

## Research Article

# LNG-IUS versus GnRH agonist for management of Heavy menstrual bleeding –An alternative Management

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### ABSTRACT

**Background & Objectives:** Heavy menstrual bleeding (HMB) is a prevalent condition affecting a significant proportion of women, particularly during the perimenopausal phase. Traditional management often leads to surgical interventions such as hysterectomy. This study examines the efficacy and safety of the levonorgestrel-releasing intrauterine system (LNG-IUS) compared to GnRH agonists for managing HMB.

**Materials and Methods:** A comparative descriptive study was conducted at Nepalgunj Medical College Teaching Hospital from October 2021 to September 2022. The participants included 37 women in the LNG-IUS group and 30 in the GnRH agonist group, following ethical approval and informed consent. Participants were randomized and evaluated for changes in

menstrual blood loss using the Pictorial Blood Loss Assessment Chart (PBAC), hemoglobin (Hb) levels, and hematocrit (Hct) over a 6-month period.

**Results:** At 3 months, the GnRH agonist group demonstrated a significant reduction in menstrual blood loss compared to the LNG-IUS group; however, by 6 months, both groups had achieved similar improvements in menstrual bleeding. The LNG-IUS group showed significant long-term benefits in anemia correction, with higher Hb and Hct levels at the 6-month follow-up compared to the GnRH agonist group. The LNG-IUS also exhibited better retention rates, indicating higher patient acceptability and fewer side effects.

**Conclusion:** The results suggest that while GnRH agonists are effective for short-term symptom relief, LNG-IUS offers sustained improvement in bleeding control and anemia management. The study underscores the importance of personalized treatment options tailored to individual patient needs, factoring in the urgency of symptom relief and long-term health outcomes. Further research is warranted to enhance understanding and address the long-term implications of these treatment modalities in managing HMB.

**Keywords:** GnRH Agonist, HMB, LNG- IUS,

## INTRODUCTION

Heavy menstrual bleeding (HMB) is the third commonest clinical condition for which patient seeks out medical consultation following vaginal discharge and pain, whereas prevalence of HMB is more common in perimenopause age group followed by reproductive age. In peri-menopausal women anovulatory cycle leads HMB. The normal menstrual cycle consists of a mean interval of  $28 \pm 7$  days with a mean duration of  $4 \pm 3$  days. The upper limit of normal menstrual blood loss is 80 ml per menstruation. An increase in amount of blood loss during menstrual cycle is diagnosed as abnormal uterine bleeding. Overall prevalence rate of HMB accounts 18 to 30 % of women in gynecological out patient's department [1]. In 1990 LNG-IUS (levonorgestrel -intrauterine system) was launched in Finland as a long-acting reversible contraceptive manufactured by Shering in name of Levonova. In recent era LNG-IUS is available in > 100 countries. It contains 52mg of levonorgestrel, releases 20 micrograms/day over 5 years of the hormone in the uterine cavity leads low serum levels, but high concentrations of levonorgestrel in the endometrium that makes endometrium atrophy of the endometrial glands and decidualization of the stroma. The cyclical activity of endometrial tissue is lost and the endometrium becomes thin and non-responsive to estrogen. In initial phase after insertion of LNG-IUS leads spotting in the initial months of insertion and later cause scanty bleeding or amenorrhoea, that's is beneficial for women with HMB. LNG-IUS highly effective long-acting reversible contraceptive tools along with positive health benefits in women with gynaecologic diseases causing heavy menstrual bleeding and dysmenorrhea. LNG-IUS has been found to be

effective in endometriosis, leiomyoma, adenomyosis, endometrial hyperplasia, and early-stage endometrial cancer. LNG-IUS approved by so many countries for contraceptive and various non-contraceptive purposes like idiopathic menorrhagia, leiomyoma, endometriosis, adenomyosis and endometrial protection during hormone replacement therapy [2].

Leuprolide acetate it's a synthetic nonapeptide, contains potent gonadotropin releasing hormone receptor (Gn RHR) agonist discovered in 1971 used for so many clinical conditions like treatment of prostate cancer, endometriosis, uterine fibroids, central precocious puberty and in vitro fertilization techniques. Leuprolide acetate acts through suppressing gonadotropin secretion of luteinizing hormone and follicle-stimulating hormone that subsequently suppresses gonadal sex steroid production. Most of this clinical condition associated with heavy menstrual flow with irregular cycle required most of the time hysterectomy [3-5]. In present time hysterectomy remains mainstay mode of treatment in case of management of abnormal uterine bleeding. To reduce the financial burden and long-term consequences associated with hysterectomy, alternative management strategies for heavy menstrual flow (HMF) are being actively explored, with the goal of providing effective and less invasive treatment options. These alternatives aim to address the underlying causes of HMB while minimizing the need for surgical intervention, improving patient outcomes, and reducing healthcare costs. This study aimed to examine the efficacy and safety of the levonorgestrel-releasing intrauterine system (LNG-IUS) compared to GnRH agonists for managing HMB.

