

## A Prospective Study on the Efficacy of Levonorgestrel-Releasing Intrauterine Device in Abnormal Uterine Bleeding

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### Abstract

**Background:** In This Study, We Wanted To Evaluate The Efficacy Of Levonorgestrel-Releasing Intrauterine Devices In The Treatment Of Abnormal Uterine Bleeding With Respect To A Decrease In Menstrual Blood Loss, Improvement In Quality Of Life, Acceptability, And Complications.

**Materials and Methods:** This Was A Hospital-Based Prospective Observational Study Conducted Among Patients Aged 30 – 50 Years With Abnormal Uterine Bleeding (Aub), Presenting To The Department Of Obstetrics And Gynaecology, King George Hospital (Kgh), Visakhapatnam For 2 Years From November 2019 To October 2021.

**Results:** Levonorgestrel Intrauterine System Is A Safe, Effective, And Highly Acceptable Mode Of Treatment For Abnormal Uterine Bleeding Which Helps Women For A Smooth Transition To Menopause. It Is Associated With Minimal Side Effects And A High Satisfaction Rate. Also, It Is A Very Good Alternative To Medical And Surgical Treatment For Heavy Menstrual Bleeding In Benign Conditions With High Efficacy And Cost-Effectiveness. It Is The Best Innovative Method For The Treatment Of Abnormal Uterine Bleeding. Hence Consider Lng-Ius As A One-Stop Answer To Aub Before Deciding On A Hysterectomy.

**Conclusion:** About One-Third Of The Outpatients Visiting Gynaecological Opd, Present With The Complaint Of Abnormal Uterine Bleeding. The Normal Menstrual Cycle Interval Is 24-38 Days. Normal Menstrual Flow Lasts For 4.5-8 Days And Normal Menstrual Blood Loss Is Around 5-80 Ml. Levonorgestrel Intrauterine System Is A Safe, Effective, And Highly Acceptable Mode Of Treatment For Abnormal Uterine Bleeding Which Helps Women For A Smooth Transition To Menopause. It Is Associated With Minimal Side Effects And A High Satisfaction Rate. It Is A Very Good Alternative To Medical And Surgical Treatment For Heavy Menstrual Bleeding In Benign Conditions With High Efficacy And Cost-Effectiveness. With This Lng-Ius We Can Even Avoid The Systemic Side Effects Caused By Cocs Like Thromboembolism, Weight Gain, Mood Changes, And Breakthrough Bleeding Which Also Requires Less Skill And No Operative Morbidity. Despite All The Limitations, It Is The Best Innovative Method For The Treatment Of Abnormal Uterine Bleeding. Hence Consider Lng-Ius As A One-Stop Answer To Aub Before Deciding On A Hysterectomy.

**Keywords:** Levonorgestrel Intrauterine Device, Abnormal Uterine Bleeding

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**Introduction**

About one-third of the outpatients visiting gynaecological OPD, present with the complaint of abnormal uterine bleeding. The normal menstrual cycle interval is 24-38 days. Normal menstrual flow lasts for 4.5-8 days. Normal menstrual blood loss is around 5-80 ml. Any deviation in the frequency, duration and amount of bleeding from a normal menstrual cycle is termed abnormal uterine bleeding. Constant research for a suitable alternative to hysterectomy showed that this minimally invasive treatment modality would indeed be a one-stop answer to abnormal uterine bleeding.

FIGO made a newer classification system known by the acronym PALM-COEIN and it was revised in 2018.

P – polyp, A – adenomyosis, L – leiomyoma, M – malignancy, C – coagulopathy, O – ovulatory disorders, E – endometrial disorders, I – iatrogenic, N – not otherwise classified.

The parameters classified as PALM are usually structural entities and can be measured using radiological and histopathological techniques.

The parameters of COEIN are non-structural and cannot be defined using imaging or histopathology.

