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Original Research Article

Efficacy of levonorgestrel intrauterine system in conservative management of abnormal uterine bleeding: an emerging tool

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ABSTRACT

Background: Intrauterine LNG IUS, introduced in 1990, reduces hysterectomies for abnormal uterine bleeding, reducing the need for costly and incapacitating surgical treatments.
Methods: Heavy menstrual bleeding patients were prescribed oral progesterone therapy with norethisterone or medroxyprogesterone in doses of 20-60 mg daily for a maximum of 6 months. 80 patients chose oral progesterone and 40 chose LNG IUS insertion. The follow-up period for patients who chose LNG IUS was conducted at a rate of one year.
Results: Reduction in PBAC score pre and post treatment was statistically significant in both oral progesterone (p value <0.001) and LNG IUS group (p value <0.001). We found statistically significant reduction in endometrial thickness after 6 months of treatment with oral progesterone (p value <0.001) and LNG IUS group (p value <0.001). The most common complaint at 6 months follow-up was spotting per vaginum, which was comparable in both groups. Infrequent cycle and secondary amenorrhea were significantly more in LNG IUS group (p value <0.05) whereas heavy flow persistence and need for hysterectomy were more in oral progesterone group (p value <0.05). LNG IUS got spontaneously expelled in one patient (2.5%) after first menstrual cycle. Mean duration from insertion to amenorrhea was 8 months. After insertion, the mean Hb% showed a significant rise of 8% form baseline. Satisfaction level was more (70%) in LNG IUS users in comparison to oral progesterone (15%).
Conclusions: LNG-IUS is a superior nonsurgical option for managing HMB and uterine pathologies, with lower net costs compared to medical treatment and hysterectomy. It can be improved with counselling about self-remission of spotting per vaginum and fertility preservation.

Keywords: Abnormal uterine bleeding, Intrauterine LNG IUS

INTRODUCTION

NICE Guidelines of the National Institute of Health and Clinical Excellence of the United Kingdom defines HMB as excessive menstrual blood loss which interferes with the woman's physical, emotional, social and material quality of life.[1] Heavy menstrual bleeding is often incapacitating and expensive to treat and may severely affect a woman's quality of life in both personal as well as social terms. HMB is largely responsible for jeopardizing a woman's social, personal, and professional life.[2] Heavy menstrual bleeding may be acute or chronic and maybe in form of increased frequency, duration and amount of flow. The main stay of non surgical management since ages has been with the progesterone.

Over the years many progesterone preparations and routes of delivery has evolved. LNG IUS being one of the most accepted one, is still lesser preferred with certain group of gynecologists. Intrauterine LNG IUS was introduced in year 1990, and graduallygained popularity resulting in reduced number of hysterectomies in cases of abnormal

uterine bleeding in cases with otherwise no specific indication for surgical treatment.

The data shows that out of all hysterectomies performed, nearly 30% of are to alleviate heavy menstrual bleeding.[3]

But today modern women prefer not to get their uterus removed andare more welcoming and happier with some nearly definitive treatment for their heavy menstrual bleeds.

Mirena is a hormonal T shaped polyethylene intrauterine device with steroid reservoir containing 52 mg of levonorgestrel.[4] The device releases the hormone at an initial rate of 20 µg/day and declines to a rate of 14 µg after 5 years, which is still in the range of clinical effectiveness.[5,6] Effectiveness is retained for 5 to 7 years. This high local concentration of LNG is responsible for atrophy of the endometrial glands and decidualization of the stroma.[7] LNG induced endometrial changes that needs 3 months to work post insertion, hence some of the patients may need additional medications for AUB control in those 3 months.

This study was a revisit to levonorgestrel intrauterine device based on their efficacy, side effects and patient's satisfaction levels.

Aim

To check the efficacy, side effects and satisfaction level of LNG IUS in abnormal uterine bleeding (adenomyosis, fibroid, endometrial cause, ovulatory disorder).

METHODS

This was a prospective observational study was conducted at the department of obstetrics and gynecology, SRN Hospital, MLN Medical College, Prayagraj, over a period of two years. After getting approval of institutional ethics committee,

Sample size

120 with 95% confidence level 5% margin of error, 8.5% population proportion taken as 10 crores according to 2011 census.

Study was conducted in 120 patients (80 in oral progesterone group and 40 in LNG IUS group) of reproductive age group.

The study included women aged 30-50 with abnormal uterine bleeding, including adenomyosis, fibroids, endometrial causes, and ovulatory disorders, with some patients in the LNG IUS group weighing the benefits and risks (Figure 1).