## MATERIALS AND METHODS

This study was carried out at Nepalgunj Medical College Teaching Hospital Kohalpur, in department of Obstetrics and Gynecology. A comparative descriptive study was conducted on 35 women who has been diagnosed as heavy menstrual bleeding between October 2021 to September 2022.

The sample size was calculated as:

Prevalence of heavy menstrual bleeding (p) = 25% = 0.25 & q = 1 - 0.25 = 0.75<sup>5</sup>

Allowable error (L) = 10% = 0.1

Z = 1.96

$N = z^2pq/L^2 =$

$1.96 \times 1.96 \times 0.25 \times 0.75 / 0.1 \times 0.1 = 72.03 = 72$

round up figure.

Divided into two group.

After counseling regarding benefits and hazards of surgical method and medical method of management of heavy menstrual bleeding, who willing's to participate in medical management was enrolled in study after taking written consent. Randomization will be done by even and odd no., in two group. Group A included GnRH agonist (Lepronex-Bharat serum, India) group where Group B has LNG-IUS (ELOIRA-Pregna international, India imported Pee Bee Nepal) group. Group A received GnRH agonist 4 weekly for 3 doses and group B, received LNG-IUS after ruling out pregnancy or malignancy. If LNG-IUS expelled out replaced immediately. Higham and Shaw first introduced the PBAC (Pictorial Blood Loss Assessment Chart) in 1990, and it was later refined and validated by Janssen and colleagues in 1995 [6]. Pictorial blood loss assessment chart will be used for the diagnosis of heavy menstrual bleeding, if score >100 will take as a case of HMB. Inclusion criteria- heavy menstrual bleeding in reproductive and perimenopause age. The

exclusion criteria was diagnosed case of malignancy in endometrial biopsy sample in perimenopause age group, allergic or contraindication of drugs and pregnancy.

Change in pictorial blood loss assessment chart between pretreatment, after three month and six months of treatment recorded. Any serious side effect of drugs found in six month was recorded. Analysis was done by using SPSS 27. Student t test will be applied to analyze PBLAC score and effectiveness of drug between two group. P Value <0.05 taken as a statistically significant.

This study was conducted after ethical approval from the Nepalgunj Medical College Ethical Board (Ref. no. 214/078-079)

## RESULTS

The study initially enrolled 42 participants in each group. However, dropouts occurred due to loss to follow-up, with 5 participants excluded from the LNG-IUS group and 12 participants excluded from the GnRH agonist group. Among the excluded participants, 1 from each group required surgical intervention after failing to respond to medical management, highlighting the limitations of medical therapy in certain cases. The final analysis included 37 participants in the LNG-IUS group and 30 participants in the GnRH agonist group. In the LNG-IUS group, 2 participants (5.4%) experienced device expulsion, which was promptly replaced. This indicates that while LNG-IUS is generally well-tolerated, expulsion remains a potential complication, albeit at a low rate. The timely replacement of the device underscores the importance of close follow-up and patient education to ensure adherence and continuity of treatment.

The higher dropout rate in the GnRH agonist group (12 participants excluded compared to 5 in the LNG-IUS group) may reflect differences in treatment tolerability, side effects, or patient preferences. This suggests that LNG-IUS may have better retention rates and patient acceptability compared to GnRH agonists, which are known to cause systemic side effects that may influence patient adherence.

In the table below (table 1), both groups have similar mean ages, suggesting that age was not a significant factor in treatment allocation. The small standard deviations indicate that participants' ages within each group were relatively consistent. Specifically, Group A had a mean age of 33.63 years with a standard deviation of 6.72 years, while Group B had a mean age of 34.14 years with a standard deviation of 6.67 years. Regarding