Not otherwise specified category includes a spectrum of diseases that may or may not be defined using histopathological and imaging techniques.

**Mechanism of heavy menstrual bleeding**

Significant elevation of COX-2 mRNA expression in women with blood loss of more than 80 ml from endometrial biopsies is seen. Excessive blood loss is

associated with a shift in the endometrial conversion of prostaglandin endoperoxide from PGF<sub>2</sub> to PGE<sub>2</sub>. The ratio of PGF<sub>2</sub>/PGE<sub>2</sub> is reduced significantly in women with menorrhagia. In the mid-late secretory phase, there is reduced vascular smooth muscle cell proliferation. There is also inefficient vasoconstriction in women with heavy menstrual blood loss.

The pathophysiology of hemostasis in normal menstruation is:

1. Platelet adhesion formation
2. Formation of platelet plug with fibrin to seal the bleeding vessels.
3. Localized vasoconstriction
4. Regeneration of endometrium
5. The increased endometrial ratio of PGF<sub>2</sub> alpha/PGE<sub>2</sub>.
6. PGF<sub>2</sub> alpha causes vasoconstriction and reduces bleeding.
7. Progesterone increases the level of PGF<sub>2</sub> alpha from arachidonic acid.

Recent advance is the intra uterine progesterone with the help of intrauterine system that secretes levonorgestrel called LEVONORGESTREL-INTRAUTERINE SYSTEM (LNG-IUS). LNG – IUS is a T – shaped device with LNG of 52mg contained in the vertical arm. T-body made of polyethylene frame is compounded with barium sulphate which is radioopaque. It releases a therapeutic daily dose of LNG of 20 mcg per day. It acts by causing endometrial glandular atrophy, stromal decidualization and endometrial cell inactivation.

It's effective for 5 years and has minimal systemic absorption. It is considered equal to hysterectomy and there is a 97% reduction in blood loss.

LNG-IUS is recommended as first-line therapy in a woman with HMB in absence of any structural or histological abnormality.

The most common side effects include amenorrhoea, spotting, lower abdominal pain, infections, intermenstrual bleeding, breast tenderness etc.

Overall, LNG-IUS proves to be a treatment of choice for women with abnormal uterine bleeding with various causes.

In our study, we tested the efficacy of LNG-IUS in the control of abnormal uterine bleeding.

### Aims and Objectives

The aim of this study is to determine the efficacy of levonorgestrel-releasing the intrauterine device in the treatment of abnormal uterine bleeding with respect to:

- Decrease in menstrual blood loss,
- Improvement in quality of life,
- Acceptability and
- Complications.

### Materials and Methods

This was a hospital-based prospective observational study conducted among patients aged 30 – 50 years with abnormal uterine bleeding (AUB), presenting to the Department of Obstetrics and Gynaecology, King George Hospital (KGH), Visakhapatnam over 2 years from November 2019 to October 2021.

### Inclusion Criteria

- Women aged 30 – 50 years with abnormal uterine bleeding with / without pain.
- Fibroid not distorting the endometrium
- Women with adenomyosis which was USG or MRI proven
- Women with endometriosis
- Uterine size less than 12 weeks with fibroid

- Premenstrual D & C / or hysteroscopy in women having endometrial hyperplasia
- HPE report negative for malignancy in women above 40 years.
- Women with no cervical / vaginal pathology and negative pap-smear
- Patients who gave consent for LNG insertion

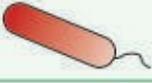
### Exclusion Criteria

- Active PID or genital infections
- Women with acquired / congenital uterine anomaly
- Genital bleeding of unknown aetiology
- Suspicion of pregnancy
- Intramural / subserosal fibroid greater than 3cm
- Submucous fibroid distorting the cavity
- Liver and renal diseases
- Atypical endometrial hyperplasia /malignancy
- Abnormal cervical cytology
- Known / suspected carcinoma of the breast