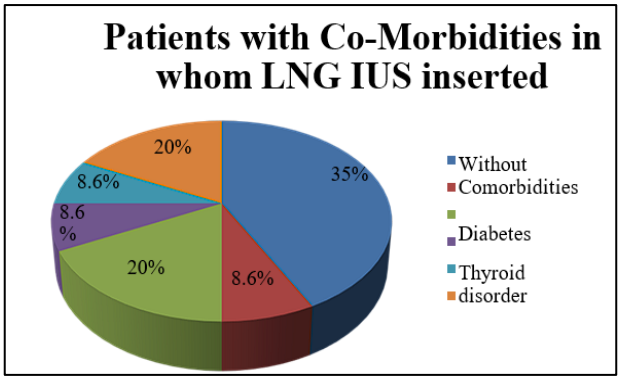

Figure 1: Distribution of comorbidities of patients in whom LNG IUS was inserted.

The exclusion criteria include uterine size over 14 weeks, uterine anomalies, submucous fibroids, atypical endometrial proliferations, EIN and endometrial carcinoma, acute pelvic inflammatory disease, uncontrolled diabetes, hypertension, and active liver disease with deranged enzymes.

Methodology

After ethical clearance from institutional ethics committee and informed consent and counselling of the patients with heavy menstrual bleed due to adenomyosis\fibroid\ endometrial cause\ovulatory disorders or combinations of uterine abnormalities were given either oral progesterone therapy with norethisterone and medroxyprogesterone in doses of 20-60 mg/day for duration of maximum 6 month and others were given LNG IUS depending on their choices.

80 patients chose oral progesterone and 40 chose LNG IUS insertion.

Follow up was done at 1 month, then 3 months, 6 months and for patients who chose LNG IUS at 1 year.

Outcomes were measured on following parameters: Pre-treatment and post treatment PABC score; menstrual pattern (based on FIGO, 2018 guidelines); hemoglobin level; endometrial thickness (on TVS); need for surgical management (hysterectomy); patient satisfaction rate. (on Likert scale).

Statistical analysis

P value was calculated using chi square with 95% confidence intervals. Statistical significance was set at 0.05.

RESULTS

The mean age group for oral progesterone and LNG IUS group was 38.5±3.81 and 40.50±2.88 years with non-significant p value (0.08).

Table 1: Age, habitat and parity distribution of patients in both oral progesterone group and LNG IUS groups.

Parameters		Oral progesterone group (n=80) (%)	LNG IUS group (n=40) (%)	Total (%)	P value
Age (mean±SD)		38.53±3.81	40.50±2.88	39.51±3.5	0.08
Locality	Urban	11 (27.5)	50 (62)	36 (45)	0.002
	Rural	29 (72.5)	30 (37)	44 (55)	0.001
Parity	Nulliparous	0 (0)	0 (0)	0 (0)	<0.001
	Multiparous	40 (100)	80 (100)	80 (100)	<0.001

Table 2: Basal and follow up PBAC score, hemoglobin levels, endometrial thickness in oral progesterone group and LNG IUS groups.

Parameters	Groups	Before treatment	After 3 months of treatment	After 6 months of treatment	P value
PBAC score	Oral progesterone	174.20±56.93	22.87±29.90	3.74±10.99	<0.001
	LNG IUS	172.08±41.50	11.76±22.72	3.97±10.96	<0.001
Endometrial thickness	Oral progesterone	9.32±3.10	7.04±1.67	5.84±0.99	<0.001
	LNG IUS	10.02±3.15	6.99±1.04	5.43±1.21	<0.001
Hemoglobin	Oral progesterone	10.22±1.36	10.61±1.15	11.03±1.02	<0.001
	LNG IUS	9.78±1.29	10.14±1.96	10.64±.99	0.001

Table 3: Distribution of final outcome at 6 months in oral progesterone group and LNG IUS groups at 6 months.

Outcome	Oral progesterone group (n=80) (%)	LNG IUS group (n=40) (%)	P value
Spotting	32 (40)	16 (40)	0.1
Infrequent menses	16 (20)	12 (30)	0.05
Secondary amenorrhea	4 (5)	10 (25)	<0.0001
Heavy flow persistence	16 (20)	2 (5)	0.02
Expulsion of LNG IUS	-/-	1 (2.5)	
Hysterectomy	12 (15)	2 (5)	0.04

Table 4: Bleeding pattern post insertion in LNG IUS group.

Pattern	1 month (n=40) (%)	3 months (n=39) (%)	6 months (n=39) (%)	1 year (n=36) (%)
Spotting	24 (60)	17 (42.5)	16 (40)	2 (5)
Moderate flow	12 (30)	11 (27.5)	13 (30)	-/-
Heavy flow	4 (10)	4 (10)	2 (5)	1 (2.5)
Secondary amenorrhea	-/-	8 (20)	10 (25)	33 (91.6)

Table 5: Comparison of adverse events in oral progesterone group versus LNG IUS group.

