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ORIGINAL ARTICLE

Effectiveness of Levonorgestrel Releasing Intrauterine System in Perimenopausal Women with Heavy Menstrual Bleeding: A Prospective Study at a Teaching Hospital in India

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Objectives: To evaluate the effect of levonorgestrel-releasing intrauterine system (LNG-IUS) on heavy menstrual bleeding in perimenopausal women.

Methods: This was a prospective, observational clinical study conducted on 42 perimenopausal women with heavy menstrual bleeding who met the study eligibility criteria. LNG-IUS was inserted in the postmenstrual phase following baseline evaluation. The patients were followed up at the 4, 12, and 24 weeks. Pictorial blood assessment chart (PBAC) score, hemoglobin and serum ferritin levels, and endometrial thickness were assessed before insertion and during the follow-up visits.

Results: Two patients (4.8%) were lost to follow-up, three patients (7.1%) opted for hysterectomy, two women (4.8%) experienced spontaneous expulsion and 35 (83.3%) women continued the usage. Menstrual blood loss assessed using the median PBAC score (interquartile range) significantly reduced ($P < 0.001$) from the pre-insertion level of 280 (246–306) to 124 (60–200) at 4 weeks to 45 (34–76) at 12 weeks and further to 32 (20–50) at the end of 24 weeks. Simultaneously, a significant ($P < 0.001$) improvement in the mean hemoglobin and serum ferritin levels and a significant ($P < 0.001$) decrease in endometrial thickness were observed. The most common side effect was spotting (50.0%) and vaginal discharge (38.1%).

Conclusions: LNG-IUS causes a remarkable reduction in menstrual blood loss and marked improvement in dysmenorrhea. It also reduces anemia by improving the hemoglobin and ferritin levels. Thus, it can serve as an effective treatment option for heavy menstrual bleeding in perimenopausal women and prevent the need for a hysterectomy.

Key Words: Heavy menstrual bleeding, Hysterectomy, Intrauterine device, Levonorgestrel, Perimenopause

INTRODUCTION

Abnormal uterine bleeding (AUB) is one of the most common problem for gynecological consultation in women of any age group and is defined as any uterine bleeding with deviation from normal menstrual pattern in term of duration, frequency or amount for an individual woman. In 2011, the PALM-COEIN acronym, a systematised nomenclature, was approved by the International Federation of Gynecology and Obstetrics (FIGO) to describe abnormal menses, the acronym PALM stands for structural or organic factors such as polyps, adenomyosis, leiomyomas, malignancies, and hyperplasia. COEIN stands for nonsructural causes such as coagulopathy, ovulatory dysfunction, endometrial dysfunction, iatrogenic causes and not yet classified [1].

The term heavy menstrual bleeding (HMB) has been proposed by FIGO for previously used term menorrhagia. Objective definition of HMB is cyclical blood loss of more than 80 mL during each menstrual period, or a score of more than 100 on the pictorial blood loss

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assessment chart (PBAC) [2]. HMB is one of the most frequent symptoms for seeking gynecological consultation in women of reproductive age group and even more in perimenopausal women. HMB is often incapacitating which influences a woman's quality of life and is often expensive to treat amounting to economic burden [3].

The various treatment options for HMB are medical treatment, conservative surgical treatment (endometrial ablation) and definitive surgical treatment (hysterectomy). Medical treatments for HMB include following oral drugs: mefenamic acid and antifibrinolytic agent, tranexamic acid; anti-hemorrhagic agent, ethamsylate; selective estrogen receptor modulators, ormeloxifene; and hormone-like combined oral contraceptive pill, oral progestins, and injectable progestins. Many women are unwilling to take medications because of daily need to take drugs and adverse effects and end up opting for surgical interventions [4]. Approximately 30% of all hysterectomies are done to relieve the symptoms of heavy menstrual bleeding [5]. Surgery always carries its own risks like infection, hemorrhage in addition to anaesthetic complications and increased need for prolonged hospitalization.

The levonorgestrel-releasing intrauterine system (LNG-IUS), which was first made available as a contraceptive in Finland in 1990, has been shown to be effective in treating severe menstrual bleeding in developed nations. LNG-IUS has been found to be more effective than usual medical treatment in women with heavy menstrual bleeding for enhancing quality of life [6]. LNG-IUS is a long acting, non-surgical alternative to the conventional medical and surgical treatment for heavy menstrual bleeding [7]. Perimenopause refers to the time frame in which physiologic changes herald the approach to a woman's final menstrual cycle. Hormonal changes occur during the perimenopausal period, and there is a high chance of developing various benign gynecologic disorders. Hence, perimenopausal women may benefit more from using LNG-IUS than women in other age group [8].