### Statistical Analysis

Data were collected, organised, categorised, and statistically analysed in tabular and pictorial representation. Patients visiting OPD with various menstrual complaints like heavy menstrual bleeding/ increased frequency of cycles/ dysmenorrhea/intermenstrual bleeding were considered for the study. A detailed history of demographic profile, obstetric history, any medical and surgical illness and detailed menstrual history regarding the amount and duration of bleeding were taken. Subjective assessment of menstrual blood loss was done with a pictorial blood loss assessment chart (PBAC). A score was calculated by multiplying the number of pads used with duration of flow with a degree of staining 1, 5, and 20 for slightly, moderately, and heavily soiled pads respectively. PBAC score  $>$  or  $=$  100 was considered as menstrual blood loss  $\geq$  80

ml, and considered as diagnostic of menorrhagia.

Pads	Day							
	1	2	3	4	5	6	7	8
								
								
								
Tampons	Day							
	1	2	3	4	5	6	7	8
								
								
								

**Table 1: PBAC Scoring Chart**

A detailed examination of general/systemic/pelvic/breast was done. After ruling out all genital infections and other pelvic pathologies, LNG – IUS was inserted post-menstrual on Day 5/6/7 on an OPD basis. Before insertion patient was counselled regarding the altered bleeding pattern with LNG – IUS for 3 to 6 months. Post insertion patient was asked to maintain a menstrual record including length of cycle or duration of bleeding and any adverse effects.

Women were called up for follow-up @ 1, 3, 6, 12, 24 months. Efficacy of LNG is measured in the form of symptomatic improvement and improvement in quality

of life which is observed by pictorial blood loss assessment charts during the follow-up.

**Results**

Our study had 37.14% of patients aged between 36 and 40 years followed by 30 – 35 years with 30%. Acceptability of LNG-IUS was favoured in patients with age 30-45 years. All the patients were categorised based on the aetiology of abnormal uterine bleeding.

In our study, adenomyosis was the most common etiological factor for AUB followed by heavy menstrual bleeding and ovulatory dysfunction.

**Table 2**

Age	No. of samples	Percentage
30 – 35 years	21	30 %
36 – 40 years	26	37.14 %
41 – 45 years	17	24.29 %
45 – 50 years	06	8.57 %
TOTAL	70	100 %
Age distribution		
Aetiology	No. of patients	Percentage

HMB	17	24.29 %
AUB – A	21	30 %
AUB – O	15	21.43 %
AUB – E	9	12.85 %
AUB – L	8	11.43 %
TOTAL	70	100 %
<b>Aetiology</b>		

**Table 3**

Adverse effects	No. of patients	Percentage
Spotting	24	34.28%
Breast Tenderness	3	4.28%
Cramps	6	8.5%
Weight Gain	2	2.85%
Headache	1	1.42%
Persistent HMB	2	2.85%
Expelled	2	2.85%
Lost to Follow Up	20	28.57%
Total	60	71.28%
<b>Adverse effects</b>		
Follow up	No. of patients	Percentage
Regular	46	65.71%
Lost to Follow-Up	20	28.57%
Hysterectomy	2	2.85%
Expelled f/b Hysterectomy	2	2.85%
Total	70	100%
<b>Follow up</b>		

Patients participating in the study had experienced a few adverse events due to hormonal effects or heavy menstrual bleed leading to expulsion. The most prominent adverse effect in the sample was taken into consideration. Of the 70-study population, 20 patients were lost to follow up; hence 50 patients were further evaluated in the study. Of the 50 patients in the study, 10 patients had no side effects whereas 80% of them had experienced side effects, of

which the most common side effect was spotting with 48%, followed by abdominal cramps with 12%.

Every patient in our study was followed-up for 2 years and managed further when required. Out of the 70 study samples, 20 patients were lost to follow up and 2 patients underwent hysterectomy due to persistent heavy menstrual bleeding. 50 patients had a regular follow-up.