Adverse event	Oral progesterone group (n=80) (%)	LNG IUS (n=40) (%)	P value
Nausea	36 (45)	3 (7.5)	<0.001
Vomiting	11 (13.75)	2 (5)	0.02
Mood disorder	14 (17.5)	8 (2)	0.05
Breast tenderness	9 (11.25)	5 (6.25)	0.08
No adverse event	10 (12.5)	22 (55)	<0.001
Total	80 (100)	40 (100)	

Table 6: Satisfaction rate with oral progesterone group versus LNG IUS (based on Likert scale).

	Very satisfied	Satisfied	Neutral	Unsatisfied	Very unsatisfied
LNG IUS	30%	40%	15%	10%	5%
Oral progesterone	5%	10%	25%	35%	25%

62% LNG IUS user group were urban whereas in oral progesterone group only 27.5% patients belong to urban population which was found to be statistically significant (0.002) (Table 1).

All the patients included in the study were multiparous (100%).

Reduction in PBAC score pre and post treatment was statistically significant in both oral progesterone (p value <0.001) and LNG IUS group (p value <0.001).

We also found statistically significant reduction in endometrial thickness after 6 months of treatment with oral progesterone (p value <0.001) and LNG IUS group (p value <0.001). Hemoglobin level also increased significantly after 6 months of treatment in both groups (p value <0.001) (Table 2).

There were three babies who developed respiratory complication 24 hours after birth (not related to prematurity) and required respiratory support. All these 3 babies survived and were discharged subsequently. Of the two intrapartum stillbirths noted in the study, one was a severe IUGR at 30 weeks and the other had intrapartum fetal distress at 32 weeks leading to stillbirth. The abnormal waveform indices were compared with major adverse outcomes (Table 1).

Since there were 2 stillbirths, and one baby died in immediate neonatal period, analysis for neonatal nursery admission is done in 107 babies. There was a total of 39 babies of 107 (36.4%) who required nursery admission for observation either due to respiratory complications, metabolic complications or sepsis. The abnormal waveforms of umbilical artery and middle cerebral artery were also compared with neonatal nursery admission (Figure 1).

At 6 months follow up, spotting per vaginum was the most frequent complaint but was comparable in both the groups. Infrequent cycle and secondary amenorrhea were significantly more in LNG IUS group (p value <0.05) whereas heavy flow persistence and need for hysterectomy were more in oral progesterone group (p value <0.05). LNG IUS got spontaneously expelled in one patient (2.5%) after first menstrual cycle.

In the first follow-up itself, 60% women had only spotting but with time 91.6% became amenorrheic by the end of 1 year. Mean duration from insertion to amenorrhea was 8 months. After insertion, the mean Hb% showed a significant rise of 8% form baseline.

Two patients failed to respond to LNG IUS in the first 6 month and underwent hysterectomy. LNG IUS was spontaneously expelled in one patient within 1 month of insertion and in one patient it was removed due to persistent complain of white discharge per vaginum after 1 year.

Adverse events like nausea (<0.001), vomiting (0.02), mood disorder (0.05) are statistically significant more in oral progesterone, breast tenderness (p value 0.08) was not significant in both groups, while no adverse events were associated mainly (55%) with LNG IUS users (p <0.001).

Satisfaction level was more (70%) in LNG IUS users in comparison to oral progesterone (15%).

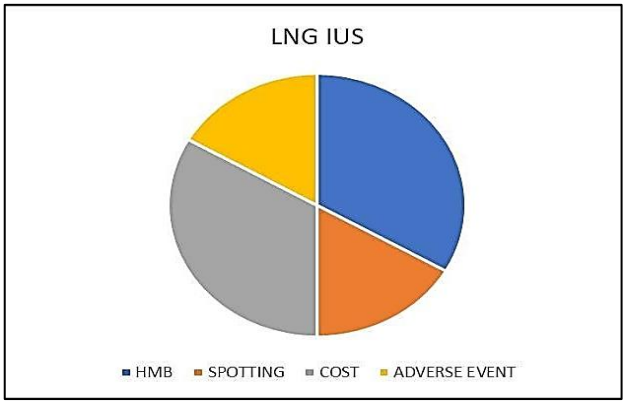

Figure 2: Reasons for dissatisfaction in patients in LNG IUS group.

DISCUSSION

Heavy menstrual bleeding is a subjective finding, making the exact problem difficult to define. Two-thirds of women with menorrhagia show evidence of iron deficiency anemia beyond 80 ml of blood loss.[8] Treatment regimens must address the specific facet of the menstrual cycle which the patient perceives to be abnormal (i.e., cycle length and quantity of bleeding). There arevarious methods available for treatment of menorrhagia which includes medical management and surgical management. Many women are not happy with medical treatment and end up undergoing surgery and many want to save their uterus and avoid surgery at any cost.