Studies have demonstrated the safety, effectiveness and acceptability of LNG-IUS as one the treatment modality in perimenopausal AUB and other causes of HMB [9-11]. There is paucity of studies related to use of LNG-IUS for HMB in perimenopausal women from India and to our knowledge no such study has been conducted in Jharkhand state. Therefore, this study was designed to evaluate the effectiveness of levonorgestrel intrauterine system in perimenopausal women with heavy menstrual bleeding coming to tertiary care teaching institution of the state.

MATERIAL AND METHODS

This was a prospective, observational clinical study conducted during January 2020 to August 2021 in Rajendra Institute of Medical Sciences (RIMS), a tertiary care teaching institution in Jharkhand, India, after approval from Institutional Ethics Committee of RIMS, Ranchi [IEC no. 223, dated 21. 12. 2019]. During the study period, perimenopausal women with HMB were enrolled after written informed consent and were screened for eligibility criteria. HMB was defined by a score of more than 100 on the PBAC corresponding to blood loss of more than 80 mL during each menstrual period. Consecutive purposive sampling technique was used for enrolment. Inclusion criteria were perimenopausal women aged between 40–51 years with HMB due to benign causes (fibroid uterus, adenomyosis, endometrial hyperplasia without atypia, AUB) and those who were willing to maintain monthly record of vaginal bleeding, to report the side effects of LNG-IUS, to have ultrasound examination and to come for follow-up visits. Exclusion criteria were uterine size > 12 weeks or those with multiple fibroids with maximum size > 3 cm, uterocervical length greater than 10 cm, distortion of uterine cavity, hemoglobin < 8 mg/dL, malignancies of uterus, cervix, or vagina, endometrial hyperplasia with atypia, an abnormal pap smear, HMB due to coagulopathy or systemic disease.

A total of 42 perimenopausal women who fulfilled the eligibility criteria were included in the study. A detailed history including menstrual and obstetric history, past medical and surgical history and personal history was taken from each study participant. The menstrual history included duration of symptom of heavy menstrual bleeding, number of days of bleeding, intermenstrual interval, presence of dysmenorrhoea, and passage of clots and also the subjective assessment of symptoms. Objective assessment of menstrual blood loss was done by PBAC score. Patients were asked to record the number of sanitary pads that were lightly, moderately, or completely stained on a daily basis using a scoring chart. Scores were given as follows: 1 point for light staining, 5 points for moderate staining, and 20 points for complete staining of each pad. Small clots received one point, while large clots received five. Each day's

points were then added. Total points per menstrual cycle greater than 100 corresponded to objective blood loss more than 80 mL.

All participants underwent complete physical examination including pelvic examination and baseline transvaginal ultrasound evaluation for pelvic pathologies and endometrial thickness. Baseline haemoglobin and serum ferritin levels were measured and endometrial biopsy and pap smear were performed.

All women enrolled in the study were counselled regarding procedure of insertion of LNG-IUS, its chances of expulsion, side effects like intermenstrual spotting and vaginal discharge and need for follow-up. The LNG-IUS (52 mg releasing 20 mcg levonorgestrel) insertion was done preferably in the post-menstrual phase, either in outdoor or in operation theatre. Anticipating difficulty in insertion of the device due to narrow cervical os in nulliparous women and in those with previous uterine scar, LNG-IUS was inserted in operation theatre. Short intravenous sedation was used for apprehensive women. Misoprostol in the dose of 400 microgram was inserted vaginally 2 to 3 hours before the procedure to facilitate cervical softening. Women were made to lie in dorsal position with thighs flexed, after emptying the bladder. A bimanual examination was done to determine the size and position of the uterus followed by measuring the length of the uterus by uterine sound. Then, under aseptic precautions, device was inserted in the uterine cavity by pushing the slider forward and advancing the inserter through the cervix while holding the slider in the furthest position.

Patients were instructed for follow-up visits at 4, 12, and 24 weeks after insertion of the LNG-IUS, or earlier, if necessary, for any deterioration of symptoms or any adverse effects. At each visit, menstrual blood loss was assessed subjectively by interviewing about improvement of symptoms and relief of dysmenorrhea, any side effects and objectively by PBAC score. At each visit transvaginal sonography (TVS) was performed to look for any possible expulsion. Endometrial thickness (by TVS), hemoglobin and serum ferritin levels were assessed before the initiation of treatment, then at 12 and 24 weeks.

