) women had spotting, 11 (27.5%) women had infrequent cycles with scanty menstruation, 9 (22.5%) women had amenorrhoea and 3 (7.5%) women continued to have HMB. Four (10%) women expelled the LNG-IUS [Table 4].

After 12 months of insertion of LNG-IUS, none of the women had regular cycles. Thirteen (32.5%) women had spotting, 11 (27.5%) women had infrequent cycles with scanty menstruation, 9 (22.5%) women had amenorrhoea. Four (10%) women had already expelled the LNG-IUS within 6 months of insertion, two LNG-IUS were removed because of persistent HMB and one was removed because it was misplaced in the cervical canal [Table 5].

The misplaced LNG-IUS which was in the cervical canal

was removed with an artery forceps.

Four (10%) devices were expelled with clots within 6 months of insertion, two (5%) devices were removed because of continued menorrhagia, and one (2.5%) LNG-IUS was removed because of misplacement within 12 months [Table 6].

Thirty three (82.5%) women continued to use LNG-IUS after 1 year. All the 33 women were satisfied using this device. The spotting and scanty menstruation were acceptable to all the 24 women as they were suffering from HMB before the insertion of LNG-IUS. Nine women who had amenorrhoea also found it acceptable as they were perimenopausal. Of the seven cases in which the LNG-IUS was expelled/misplaced or removed, five of them underwent a hysterectomy, one patient underwent endometrial ablation and one patient is on oral progestogens [Table 7].

DISCUSSION

Table 1: Age incidence

Age (years)	Number	Percentage
41-45	23	57.5
46-50	17	42.5

Table 2: Etiology of HMB

Etiology	Number	Percentage
Ovulatory/endometrial dysfunction	30	75
Fibroid	5	12.5
Adenomyosis	4	10
Endometrial hyperplasia	1	2.5

Table 3: Menstrual pattern after 3 months follow up

Menstrual pattern	Number	Percentage
Regular cycles	3	7.5
Spotting	24	60
Infrequent cycles with scanty menses	5	12.5
Amenorrhoea	-	-
HMB	8	20

Table 4: Menstrual pattern after 6 months follow up

Menstrual pattern	Number	Percentage
Regular cycles	-	-
Spotting	13	32.5
Infrequent cycles with scanty menses	11	27.5
Amenorrhoea	9	22.5
HMB	3	7.5
Expelled	4	10

HMB is a common symptom in perimenopausal women. Approximately 10–15% of women have HMB, defined as a menstrual blood loss (MBL) of >80 ml. Menstrual blood loss increases with age. Medical treatment for benign lesions causing HMB include nonhormonal and hormonal treatment for several months. Many patients refuse to take these medications because of prolonged treatment and adverse effects. Oestrogens cause nausea, vomiting and thrombo-embolic complications. Progestogens are preferred to oestrogens in the peri-menopausal women. Progestogens when taken orally cause nausea, vomiting, bloating, mastalgia, and depression. Surgical treatment such as hysterectomy and endometrial ablation techniques require hospitalization and anesthesia. The risks of surgical intervention, anesthetic complications and surgical site infection are considerable. The levonorgestrel intrauterine system which was initially introduced as an intrauterine contraceptive device has recently been used for the treatment of HMB. Intrauterine delivery of progestin is an effective way to administer local treatment and bypass systemic side effects. It has emerged as an alternative to the usual medical and surgical methods of treatment for AUB.^[3] The LNG-IUS consists of a 32 mm T shaped polyethylene frame with a reservoir containing 52 mg of Levonorgestrel. The LNG-IUS releases 20 µg of levonorgestrel per day. A plasma concentration of 150–200 pg/ml is achieved after a few weeks. The plasma concentration of levonorgestrel in LNG-IUS users is 25% less than that seen when 150 µg of levonorgestrel is taken orally. The slow release

