


Original Research Article

Role of levonorgestrel releasing intrauterine device in management of heavy menstrual bleeding: A safe and effective option for all PALM COEIN variants

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Abstract

Introduction: Heavy menstrual bleeding (HMB) is defined as prolonged (>7 days) or excessive menstrual blood loss greater than or equal to 80 ml per menstrual cycle. Levonorgestrel-releasing intrauterine device (LNG-IUS) has become one of the most acceptable medical treatments for menorrhagia, reducing referrals to specialists and decreasing the need for operative gynecological surgery.

Aim: To study the efficacy of levonorgestrel intrauterine system (LNG-IUS) in conservative management of abnormal uterine bleeding (AUB).

Materials and Methods: Fifty women between 40 and 50 years with AUB were included in a study conducted over a period of 2 years. Response was assessed monthly for first 6 months and then bi annually for total 2 years.

Results: LNG IUS caused 80% decrease in median menstrual blood loss (MBL) at 6 months, 95% decrease in MBL by 1 year, and 100% decrease (amenorrhea) by 2 years. Mean hemoglobin (Hb) % showed a significant rise of 10.0% from baseline 6 months post insertion. LNG IUS is as an effective alternative in women with AUB of varied etiology. Hysterectomy could be avoided in most of the women.

Conclusion: LNG IUS provides an incredible nonsurgical alternative in treatment of menorrhagia.

Key words

Abnormal uterine bleeding, PALM COEIN classification, LNG IUS, Hysterectomy.

Introduction

Heavy menstrual bleeding (HMB) is defined as prolonged (>7 days) or excessive menstrual blood loss greater than or equal to 80 ml per menstrual cycle [1]. It interferes with a woman's physical, social, emotional and/or material quality of life. Abnormal uterine bleeding is a common reason for consulting a gynecologist and hysterectomy is often used to treat women with menorrhagia but medical therapy may be a successful alternative [2]. Levonorgestrel-releasing intrauterine device (LNG-IUS) has become one of the most acceptable medical treatments for menorrhagia, reducing referrals to specialists and decreasing the need for operative gynecological surgery [3]. Levonorgestrel is released from this system at a rate of 20 mcg/24 hours. It suppresses endometrial growth, the glands of the endometrium become atrophic and the epithelium becomes inactive. Along with the high contraceptive efficacy, LNG-IUS has shown benefits and improvement of symptoms in menorrhagia, adenomyosis and endometriosis [4, 5]. LNG-IUS device has also been found to be cost-effective with less side effects and to increase the quality of life (QOL) [6]. The QOL of women treated with the LNG-IUS is markedly improved, causing high levels of patient satisfaction [7]. Hence, this study was conducted to evaluate the efficacy, acceptability and side effects of LNG-IUS in women with heavy menstrual bleeding.

Materials and methods

50 women aged between 40 and 50 years with at least one issue with abnormal uterine bleeding (AUB) were included in the study after taking written and informed consent, over a period of 2 years. These patients came to the outpatient department (OPD) with various menstrual complaints like menorrhagia in 70% patients (35/50), polymenorrhagia in 20% patients (10/50), menometrorrhagia in 6% patients (3/50),

while some patients presented with only dysmenorrhea in 4% patients (2/50).

The study included women with

- Uterine size <12 weeks with leiomyoma.
- Premenstrual dilatation and curettage (D & C) and or hysteroscopy was done in women who were having endometrial hyperplasia of EMT on TVS more than 10mm and
- Women with histopathology report negative for malignancy were included.
- Women with USG or MRI proved adenomyosis
- Women with no other anatomical uterine lesions

All women had TVS scan, pap smear, thyroid profile and complete blood picture as preliminary workup for AUB. Women with no cervical, vaginal pathology, Leiomyomas of less than 12 weeks uterine size and a negative pap smear only were included in our series.

Exclusion criteria

- Women with congenital or acquired uterine anomaly,
- Intramural and subserous fibroids more than 3 cm
- Submucous fibroids distorting the uterine cavity,
- Acute pelvic inflammatory disease,
- Genital bleeding of unknown etiology,
- Liver disease and renal diseases
- Known or suspected carcinoma of the breast was excluded.

A detailed history and examination (general, systemic, pelvic, and breasts) was done. Transvaginal ultrasound was done using a 7.5 MHz transducer probe on day 4, 5, or 6 of menses. Any obvious pathologies like fibroids, adenomyosis, endometriosis, endometrial polyps, ovarian cysts, or any other adnexal pathology were diagnosed. The patient was called for

follow-up in OPD and the histopathology report was reviewed.

In case of no contraindications, LNG IUS was inserted post-menstrually on day 5, 6 or 7 when bleeding had stopped. Prior to insertion, the patient was counseled regarding the altered bleeding pattern known to occur with the device for 3-6 months. She was counseled regarding amenorrhea post insertion. It was inserted on OPD basis Post insertion, the patient was asked to maintain a menstrual calendar for 6 months, wherein she would mark the days when she has spotting or bleeding.