Primary outcome measure (PBAC score) in the pre-insertion cycle was compared to that in post-insertion cycles at 4, 12, and 24 weeks. Secondary outcome measures (hemoglobin level, serum ferritin level, and endometrial thickness) in pre-insertion cycle were compared to those in post insertion cycle at 12 and 24 weeks.

Statistical analysis of data

Predesigned case record forms were used to collect data obtained from pre-insertion (before the insertion of LNG-IUS) baseline cycle and the post-insertion (after the insertion of LNG- IUS) cycles, which served as the source data verification document. A proper template for data entry was created, and after data entry 10% of the data was checked at random to ensure data quality. The data was compiled and statistically analysed using a statistical package for social sciences (IBM SPSS Statistics 20.0; IBM SPSS Inc, Armonk, NY, USA). Paired *t* test for normally distributed data and Wilcoxon signed rank test for non-normally distributed data were used to see the effect of the LNG-IUS device. Five percent level of significance was considered for these tests.

RESULTS

Figure 1 shows the recruitment of patients in the study. Out of 42 women included in the study, 2 were

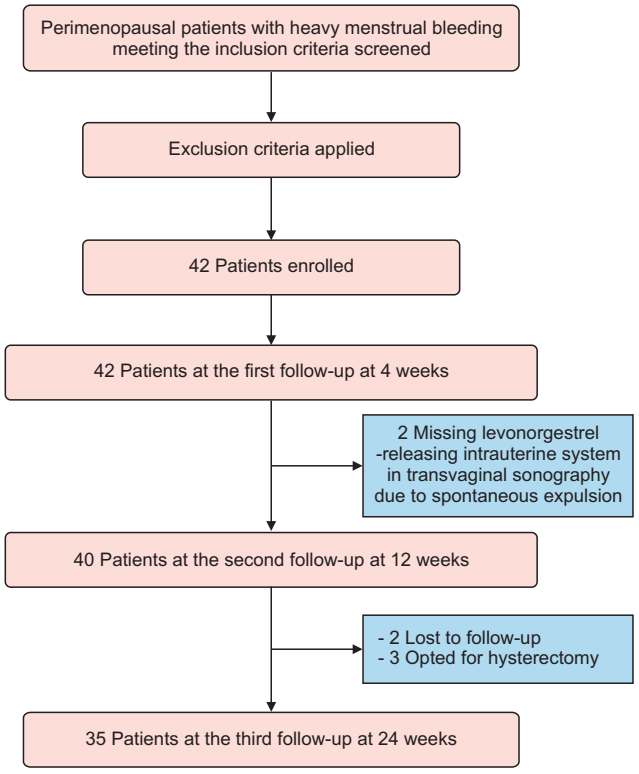

Fig. 1. Flow diagram showing details of the patients recruited in the study.

lost to follow-up after 12 weeks, 3 women opted for hysterectomy at 12 weeks. Besides, 2 women had spontaneous expulsion of the device at 4 weeks. Thus, the outcome measures were analyzed on 35 women.

Table 1 depicts demographic characteristics of study participants. The mean age of 42 women included in the study was 44.73 ± 3.14 years. Majority (95.2%) of the patients were of parity 1–4, one (2.4%) woman was nulliparous. Most patients (66.7%) were from urban areas. Eighteen out of 42 (42.9%) patients belonged to middle socioeconomic status. Twenty out of 42 patients had comorbidities, of which 5 (25.0%) had diabetes mellitus, 3 (15.0%) had hypertension, and 8 (40.0%) patients were known case of hypothyroidism. Those with diabetes were taking oral hypogycemic drugs -metformin, glimepiride. Those with hypertension were taking antihypertensive medications -amlodipine, telmisartan without any anticoagulant as prescribed by physician. Only one patient with hypertension and history of myocardial infarction was taking anticoagulant: aspirin.

