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Original Research Article

## Role of LNG-IUS in abnormal uterine bleeding

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### ABSTRACT

**Background:** Abnormal uterine bleeding (AUB), is defined as a change in any or a combination of frequency, duration, or amount of bleeding, is a common gynecological complaint that affects 10-30% of reproductive-aged women and constitute about one-third of all outpatient gynecological visits. Mirena is a hormonal intrauterine device classified as a long-acting reversible contraceptive method. Women with heavy menstrual blood loss, the LNG-IUS can normalize blood flow. This high level of levonorgestrel in the endometrium induces dramatic effects leading to the unique mode of contraceptive and therapeutic action of the LNG-IUS. Initially developed to decrease the risk of expulsion of the intrauterine contraceptive device by reducing myometrial contractility.

**Methods:** This study was a prospective interventional study conducted in the department of Obstetrics and Gynaecology, Muzaffarnagar Medical College, Muzaffarnagar, Uttar Pradesh, over a period of 6 months. MIRENA insertion was done in outpatient department. The effectiveness of device was assessed by reduction in amount of bleeding in case of abnormal uterine bleeding and in the form of subjective symptomatic improvement along with improvement in quality of life. Record of menstrual pattern. Pictorial Blood loss Assessment Chart was used to assess the amount of blood loss in each cycle. The women were called for follow-up after 1 month, then 3 months, and then 6 months and asked regarding the relief they have obtained from the antecedent menstrual complaints. Hemoglobin (Hb) estimation was done on the subsequent visits.

**Results:** The mean subjective percentage reduction of blood loss reduced from 13.64% at the first visit to 72.16% at 6<sup>th</sup> month and the mean Hb level in our study before treatment was 6.8 which increased to 9.8 at the end of 6 month.

**Conclusions:** The levonorgestrel-releasing intrauterine system-mirena, provides an incredible nonsurgical alternative in treatment of menorrhagia which is reversible and spares fertility.

**Keywords:** AUB, Dysmenorrhoea, LNG-IUS, Menometrorrhagia, Menorrhagia, Mirena, Polymenorrhagia

### INTRODUCTION

Abnormal uterine bleeding (AUB), can be defined as a change in any or a combination of duration, frequency or amount of bleeding, is a common complaint that affects 10-30% of reproductive-aged women and constitute about one-third of all outpatient gynecological visits.<sup>1</sup> The quality of woman's life can be adversely affected by

abnormal bleeding patterns as unpredictable/ heavy bleeding can lead to psychological, medical, social and sexual problems and therefore, necessitates management appropriately and adequately. Nearly 30% of all hysterectomies are performed to relieve women of heavy menstrual bleeding.<sup>2</sup> By and large, The backbone of treatment for menorrhagia was conclusive medical procedure. Yet, today current gynecology has moved

towards moderate treatment both for controlling expenses and the longing of numerous ladies to protect their uterus. Mirena is a hormonal intrauterine gadget named a long-acting reversible preventative technique. T-molded polyethylene outline (T-body) with a steroid supply (chemical elastomer center) made of a combination of levonorgestrel and silicone (polydimethylsiloxane), containing all out 52 mg of levonorgestrel around the upward stem. The device releases the hormone at an initial rate of 20 µg/day and declines to a rate of 14 µg following 5 years, which is still in the range of clinical effectiveness.<sup>3,4</sup>

The raised level of levonorgestrel in the endometrium induces significant effects leading to the unique mode of contraceptive and therapeutic action of the LNG-IUS. Initially developed to reduce the risk of expulsion of the intrauterine contraceptive device by decreasing myometrial contractility, LNG-IUS has resulted in huge reduction in the menstrual blood loss which drove researchers to investigate its role as an alternative to surgery for the treatment of AUB.

The mechanism(s) by which intrauterine release of LNG reduces uterine bleeding have been studied intensively since the 1970s. In the first histological studies, a strong suppression of the endometrial epithelium and glands was seen with LNG-IUS use. However, the stroma was marked by intense decidual reaction, which is typical of early pregnancy.<sup>5</sup> In addition, the LNG-exposed endometrial stroma expressed similar markers of decidualization as that of first trimester of pregnancy.<sup>6</sup> The mediators of sex steroid action, namely steroid receptors and steroid-metabolizing enzymes, in endometrium are altered with LNG IUS use. There is a marked downregulation of both epithelial and stromal expression of estrogen and progesterone receptors.<sup>7</sup> An increased expression of endometrial 17 $\beta$ -hydroxysteroid dehydrogenase type 2, which is responsible for converting estradiol into estrone, has been described.<sup>8</sup> These alterations possibly reduce the proliferative effects of estradiol on endometrium and explain in part the endometrial suppression and reduced bleeding with LNG-IUS use. Use of LNG IUS was found to reduce blood loss by 86% after 3 months of use and up to 97% by 12 months of use.<sup>9</sup>