The women were called for follow-up after 1 month, then 6 months, and then half yearly (for maximum 2 years); and asked regarding the relief they have obtained from the antecedent menstrual complaints. A detailed general, systemic, pelvic (to see for threads), and breasts examination was done at every visit. Follow-up ultrasound was done at every visit to see for LNG IUS location and if there were any changes in the original pelvic pathology or development of a new pathology like ovarian cysts. Hemoglobin (Hb) estimation was done after 6 months. The efficacy of LNG IUS was measured in the form of subjective symptomatic improvement along with improvement in quality of life.

Results

Reduction in menstrual blood flow vs time

In first 3 months, 20% patients achieved normal menstrual cycle, and at 6 months 40% had scanty menstrual flow. After 1 year of use 80% achieved amenorrhoea whereas 10% had regular scanty bleeding. After 6 months of use there was significant reduction in pain and bleeding in cases of endometriosis, severe dysmenorrhea and chronic pelvic pain. In cases of adenomyosis there was decrease in uterine size as well as in menstrual bleeding. Distribution of cases according to PALM COEIN classification was as per **Table – 1**.

Table – 1: Distribution of cases according to PALM COEIN classification.

Group	No. of cases	%
Polyps after removal	2	4
Adenomyosis	10	20
Fibroids	10	20
Non atypical endometrial hyperplasias	20	40
Ovulatory	5	10
Endometrial etiology by exclusion	3	6

Side effects

The most frequent complaint in initial 3 months was irregular heavy bleeding in 40% patients which reduced to 10% at 6 months and 0% at 1 year follow up. Irregular spotting was second most complaint in 30% patients in initial 3 months that persisted in 5% patients at 1 year follow up. In 5% patients, there was spontaneous expulsion of the device in first 3 menstrual cycles. 2 patients requested for removal of the device due continued irregular heavy bleeding and opted for hysterectomy. Post insertion pain and vaginal discharge was a common complaint in many patients in initial 3 months.

Satisfaction rate

After 3 months of use 60% patients were satisfied with the device and at the end of 1 year 90% were satisfied whereas 10% patients were not completely satisfied due to irregular spotting. After 2 years all patients who came for follow up were satisfied. Parameters for follow up were as per **Table – 2**.

Discussion

Approximately 30% of women of reproductive age experience heavy bleeding during menstruation [8]. While in nearly half of all cases no organic pathology is found, a number of risk factors may contribute to the development of HMB [8]. In present study 69% patients had heavy menstrual bleeding with no identifiable cause. There were many treatment options including hemostatic drugs, hormones,

endometrial ablation, LNG-IUS and the definitive treatment was hysterectomy. Medical management of HMB with hormones was really

challenging due to poor compliance, side effects, cost, troublesome breakthrough bleeding and actual failures.

Table – 2: Parameters for follow up.

Parameter	6m	12m	24m
Break through bleeding	10%	0%	0%
Amenorrhea	10%	40%	80%
Dysmenorrhea	5%	0%	0%
Normal menses	80%	20%	0%

According to Value study, a survey of outcomes of 37,000 hysterectomies, operative and postoperative complication was reported in 3.5% and 9% cases [9]. Postoperative mortality was 0.38/1000 patients and psychological implication was seen in 35-45% patients [9]. This was a well-recognized and established fact that the LNG-IUS offers potential therapeutic benefits in menorrhagia and symptomatic fibroids etc. [10]. However, it frequently produced menstrual disturbances initially that can limit its use by clinicians.

This prospective interventional study was done to evaluate the efficacy, acceptability and side effects of LNG-IUS in women with heavy menstrual bleeding. According to the ACOG (American College of Obstetricians and Gynecologists), the LNG-IUS appears to reduce menstrual blood loss significantly in women with HMB.

In a study by Garg, et al. at six months post IUS insertion 10% had amenorrhea, 40% had irregular spotting (decreased flow), 23.33% had infrequent bleeding, 20% had scanty regular bleeding and only two women (6.66%) had irregular heavy bleeding [12]. By the end of 12 months 90% of women in this group developed amenorrhea.

In present study, at 6 months 13.9% had amenorrhea, 44.44% had scanty menstrual flow 11.1% had irregular spotting, 16.7% had normal menstrual cycle, and only 5 (13.89%) patients had irregular heavy bleeding. At 1 year of use

81.5% had amenorrhea, 11.1% had regular scanty flow and only 2 (7.4%) had irregular spotting.

In a study by Kriplani, et al. HMB was cured in 77.7% patients at 3 months and in all patients at 36 months [13]. There was a significant decrease in the number of bleeding days and decrease continued with increasing duration of treatment. 28.57% women developed amenorrhea at the end of six months whereas in our study 13.9% developed amenorrhea at six months, 81.5% at 12 and 91.6% at 24 months.

Conclusion

LNG-IUS is a safe, effective and acceptable mode of treatment of heavy menstrual bleeding. It can be a good alternative to hysterectomy for heavy menstrual bleeding due to many benign etiologies. It is associated with lesser side effects and higher satisfaction rate. LNG-IUS can be choice of treatment for entire reproductive years and it also helps in smooth transition to menopause. So, hysterectomy should be avoided for inappropriate reasons and femininity must be preserved.

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