Table 1. Demographic characteristics of study participants

Variable	
Age (yr) (n = 42)	44.73 ± 3.14
Parity (n = 42)	
Nulliparous	1 (2.4)
Para 1–4	40 (95.2)
Para ≥ 5	1(2.4)
Residence (n = 42)	
Rural	14 (33.3)
Urban	28 (66.7)
Socio-economic status (n = 42)	
Low	16 (38.1)
Middle	18 (42.9)
High	8 (19.0)
Comorbid condition (n = 20)	
Diabetes	5 (25.0)
Hypertension	3 (15.0)
Hypothyroidism	8 (40.0)
Hyperthyroidism	1 (5.0)
Hypertension with myocardial infarction	1 (5.0)
Tuberculosis	1 (5.0)
Diabetes and hypertension	1 (5.0)

Data are presented as mean ± SD or number (%).

Baseline clinical characteristics of the patients are listed in Table 2. The mean duration of symptom of heavy menstrual bleeding was 11.12 ± 10.05 months. Dysmenorrhea was associated with HMB in 23 (54.8%) women. 35.7% patients had normal size uterus, and equal number had bulky uterus (uterine size above normal), 26.2% patients had 6–8 weeks size uterus and 1 (2.4%) patient had uterine size of 10 weeks. Baseline transvaginal sonography revealed adenomyosis in 11 (26.2%) patients and fibroid uterus in 8 (19.0%) patients. Baseline pre-insertion endometrial biopsy showed cystic glandular hyperplasia in 14.3%, non-secretory endometrium in 35.7% and simple endometrial hyperplasia in half of the patients.

The median PBAC score (interquartile range [IQR]) was reduced from pre-insertion score of 280 (246–306)

Table 2. Baseline clinical characteristics of study participants (n = 42)

Clinical characteristics	
Duration of heavy menstrual bleeding (mo)	11.12 ± 10.05
Association with dysmenorrhoea	
Yes	23 (54.8)
No	19 (45.2)
Previous caesarean scar	
Yes	10 (23.8)
No	32 (76.2)
History of permanent sterilisation	
Yes	6 (14.3)
No	36 (85.7)
Size of uterus	
Normal	15 (35.7)
Bulky (above normal size)	15 (35.7)
6 wk	5 (11.9)
8 wk	6 (14.3)
10 wk	1 (2.4)
Pre-treatment transvaginal sonography findings	
Adenomyosis	11 (26.2)
Bulky uterus	11 (26.2)
Fibroid	8 (19.0)
Normal study	12 (28.6)
Endometrial biopsy finding	
Cystic glandular hyperplasia	6 (14.3)
Non-secretory endometrium	15 (35.7)
Simple endometrial hyperplasia	21 (50.0)

Data are presented as mean ± SD or number (%).

to 124 (60–200) at 4 weeks, 45 (34–76) at 12 weeks and further to 32 (20–50) at end of 24 weeks (Table 3). There was reduction in menstrual blood loss by 55.7%, 83.9%, and 88.6% at 4, 12 and 24 weeks respectively. Thus, percentage reduction versus the baseline value at every observation point was significant ($P < 0.001$).

Table 4 shows comparison of hemoglobin level, serum ferritin level, and endometrial thickness before LNG-IUS insertion and after LNG-IUS insertion at 12 and 24 weeks. The pre-insertion mean hemoglobin was 9.39 ± 0.4 g/dL which increased to 10.07 ± 0.65 g/dL at 12 weeks and to 10.36 ± 0.66 g/dL at 24 weeks. These changes were significant ($P < 0.001$) at each observation point. The pre-insertion mean serum ferritin was 36.77 ± 13.76 ng/mL, which increased to 47.89 ± 14.58 ng/mL and to 55.14 ± 19.87 ng/mL at the end of 12 and 24 weeks respectively. This increase of 11.12 ng/mL at 12 weeks and of 18.37 ng/mL at the end of 24 weeks was statistically significant ($P < 0.001$). In our study, the mean endometrial thickness before insertion of device was 9.07 ± 4.72 mm, which was reduced to 4.97± 1.84 mm at 12 weeks showing a reduction of 45.2%, which further reduced to 3.57± 1.23 mm at 24 weeks showing reduction of 60.6% from its baseline level ($P < 0.001$).

Table 5 depicts that at the end of 12 weeks, 19 (54.3%) women had mild improvement, 1 (2.9%) had moderate improvement, and 7 (20.0%) had marked improvement of symptoms in terms of relief of dysmenorrhea and decrease in menstrual blood flow. Further, at the end of 24 weeks, marked improvement was observed in 22 (62.9%) women. During the course of follow-up, 2 women (4.8%) had spontaneous expulsion, 19.0% had abdominal cramps, 50.0% of patients experienced intermenstrual spotting, vaginal discharge was observed in 38.1%, while 35.7% had no side effects (Table 6).