More recent evidence shows that in women with heavy menstrual blood loss, the LNG-IUS can normalize blood flow, with up to 35% of women being amenorrheic at 24 months. Indirect comparison has shown that LNG-IUS generates more quality-adjusted life years (QALY) than other medical treatments (tranexamic acid, NSAIDs, COCP) and at a lower cost.

## METHODS

This study was a prospective interventional study conducted in the department of Obstetrics and Gynaecology, Muzaffarnagar Medical College,

Muzaffarnagar, Uttar Pradesh, over a period of 6 months from February 2022 to August 2022.

### *Inclusion criteria*

Inclusion criteria were the women between 30-45 years complaining of heavy menstrual bleeding and the study included women with uterine size <12 weeks.

### *Exclusion criteria*

Exclusion criteria were 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 aetiology, liver disease, renal disease, neurological disease or endocrinological disease, severe cardio-respiratory disorders, morbid obesity, uncontrolled systemic hypertension. Also known or suspected carcinoma of the breast, cervix or uterus were excluded, pregnant and lactating patients, if intended to become pregnant over the next 2 years, were taking hormone replacement therapy or tamoxifen, had intermenstrual bleeding (between expected periods), and any contraindications levonorgestrel-IUS.

### *Study procedure*

Detailed history of the patient, general physical and systemic examination was done. Per abdominal examination was done for all subjects followed by per speculum and per vaginal examination. It was done to assess the position, size, shape, mobility, consistency and tenderness of uterus. Both adnexa were examined, and findings were noted. Complete hematological and biochemical screening was done which included hemoglobin, total leucocyte count, differential leucocyte count, ESR, blood sugar, lipid profile, urine-routine and microscopy, TSH, ECG and chest X-ray to look for inclusion and exclusion criteria. Subjects with confirmed diagnosis of abnormal uterine bleeding as per "PALM-COEIN" classification and on ultrasonography, fulfilling the criteria and ready to follow up were enrolled in the study. All 42 women underwent transvaginal ultrasonography and pathology was diagnosed. Papanicolaou test and endometrial biopsy report negative for malignancy were enrolled in the study.

Approval from ethical committee was taken. MIRENA insertion was done in outpatient department, patient was asked to empty her bladder, kept in dorsal lithotomy position per speculum was done anterior lip of cervix was held with all-ies forceps then uterine sound was inserted into uterine cavity, position of uterus and length of endometrial cavity was measured. MIRENA was loaded plunger was adjusted according to the length measured by uterine sound. The device was inserted with no touch technique, patient was asked to follow up in one month, and then yearly for at least next two years.

The effectiveness of device was surveyed by decrease in amount of bleeding in case of abnormal uterine bleeding and in the form of improvement in quality of life and subjective symptomatic improvement. Patients were followed up using record of menstrual pattern and associated side effects which were maintained by the patient. Usage of pictorial blood loss assessment Chart to assess the amount of blood loss in each cycle. PBAC scoring >100 was considered as HMB, PBAC<10 was considered as hypomenorrhoea, 10-99 was considered as normal menstrual flow. Post insertion, the patient was asked to maintain a menstrual calendar for 4 months, wherein she would mark the days when she has spotting or bleeding. The women were called for follow-up after 1 month, then 3 months, and then 6 months and asked regarding the relief they have obtained from the antecedent menstrual complaints.

A detailed general, systemic, pelvic (to see for Mirena threads), and breasts examination was done at every visit. Follow up ultrasound was done at every visit to see for Mirena location and if there were any changes in the original pelvic pathology or development of a new pathology like ovarian cysts. Hemoglobin (Hb) estimation on the subsequent visits.

**RESULTS**

Table 1 shows that in our study maximum number of patients were of AUB (L) followed by AUB (A) which constituted 23.80% of the women. 19.04% of the women had AUB (O) which was followed by AUB (M) and AUB (P).