**Table 4: Outcome**

Outcome	No. of Patients	Percentage
Improved	46	92%
Not Improved	4	8%
Lost to follow-up	20	

Patients have been categorized based on the outcome of improvement from bleeding by LNG-IUS excluding lost to follow-up patients. 46 patients in our study sample had satisfactory outcomes with 92%. 4 patients underwent hysterectomy and 20 patients were lost to follow-up.

**Table 5: P.B.A.C. Score**

Time	Average P.B.A.C. Score
Pre-Insertion	299
Post Insertion	89.12, 57.5, 41.1, 29.4
Time of follow-up	Average P.B.A.C. Score
3 months	89.12
6 months	57.5
1 year	41.1
2 years	29.4

All the follow-up 50 patients were assessed by P.B.A.C. scoring before LNG IUD insertion and also post insertion.

**Table 6: Reduction in menstrual blood loss in percentage**

Time of follow-up	Reduction in menstrual blood loss in percentage
3 months	70.19%
6 months	80.7%
1 year	86.25%
2 years	90%

50 patients were followed up for 2 years after excluding 20 patients who were lost to follow up and reduction in blood loss was assessed in every visit and the average was analyzed with reference to the pre-insertion value.

In our study post-LNG IUD insertion, there was a 70.19% reduction in menstrual blood loss in the first three months, followed by an 80.7% reduction in 6 months. After 1 year of follow-up, there was 86.25% reduction followed by a 90% reduction of menstrual blood loss after 2 years of follow-up.

### Discussion

About 30% of reproductive-age women suffer from abnormal uterine bleeding. While in the majority of them there was no organic pathology found. A number of risk factors may contribute to the development of heavy menstrual bleeding. Our prospective observational study was done to evaluate the efficacy, acceptability and side effects of LNG- IUS in women with abnormal uterine bleeding. Safety, patient satisfaction, quality of life and cost-effectiveness were evaluated in our study.

In our study, we found that levonorgestrel IUS was an effective, safer and simple alternative treatment for abnormal uterine bleeding. In our study, women with HMB, leiomyoma, endometriosis, and adenomyosis were included.

It was found that LNG-IUS caused a significant reduction in menstrual blood loss with minimal side effects and significant improvement in quality of life. At the end of 2 years of study, 46 women continued to use LNG-IUS. As LNG acts locally on the endometrium, most women experienced a change in bleeding patterns. In the initial months, irregular spotting, and abdominal cramps could occur. Evidence-based treatment can avoid a number of unnecessary hysterectomies as 25% of all gynaecological surgeries are done because of AUB.

Kriplani et al in 2007 published a study on LNG-IUS with a sample of 63 women with menorrhagia. The study showed the effectiveness of levonorgestrel IUS in patients with leiomyoma and idiopathic menorrhagia. In the study group, 45 patients (71.4%) continued to use LNG-IUS for 3 years. Of the 63 patients, IUD expulsion was seen in 6 (9.52%) patients,

elective removal was done in 9 patients (14.3%) and 3 patients (4.8%) were lost to follow-up. There was a significant decline in the duration of bleeding and PBAC score and a significant rise in haemoglobin. In the study, spotting was the most common side effect. It was concluded that LNG-IUS is well accepted and an effective option for the treatment of menorrhagia.

Kriplani et al 2012 studied the effect of LNG-IUS in women with AUB-L and idiopathic menorrhagia with a working sample of 54 and 50 patients respectively. This study showed a significant reduction in menstrual blood loss and mean uterine volume in both groups. [1]

Singh k et.al in 2017, studied 42 women with heavy menstrual bleeding with or without dysmenorrhea and chronic pelvic pain. LNG-IUD was inserted in these patients and they were followed up at 3, 6, 12 and 24 months post insertion. It was observed that at first 3 months, 20% achieved a normal cycle and at 6 months 44.44% had scanty flow and at 1 year 81.5% attained amenorrhea. 5% of the patients had spontaneous expulsion of the IUS device in the first 3 months. This study concluded that LNG-IUS was effective in controlling menstrual blood loss with good acceptance and was found to be a better alternative to hysterectomy. [2]