Table 3. Pictorial blood assessment chart (PBAC) score before and after levonorgestrel releasing intrauterine system (LNG-IUS) insertion at 4, 12, and 24 weeks (n = 35)

Time related to LNG-IUS insertion	PBAC score	*P* value
Preinsertion	280 (246–306)	Reference
Postinsertion		
4 wk	124 (60–200)	< 0.001 (z = –4.630)
12 wk	45 (34–76)	< 0.001 (z = –5.747)
24 wk	32 (20–50)	< 0.001 (z = –5.747)

Data are presented as median (interquartile range).
P value calculated by Wilcoxon signed rank test.

Table 4. Hemoglobin, serum ferritin, and endometrial thickness before and after levonorgestrel-releasing intrauterine system (LNG-IUS) insertion at 12 and 24 weeks (n = 35)

Time related to ILNG-IUS insertion.	Hemoglobin (g/dL)				Serum ferritin (ng/mL)				Endometrial thickness (mm)			
	Mean ± SD	95% CI	*P* value	*t*	Mean ± SD	95% CI	*P* value	*t*	Mean ± SD	95% CI	*P* value	*t*
Preinsertion	9.39 ± 0.4		Ref		36.77 ± 13.76		Ref		9.07 ± 4.72		Ref	
Postinsertion												
12 wk	10.07 ± 0.65	–0.91 to –0.43	< 0.001	–5.68	47.89 ± 14.58	–15.65 to –6.58	< 0.001	–4.97	4.97 ± 1.84	2.944 to 5.249	< 0.001	7.22
24 wk	10.36 ± 0.66	–1.23 to –0.71	< 0.001	–7.58	55.14 ± 19.87	–24.65 to –12.09	< 0.001	–5.95	3.57 ± 1.23	4.127 to 6.867	< 0.001	8.15

Data are presented as mean ± SD and 95% CI.
P value calculated by paired *t* test.
CI: confidence interval, Ref: Reference.

Table 5. Subjective assessment of symptoms and relief of dysmenorrhoea (n = 35)

	Subjective assessment of symptoms			
	No improvement	Mild improvement	Moderate improvement	Marked improvement
4 wk	13 (37.1)	6 (17.1)	16 (45.7)	0 (0)
12 wk	8 (22.9)	19 (54.3)	1(2.9)	7 (20.0)
24 wk	1 (2.9)	12 (34.3)	0 (0)	22 (62.9)

Data are presented as number (%).
The sum of the percentages does not equal 100% because of rounding.

Table 6. Side effects during course of treatment (n = 42)[a]

Side effects	
Spontaneous expulsion	2 (4.8)
Cramps	8 (19.0)
Spotting	21(50.0)
Discharge per vaginum	16 (38.1)
None	15 (35.7)

Data are presented as number (%).
[a]The sum of the percentages does not equal 100% because some women experienced more than one symptom.

DISCUSSION

In this study, the effectiveness of LNG-IUS in HMB among perimenopausal women has been analyzed. The parity was between 1–4 in most of the patients. Only one patient in our study was nulliparous, but effectiveness of LNG-IUS in nulliparous women has been demonstrated in previous studies [12]. In 10 patients (23.8%) LNG-IUS was inserted in women having previous cesarean scar. A similar study by Dhamangaonkar et al. [13] in their series of 70 patients had 14.2% cases of previous caesarean. Ten women with previous uterine scar in our study did not have any complicatons like uterine perforation or expulsion. LNG-IUS appears to be safe in women who underwent previous uterine surgeries.

In the present study, majority 66.7% (28/42) were from urban areas and 61.9% (26/42) belonged to middle and high socio-economic group. This observation has little relevance to etiology of HMB but higher education level in these groups played an important role in counselling for acceptance of LNG-IUS and compliance to follow up visits.

We used LNG-IUS in patients with co-morbid conditions. Comorbidity was present in 47.6% (20/42) of the women which included diabetes, hypertension, thyroid disorder, history of myocardial infarction and tuberculosis. Several other studies have also demonstrated LNG-IUS to be effective in women with comorbid conditions including valvular heart disease, human immunodeficiency virus infection, diabetes and hemostatic disorders [13,14-19]. Therefore, one advantage of LNG-IUS is its ability to be used in medical comorbid condition, where surgical treatment may be contraindicated.