**Table 1: Categorisation of AUB.**

	Number of patients (n=42)	Percentage
<b>AUB-P (polyp)</b>	4	9.52
<b>AUB-A (adenomyosis)</b>	10	23.80
<b>AUB-L (Leiomyoma)</b>	15	35.71
<b>AUB-M (hyperplasia)</b>	5	11.90
<b>AUB-O (ovulatory dysfunction)</b>	8	19.04

**Table 2: Clinical presentation.**

Symptoms	Frequency	Percentage
<b>Menorrhagia</b>	15	35.71
<b>Menometrorrhagia</b>	8	19.05
<b>Polymenorrhagia</b>	9	21.43
<b>Dysmenorrhoea</b>	10	23.81

The Table 2 shows the distribution of clinical symptoms of the studied patients. 35.71% of the patients in our study presented with menorrhagia followed by 23.81% of the patients who presented with dysmenorrhoea.

*Profile of uterine size*

During the course of their 1<sup>st</sup> visit, the uterine size of 42.85% of the patients was of 12 weeks followed by 57.14% of the patients having the uterine size of 8-10 weeks.

**Table 3: Symptomatic response in subsequent visits post LNG-IUS insertion (n=42).**

Symptoms	First visit (%)	Second visit (3 <sup>rd</sup> month) (%)	Third visit (6 <sup>th</sup> month) (%)
<b>Polymenorrhoea</b>	13(30.95)	2 (4.76)	0
<b>Oligomenorrhoea</b>	0	11 (26.19)	16 (38.1)
<b>Hypomenorrhoea</b>	0	0	3 (7.14)
<b>Amenorrhoea</b>	0	4 (9.52)	7 (16.66)
<b>Intermenstrual spotting</b>	29 (69.04)	25 (59.52)	16 (38.1)

**Table 4: Symptomatic response in subsequent visits for AUB.**

AUB	Symptoms	First visit (%)	Second visit (%)	Third visit (%)
<b>AUB (P) (n=4)</b>	Polymenorrhoea	2 (50)	0	0
	Oligomenorrhoea	0	2 (50)	2 (50)
	Hypomenorrhoea	0	0	0
	Amenorrhoea	0	0	0
	Intermenstrual spotting	2 (50)	2 (50)	2 (50)
<b>AUB (A) (n=10)</b>	Polymenorrhoea	2 (20)	0	0
	Oligomenorrhoea	0	4 (40)	6 (60)
	Hypomenorrhoea	0	0	1 (10)
	Amenorrhoea	0	0	0
	Intermenstrual spotting	8 (80)	6 (60)	3 (30)
<b>AUB (L) (n=15)</b>	Polymenorrhoea	2 (13.33)	0	0
	Oligomenorrhoea	0	3 (20)	3 (20)

Continued.

AUB	Symptoms	First visit (%)	Second visit (%)	Third visit (%)
AUB (M) (n=5)	Hypomenorrhoea	0	0	2 (13.33)
	Amenorrhoea	0	2 (13.33)	2 (13.33)
	Intermenstrual spotting	13 (86.66)	10 (66.66)	8 (53.33)
	Polymenorrhoea	3 (60)	2 (40)	0
	Oligomenorrhoea	0	0	2 (40)
AUB (O) (n=8)	Hypomenorrhoea	0	0	0
	Amenorrhoea	0	1 (20)	2 (40)
	Intermenstrual spotting	2 (40)	2 (40)	1 (20)
	Polymenorrhoea	4 (50)	0	0
	Oligomenorrhoea	0	2 (25)	3 (37.5)
AUB (P) (n=8)	Hypomenorrhoea	0	0	0
	Amenorrhoea	0	1 (12.5)	3 (37.5)
	Intermenstrual spotting	4 (50)	5 (62.5)	2 (25)

Table 3 shows symptomatic response post LNG-IUS insertion in subsequent visits. 30.95% of the patients had polymenorrhoea in their first visit and 69.04% of patients had intermenstrual spotting which decreased to 38.1% at the end of 6<sup>th</sup> month. 26.19% of the patients had oligomenorrhoea by the end of 3<sup>rd</sup> month which increased to 38.1% by the end of 6<sup>th</sup> month. 4.76% of the patients had polymenorrhoea on their second visit which was completely relieved at the end of 6 months. 7.14% of the patients had hypomenorrhoea on their third visit with 16.66% of the women who showed amenorrhoea.

Table 4 shows symptomatic response of patients of AUB (P) post LNG-IUS insertion where 50% of the patients had polymenorrhoea at their first visit and 50% of them had intermenstrual spotting which was seen even at the end of 6 months. Patients were relieved of polymenorrhoea by the end of 6 months. 50% of the patients had oligomenorrhoea on their third follow up visit.