Pontis et al in 2016, did a systematic review of the medical management of adenomyosis with LNG-IUS and other modalities. This study concluded that LNG-IUS is the most effective medical therapy with fewer adverse effects. [3]

Gupta J et al published a research paper popularly known as the "eclipse trail" in 2013, and did a comparative study on 571 women diagnosed with menorrhagia. The study group was divided into the LNG-IUS group and other medical management groups. Improvement was seen significantly higher in the LNG-IUS group

than in the usually treated groups. Improvements in all menorrhagia multi-attribute scales were significantly higher in the LNG-IUS group. There was no prominent difference seen in adverse effects between the groups. The study concluded that LNG-IUS was far more effective than the usual medical management in the reduction of heavy menstrual bleeding and improved quality of life. [4]

The Cochrane database systematic review 2015 included 2082 women in the study through 21 randomised controlled trials for assessment of LNG-IUS effectiveness in all causes of AUB. The comparison was done with placebo, endometrial ablation, oral drugs, and hysterectomy. This study found that quality of life and reduction in menstrual blood loss were improved with LNG-IUS compared to medical and other treatment options. Minor side effects are more with LNG-IUS, but cost-effectiveness is a major useful point. [5]

Garg seeru et al 2016 did a prospective comparative study on patients with HMB, dysmenorrhoea, adenomyosis, and idiopathic AUB for 2 years. 30 patients had LNG-IUS insertion and 30 underwent hysterectomy. Patients were analysed based on symptomatic relief, cost-effect, and psychological impact. 93.3% had a significant reduction in blood loss and 76.6% had a decrease in pain with LNG-IUS. This study concluded that there was significant relief of symptoms and cost-effectiveness and also less hospital stay and no surgical morbidity with LNG-IUS. [6]

Dhamangaonkar PC et al in 2015 studied 70 women between 30 and 55 years diagnosed with AUB for 3 years. The results were analysed for the first 4 months and then annually for 2 years. This study showed that LNG-IUS caused an 80% decline in menstrual blood loss at 4 months and 95% by 1 year and 100% decline by 2 years and a significant rise in

haemoglobin. This study concluded that LNG-IUS is an effective non-surgical alternative treatment for menorrhagia and also an effective contraceptive device. [7]

Yazback et al 2006 included 49 women with menorrhagia not responding to medical treatment and referred for hysterectomy. A score of menstrual bleeding and satisfaction was analysed on each visit after LNG-IUS insertion. After one year of follow up, 86.1% of women were satisfied with their clinical status and also a significant rise in baseline haemoglobin was recorded. This study concluded that LNG-IUS is efficacious in the reduction of menstrual blood loss in women with dysfunctional uterine bleeding. [8]

Jayasree Nayar et al 2018 published a meta-analysis concluding that LNG-IUS is a substitute for hysterectomy in AUB-PALM COIEN. And a one-stop answer to abnormal uterine bleeding in reproductive age group women. [9]

Mahapatra et al 2015 published a meta-analysis concluding that LNG-IUS is one of the medical modalities of management for heavy menstrual bleeding. In this study, LNG-IUS was compared with other medical options like tranexamic acid, progesterone, medroxyprogesterone acetate, and COCs. The study concluded that LNG-IUS was more effective than medical management in the reduction of heavy menstrual bleeding and also in the improvement of quality of life. [10]

Kumar Sushil et al 2005, studied 20 women diagnosed with menorrhagia due to non-malignant aetiology aged between 20-42 years. LNG was inserted in those women within a week of menstrual cycle cessation. Blood loss was assessed pre and post-insertion of LNG IUS. Spotting was common at 3 months post insertion and the majority became amenorrhoeic by 1 year. This study concluded that LNG-IUS is effective in menorrhagia due to benign

aetiology and is an effective alternative to hysterectomy. [11]