This study demonstrated preferences of oral progesterone in younger age groups while most of perimenopausal women preferred LNG IUS. On analyzing the relation of habitat and preferences of oral progesterone vs LNG IUS, urban women preferred LNG IUS whereas rural women chose oral therapy over LNG IUS (Table 1). Although the all women were counseled in the same way for both modes of therapy, significant differences in choices of one therapy over another in different ages and habitat is reflection of still persisting disbelief of intrauterine devices amongst younger and rural women. All women were counseled with the same sentence that “you will have to take oral tablets on the specified time everyday without fail,while with LNG IUS it will be like just get inserted and forget, no need to remember everyday”, yet many of younger women and rural women were not happy with something getting inserted in their uterus. Studies by Lähteenmäki et al and Kailasam et al also got similar preferences.[9]

Response to the therapy in both the groups were statistically significant at 3 and 6 months follow ups, whereas on reviewing the side effects, the percentage was more in the patients having oral progesterone especially GI related nausea and vomiting (Tables 3 and 5). In the first follow-up itself, 60% women had only spotting but with time 91.6% became amenorrheic by the end of 1 year. Mean duration from insertion to amenorrhea was 8 months. After insertion, the mean Hb% showed a significant rise of 8% form baseline. Results of this study are similar to other studies done in the past.[10-18]

LNG-IUS acting locally has already been described to be more effective in controlling heavy uterine bleeds with minimal systemic side effects like nausea, headache, mood disturbances in the studies by Dhamangaonkar et al and Kailasam et al.[9]

While assessing the satisfaction levels in both the groups, menstrual abnormality in the form of irregular spotting was the most distressful complaints among women that was more in oral progesteronegroup than in LNG- IUS, while secondary amenorrhoea was more with LNG-IUS. Detailed interrogation on satisfaction levels revealed that the ones whowere not satisfied with either of them were mostly because irregular spotting followed by unpredictability of menstrual cycles (Figure 2). Religious women often experience discomfort and distress during menstruation due to prayers, fasts, and going to religious places. However, most symptoms subside within six months. Counseling women about progesterone therapies and LNG IUS can increase their acceptance, as it relieves symptoms without surgery and has lesser systemic side effects. This can help increase the acceptance of these treatments.

Another worry of having secondary amenorrhoea and suspicion of conception also needed very robust counseling. The study used LNG IUS in patients with various comorbidities, including hypertension, diabetes, thyroid disorders, bronchial asthma, HIV, hepatitis B, ischemic heart disease, epilepsy, and triple vessel disease. It also inserted in high-risk patients with rheumatic mitral stenosis, previous LSCS with incisional hernia repair, and previous LSCS with a prior abdominal exploration for ectopic pregnancy. 20% of women had hypertension, 8.6% had diabetes, 8.6% both hypertension and diabetes, and 8.6% had thyroid disorders (Figure 1). This has also been proven in other studies done in the past like Kaisalam et al and Mukherjee et al.[19] Truly speaking, LNG IUS is like a boon to the AUB Patients with surgical contraindications and this enables us to effectively treat disabling abnormal uterine bleeds avoiding major surgeries.

The levonorgestrel intrauterine system (LNG-IUS) is an effective, minimally invasive option for managing abnormal uterine bleeding (AUB), yet it has limitations. Its efficacy may be reduced in women with large or irregularly shaped uteri, such as in fibroid-related AUB. Expulsion or malposition of the device can lead to treatment failure. Initial irregular spotting may reduce patient compliance. Access and cost may be limiting factors in low-resource settings. Additionally, LNG-IUS is unsuitable for women with active pelvic infections or certain cancers. Regular follow-up is essential, and not all patients may tolerate the device due to discomfort or hormonal side effects.

The study highlights the levonorgestrel intrauterine system (LNG-IUS) as a minimally invasive alternative to hysterectomy for managing abnormal uterine bleeding. It offers symptom control, improved quality of life, and endometrial protection. However, limitations include small sample size, short follow-up, lack of control group, patient compliance, cost, and device-related complications.

CONCLUSION

LNG-IUS is a superior option for managing HMB and other uterine pathologies, with dissatisfaction due to irregular spotting and cost. It can be improved by proper counselling about self-remission of spotting over time and lower net therapy costs. LNG-IUS releases low dose progesterone, making it safe for medical conditions where oral progesterone is unsafe or surgery is not possible. It also provides a nonsurgical alternative that spares fertility.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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