For the patients with AUB (A) post LNG-IUS insertion, 20% of the patients had polymenorrhoea at their first visit which was relieved by the end of 6 months. 60% of the women had oligomenorrhoea on their third visit and 10% had hypomenorrhoea at their third visit. Intermenstrual spotting was seen in 80% of the patients on their first visit which reduced to 30% on their third visit.

For the patients with AUB (L) post LNG-IUS insertion, 13.33% of the patients had polymenorrhoea which was ultimately relieved by the end of 6 months. Oligomenorrhoea was seen in 20% of the patients on their 2<sup>nd</sup> and 3<sup>rd</sup> visit, 13.33% of the patients had hypomenorrhoea and amenorrhoea at their third follow up visit to the hospital. 86.66% of the patients had intermenstrual spotting at their first visit of follow up which decreased to 53.33% by the end of 6<sup>th</sup> month.

Patients with AUB (M) post LNG-IUS insertion where 40% of the women had intermenstrual spotting at their 1<sup>st</sup> and 2<sup>nd</sup> visit which reduced down to 20% at their third visit contrary to which 20% of the women had amenorrhoea on

their second visit which was 40% by the end of 6<sup>th</sup> month. Oligomenorrhoea was seen in 40% of women by the end of 6<sup>th</sup> month and 40% women had polymenorrhoea by the end of 3<sup>rd</sup> month which was relieved on their third visit.

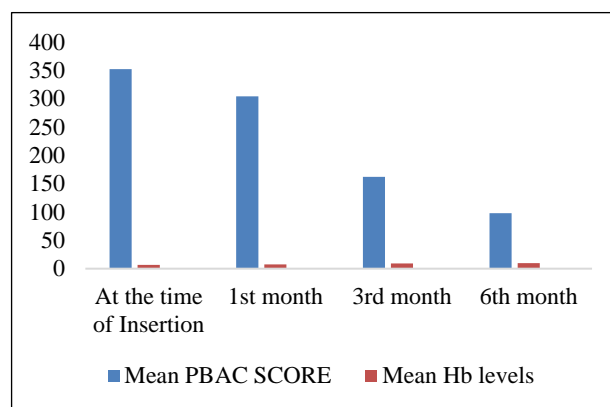


Figure 1: Changes in HMB patterns and haemoglobin levels after treatment.

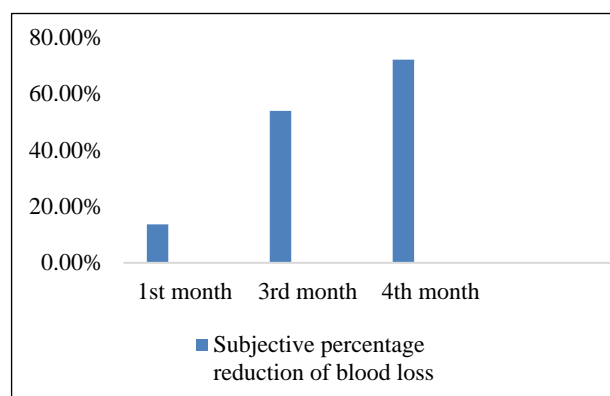


Figure 2: Subjective percentage reduction of blood loss.

Patients with AUB (O) post LNG-IUS insertion where 50% of the females had polymenorrhoea on their first visit

which was relieved by the end of 3<sup>rd</sup> month. Oligomenorrhoea was seen in 37.5% of the patients on their third follow up visit. 37.5% of the women had amenorrhoea by the end of 6<sup>th</sup> month. Intermenstrual bleeding was seen in 50% of the patients on their first follow up visit which reduced to 25% on their third follow up visit.

Figure 1 shows that at the time of insertion of LNG-IUS, the mean PBAC score was 352 which reduced to 304 on the first follow up visit of the patients. By the end of 6<sup>th</sup> month the mean PBAC score reduced to 98. Mean Hb levels were also recorded which at the time of insertion of LNG-IUS was 6.8g/dl and showed an increase to 7.4g/dl, 9.2g/dl and 9.8g/dl at the end of 1<sup>st</sup>, 3<sup>rd</sup> and 6<sup>th</sup> month respectively. Figure 2 shows subjective percentage reduction of blood loss which was 13.64%, 53.97% and 72.16% at the end of 1<sup>st</sup>, 3<sup>rd</sup> and 6<sup>th</sup> month respectively.