Rathnamala et al 2012 conducted a study on 40 women having menorrhagia due to fibroid adenomyosis and idiopathic menorrhagia. All the women underwent pap-smear, endometrial biopsy and TVS. Carcinomas were excluded. Post insertion of LNG-IUS was done and assessment of blood by P.B.A.C score and follow-up was done at 3,6,12 months. 33 patients continued to use LNG-IUS and it was expelled in 4 cases. 2 patients had continuous bleeding and hence IUS was removed. The majority of women had spotting and amenorrhoea by one year. This study concluded that LNG-IUS is a safer and more effective alternative in women with AUB due to benign conditions in perimenopausal women. [12]

Gupta B et al 2006 compared the efficacy, acceptability of side effects and satisfaction scores in 50 women. In women with PBAC score, more than 100.25 of them had LNG-IUS insertion and 25 underwent transcervical resection of the endometrium. Results were analysed at 3 months and 1 year. There was a 94% and 97% decline in blood loss in TCRE and LNG-IUS groups respectively. The study concluded that both treatments were effective equally but LNG-IUS insertion required less skill and no operative complications compared with TCRE. [13]

Chattopadhyay et al 2011 studied 42 women aged between 35-55 years with menorrhagia and treated with LNG-IUS insertion. All the patients were followed up for 3 years. They were evaluated for the efficacy, side effects and acceptability of LNG-IUS. The study concluded that LNG-IUS is an effective, patient-friendly device with high compliance, cost-effectiveness and an alternative method to surgery in patients with DUB. [14]

Mansukhani N et al 2013 included 80 women over 35 years with abnormal

uterine bleeding in the study. The mean age group was 42 years. LNG-IUS was inserted post-menstrually after a thorough evaluation and examination. 49.3% of women were asymptomatic at 6 months, and 27.5% had amenorrhoea by 18 months. The device was expelled or removed in 14 women due to the persistence of HMB. This study concluded that LNG-IUS is an effective treatment for AUB over 35 years with a significant patient satisfaction score. [15]

The present study included 70 patients aged between 30 and 50 years having abnormal uterine bleeding with a mean age of 38 years. [16] All the women were evaluated systematically and excluded from carcinomas. Patients were explained about the procedure, risks and side effects of LNG-IUS insertion. After formal written consent, LNG-IUS was inserted post menstrually and followed up at 3,6,12 and 24 months. Every patient was evaluated for improvement, side effects and decrease in menstrual blood flow by PBAC score. Of the whole study population, 20 patients were lost to follow-up i.e. 28.5%. 50 patients were followed up for 2 years, of which 4 patients underwent hysterectomy (8%). And there was a significant reduction in menstrual blood loss with a 70.19% reduction in the first 3 months, 80.7% at 6 months, 86.25% at 1 year and 90% reduction at 2 years in remaining patients. Spotting was the most common side effect elicited followed by abdominal cramps. All 46 patients were satisfied with the usage of LNG-IUS and reported improvement in their quality of life.

### Conclusion

Levonorgestrel intrauterine system is a safe, effective, and highly acceptable mode of treatment for abnormal uterine bleeding which helps women for a smooth transition to menopause. It is associated with minimal side effects and a high satisfaction rate. It is a very good

alternative to medical and surgical treatment for heavy menstrual bleeding in benign conditions with high efficacy and cost-effectiveness. With this LNG-IUS we can even avoid the systemic side effects caused by COCs like thromboembolism, weight gain, mood changes, and breakthrough bleeding which also requires less skill and no operative morbidity. In spite of all the limitations, it is the best innovative method for the treatment of abnormal uterine bleeding. Hence consider LNG-IUS as a one-stop answer to AUB before deciding on a hysterectomy.

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