of levonorgestrel in the uterine cavity suppresses the endometrium and causes endometrial glandular atrophy and stromal decidualization. Levonorgestrel is a potent blocker of oestrogen activity on the endometrium. Levonorgestrel also thickens the cervical mucus. All these actions of levonorgestrel on the endometrium and the cervix make LNG-IUS an effective contraceptive and a non-surgical minimally invasive long-term treatment option for menorrhagia.^[4] This prospective observational clinical study shows that LNG-IUS is an effective mode of treatment for HMB due to benign lesions of the uterus in perimenopausal women. In this study, 82.5% of the women were relieved of the symptoms of HMB and continued to use LNG-IUS after 12 months. Majority of the women were satisfied using LNG-IUS for the treatment of HMB. Anemia affects 55% of Indian women due to various causes.^[5] A nonsurgical intervention is a better option for women who are suffering from HMB and anemia. The LNG-IUS releases 20 µg of levonorgestrel in the uterine cavity and makes the endometrium nonproliferative, and reduces the symptoms of HMB, thus significantly preventing anemia. LNG-IUS also acts as an effective contraceptive in the perimenopausal woman who may ovulate occasionally. LNG-IUS can also be used in conjunction with hormone replacement therapy, to prevent endometrial hyperplasia in perimenopausal and postmenopausal women.^[6]

Various studies have reported LNG-IUS to be an effective treatment for menorrhagia and an alternative to hysterectomy. Antifibrinolytic agents reduce the bleeding by 40–50%, prostaglandin synthetase inhibitors reduce the bleeding by 20–25%, oral contraceptives reduce the bleeding by 40–50%, and LNG-IUS reduces the bleeding by 86–97%. LNG-IUS has shown the greatest reduction in menstrual blood loss, and, hence has been proposed as an alternative to hysterectomy in perimenopausal women.^[7]

In another study LNG-IUS is shown to be effective and a patient friendly device with high degree of compliance. It could be considered as a viable alternative to surgical treatment for HMB in developing countries like India.^[8] The LNG-IUS is effective in controlling HMB in 77.7% of cases and the common side effect is menstrual spotting for a few months after insertion.^[9] LNG-IUS has been compared with transcervical resection of endometrium (TCRE). It was found that amenorrhoea was more common in TCRE and spotting in LNG-IUS group. The menstrual blood loss reduction was 93.9% in TCRE group and 88.4% in the LNG-IUS group. Though the patient satisfaction was almost the same in both the groups, the advantage of LNG-IUS is it is less invasive.^[10] LNG-IUS can reduce the menstrual blood loss by 92.9% (97.6–81.1%) and help to improve anemia.^[11] LNG-IUS is also a very good alternative for women who have HMB and desire contraception.^[12]

Table 5: Menstrual pattern after 12 months follow up

Menstrual pattern	Number	Percentage
Regular cycles	–	–
Spotting	13	32.5
Infrequent cycles with scanty menses	11	27.5
Amenorrhoea	9	22.5
Expelled	4	10
Removed	3	7.5

Table 6: LNG-IUS expelled /misplaced /removed

LNG-IUS	Number	Percentage
Expelled	4	10
Misplaced	1	2.5
Removed	2	5

Table 7: Treatment opted by patients who had failed to respond to LNG-IUS

Treatment options	Number	Percentage
Hysterectomy	5	12.5
TCRE	1	2.5
Hormonal therapy	1	2.5

LNG-IUS is useful in treating HMB in obese women.^[13] LNG-IUS is safe in women who have undergone prior surgeries such as cesarean or myomectomy. LNG-IUS is beneficial in the treatment of uterine fibroid, endometriosis, adenomyosis and endometrial hyperplasia.^[14] Health related quality of life outcomes and cost effectiveness with LNG-IUS was found to be similar to hysterectomy or endometrial ablation in several developed countries.^[15]

CONCLUSION

This prospective observational clinical study shows that LNG-IUS is a better option for peri-menopausal women requiring treatment for HMB. LNG-IUS is an effective, long acting nonsurgical treatment for perimenopausal women with HMB.

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