Although uterine size of more than 12 weeks was exclusion criteria in our study and maximum uterine size in which LNG-IUS was inserted was 10 weeks, but effectiveness of device in heavy menstrual bleeding due to adenomyosis in women with uterine size more than 12 weeks has been demonstrated [20].

In the present series, 45.2% (19/42) had structural abnormalities of uterus, which included fibroid uterus in 19.0% (8/42) and adenomyosis in 26.2% (11/42). Significant reduction in the menstrual blood loss associated with LNG-IUS in women with uterine leiomyomas has been reported by Kriplani et al [21]. A prospective controlled trial by Soysal et al. [22] demonstrated the effectiveness of LNG-IUD in presence of myoma as compared to thermal balloon application.

Our study demonstrated significant reduction ($P < 0.001$) in menstrual blood loss in terms of median PBAC score by 55.7%, 83.9%, and 88.5% versus the baseline value at 4, 12 and 24 weeks respectively. At the end of 24 weeks, 9.52% (4/35) women achieved complete amenorrhea (PBAC = 0). This finding is similar to a pooled analysis of five randomized studies by Endrikat et al. [23] who observed that median (IQR) menstrual blood loss decreased from baseline by 84.5% after 3 months and by 92.9% after 6 months respectively ($P < 0.0001$). Our results are also comparable to study by Tang and Lo [24], showing significant reduction in menstrual blood loss at 4, 12 and 24 weeks after LNG-IUS insertion compared to pre-insertion cycle. A randomized trial conducted on 58 women by Sayed et al. [25] demonstrated greater reduction of PBAC scores in the LNG-IUS group compared to combined oral contraceptive group.

In addition to decrease in menstrual blood loss, this study showed subjective improvement of symptoms especially dysmenorrhea in 34/35 (97.15%) of women at the end of 24 weeks. Previous studies have also reported significant improvement of subjective symptoms and dysmenorrhea with LNG-IUS in women with adenomyosis [20,26,27].

In the present study, the mean endometrial thickness decreased from 9.07 ± 4.72 mm baseline level to 3.573.57 ± 1.23 at 6 months. Another study also demonstrated significant decrease in endometrial thickness at 12 months after LNG-IUS insertion [10].

In parallel to decrease in menstrual blood loss, our study demonstrated significant increase in mean hemoglobin level by 0.97 g/dL and mean serum ferritin level by 18.37 ng/mL at the end of 24 weeks. Other studies have also showed significant improvement in hemoglobin and serum ferritin levels after LNG-IUS insertion in cases of heavy menstrual bleeding [9,13,25]. LNG-IUS is a nonsurgical treatment which releases levonorgestrel locally, makes the endometrium nonproliferative thus, reduces bleeding and corrects anemia.

Most common side effect was spotting observed in 50.0% of the patient followed by vaginal discharge (38.1%) Spotting has been reported as most common side effect in other studies also [10,20]. Spotting usually lasts for 3 months and improves with passage of time. Changes in the vascular pattern of endometrium exposed to the LNG-IUS could explain the improvement in spotting with passage of time [28]. Spontaneous expulsion of device was noted in 4.8% (2/42) patients in this study. Other studies have reported lower expulsion rate from 1.4% (1/70), 9.5% (6/63), 10.0% (4/40), and 16.0% (15/94) to as high as 37.5% (18/48) [10,11,13,20,26].

Main strength of this study is its prospective design. However, the limitation of this study is small sample size. Study was done during COVID-19 pandemic in India, which might have affected the visit of women to hospital. Another limitation is relatively short follow-up period till 24 weeks. Larger prospective studies for longer period of time are required to study the long term effects of LNG-IUS.

CONCLUSION

The prospective study shows that LNG-IUS causes significant reduction in menstrual blood loss, marked improvement in subjective symptoms, especially dysmenorrhea in perimenopausal women with heavy menstrual bleeding. Simultaneously, significant reduction of endometrial thickness and correction of anemia in terms of improvement of hemoglobin and serum ferritin level is also observed. LNG-IUS can serve as effective treatment option for small fibroids and adenomyosis in perimenopausal women obviating the need for hysterectomy. Minor side effects include spotting and vaginal discharge which require proper pre-insertion counselling.

Hysterectomy is the most commonly accepted mode of treatment of abnormal uterine bleeding in the perimenopausal age group in India. LNG-IUS has the advantage of administering local hormonal treatment as one time procedure which leads to improved patient compliance and thus, can be a cost effective treatment option as an alternative to hysterectomy. Population needs to be made aware that LNG-IUS can be used as a medical hysterectomy.

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