In our study, 20%, 72.4% and 90% of the patients were satisfied with LNG-IUS after 1 month, 3 months and 6 months of LNG-IUS insertion spotting. In the present study, no patient reported expulsion of LNG-IUS and only three patients (7.14%) requested for removal of LNG-IUS and opted for hysterectomy after six months of treatment.

## DISCUSSION

In our study majority of the women (42.85%) fell in the age group of 35-40 years and the mean age was 37.5±5.1 years which is similar to the study conducted by Gupta et al where the majority of the patients were in the age group of 31-40 years with mean age of 36.40±5.19 years.<sup>10</sup>

In our study majority of the patients were of AUB (L) [35.71%] followed by AUB (A) which was 23.80%. AUB due to endometrial hyperplasia was 11.90%. It is similar to the study conducted by Raghuvanshi et al where AUB-L was found to be the most frequent cause of AUB accounting for almost 26.3% followed by AUB-A which was found in 24.0% of the cases and AUB-O was the most common cause of AUB among non-structural causes being similar to our study.<sup>11</sup> Similar study conducted in 2017 by ESIC Medical College, the maximum number of AUB cases according to the PALM-COEIN classification belonged to the category AUB-L (30%) closely followed by AUB-A (29.66%).<sup>12</sup>

In our study the most common clinical presentation was Menorrhagia (35.71%) followed by dysmenorrhoea (23.81%). 21.43% of the patients had polymenorrhagia followed by 19.05% of the patients who had menometrorrhagia. In the prospective interventional study done by Singh et al, it was observed that 69% patients had dysfunctional uterine bleeding, 14.3% had fibroid uterus, 9.5% patients had adenomyosis and rest patients had menorrhagia associated with endometriosis and severe dysmenorrhoea.<sup>13</sup>

In our study, at the end of 6 months 38.1% of the patients had oligomenorrhoea and intermenstrual spotting followed by 16.66% of the patients who had amenorrhoea and 7.14% of the patients had hypomenorrhoea. The results were compared to the study conducted by Desai et al where After 6 months of insertion of LNG-IUS, 32.5% of women had intermenstrual spotting with 27.5% of women who had oligomenorrhoea, 22.5% of women had amenorrhoea and 7.5% of women continued to have HMB whereas in our study no women had HMB after 6 months of LNG-IUS insertion.<sup>14</sup> The results in our study were somewhat similar to the study conducted by Kriplani et al where 13.79% of women had amenorrhoea, 32.75% of women had intermenstrual spotting.<sup>15</sup>

Post LNG-IUS insertion, symptomatic relief in menstrual pattern was evaluated (by PBAC scores) and it was seen that at the time of insertion, the mean PBAC score was 352 and at the first follow up visit the mean subjective percentage reduction of blood loss was 13.64% and 72.16% at 6<sup>th</sup> month. The mean Hb level in our study before treatment was 6.8 and it increased to 9.8 at the end of 6 months. Hence, our study has proved that Mirena is an excellent alternative to hysterectomy. In a similar study conducted by Kriplani et al the mean subjective percentage reduction of blood loss at the end of 6 months of post LNG-IUS insertion was 80% and the mean Hb at the end of 6 months also showed a rise.<sup>15</sup>

In the study, 20%, 72.4% and 92.8% of the patients were satisfied with LNG-IUS after 1 month, 3 months and 6 months of LNG-IUS insertion. Reasons for disliking were minor side effects like threads being felt by partner, and intermenstrual spotting. In the present study, no patient reported expulsion of LNG-IUS. The result were almost similar to the study conducted by Desai RM where 82.5% of the patients were satisfied after 1 year of LNG-IUS usage.<sup>14</sup>

Three patients (7.14%) requested for removal of LNG-IUS and opted for hysterectomy after six months of treatment. The results were similar to the study conducted by Durga where 7.1% of women had to undergo hysterectomy.<sup>16</sup>

## CONCLUSION

It provides excellent patient satisfaction and compliance. LNG- IUS can reduce the Menstrual Blood loss and helps to improve anemia. It is also a very good alternative for women who have AUB and desire contraception. Side effects are very mild and the device can be continued to be used after patient assurance. Health-related quality of life outcomes and cost effectiveness with the use of LNG-IUS was found to be better than hysterectomy. Thus the study concluded that the levonorgestrel-releasing intrauterine system-Mirena, provides an incredible nonsurgical alternative in treatment of menorrhagia which is reversible and spares fertility.

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