**Table 1: Demographic and Baseline Characteristics**

Age	No. of participants	Mean	Std.deviation				
Group A	30	33.63	6.724				
Group B	37	34.14	6.672				
Cast		Group 1	Group 2	Group 3	Group4	Group5	
Group A	30	7(23.33%)	11(36.66%)	0(0%)	12(40%)	0	
Group B	37	2(5.4%)	12(32.43%)	1(2.7%)	20(54.05%)	2(5.4%)	
Parity		0	1	2	3	4	5
Group A	30	5(16.66%)	3(10%)	9(30%)	7(23.33%)	4(13.33%)	2(6.66%)
Group B	37	0	3(8.1%)	14(37.83%)	18(48.64%)	1(2.7%)	1(2.7%)
Contraceptive		None user	Long acting	Permanent			
Group A	30	24(80%)	3(10%)	3(10%)			
Group B	37	32(86.48%)	3(8.1%)	2(5.4%)			
Diagnosis		Fibroid	Endometrial disorder	Endometriosis	Endometrial polyp		
Group A	30	18(60%)	3(10%)	7(23.33%)	2(6.66%)		
Group B	37	28(75.67%)	4(10.81%)	3(8.1%)	2(5.4%)		

**Table II: Pictorial Blood Loss Assessment Chart (PBAC) Score over time**

Group	At Enrollment	p-value	At 3 Months	p-value	At 6 Months	p-value
	Mean $\pm$ SD		Mean $\pm$ SD		Mean $\pm$ SD	
Group A (n=30)	163.67 $\pm$ 22.82	0.550	88.67 $\pm$ 27.76	<0.001	87.00 $\pm$ 27.68	0.5
Group B (n=37)	160.81 $\pm$ 13.82		124.59 $\pm$ 27.45		227.74	

**Table III: Haemoglobin (Hb) level over time**

Group	At Enrollment	p-value	At 3 Months	p-value	At 6 Months	p-value
	Mean $\pm$ SD		Mean $\pm$ SD		Mean $\pm$ SD	
Group A (n=30)	8.10 $\pm$ 0.61 g/dL	0.278	9.87 $\pm$ 0.94 g/dL	0.057	10.90 $\pm$ 1.61 g/dL	0.005
Group B (n=37)	7.92 $\pm$ 0.72 g/dL		10.27 $\pm$ 0.77 g/dL		11.84 $\pm$ 0.65 g/dL	

caste distribution, as per the Government of Nepal's classification, caste group 4 had the highest number of participants in the LNG-IUS group, with 20 out of 37 participants (54.05%), followed by caste group 2 with 12 out of 37 participants (32.43%). Caste groups 1 and 5 had 2 participants each (5.4%), while caste group 3 had the least number of participants, with 1 out of 37 participants (2.7%). In the GnRH agonist group, caste group 4 had the highest number of participants, with 12 out of 30 participants (40%), followed by caste group 2 with 11 out of 30 participants (36.67%). Caste group 1 had 7 out of 30 participants (23.33%), and caste group 5 had no participants (0%). In terms of parity distribution, the LNG-IUS group had the largest number of participants with parity 3, comprising 18 out of 37 participants (48.64%), followed by parity 2 with 14 out of 37 participants (37.83%). Parity 1 accounted for 3 out of 37 participants (8.1%), while parity 4 and 5 each had 1 out of 37 participants (2.7%). In the GnRH agonist group, the largest number of participants had parity 2, with 9 out of 30 participants (30%), followed by parity 3 with 7 out of 30 participants (23.33%). Parity 0 had 5 out of 30 participants (16.67%), and parity 4 had 4 out of 30 participants (13.33%). Parity 5 accounted for the least number, with 2 out of 30 participants (6.67%). Regarding contraceptive use, in Group A (GnRH agonist), the majority of participants were non-users (24 participants, 80%), followed by those using long-acting and permanent methods (3 participants each, 10%). In Group B (LNG-IUS), 32 participants (86.48%) were non-users, followed by those using long-acting methods (3 participants, 8.1%), and permanent methods (2 participants, 5.4%). The majority of participants in both groups were non-users of contraception, which is

expected given that the study focused on managing heavy menstrual bleeding (HMB). The slightly higher proportion of non-users in Group B (86.48%) may reflect the contraceptive benefits of LNG-IUS, making it a preferred choice for women not using other methods. The table below shows the distribution of clinical diagnoses at enrollment for participants in Group A (GnRH agonist) and Group B (LNG-IUS). In Group A, the most common diagnoses were fibroids (60%), followed by endometriosis (23.33%), endometrial disorders (10%), and endometrial polyps (6.66%). In Group B, fibroids were also the most prevalent diagnosis (75.67%), followed by endometrial disorders (10.81%), endometriosis (8.1%), and polyps (5.4%).

Fibroids were the most common diagnosis in both groups, with a significantly higher proportion of participants in Group B. This suggests that LNG-IUS may be particularly effective for managing fibroid-related heavy menstrual bleeding (HMB). Conversely, endometriosis was more prevalent in Group A, indicating that GnRH agonists may be preferred for addressing endometriosis-related symptoms. The similar distribution of endometrial disorders and polyps across both groups suggests that these conditions did not play a major role in treatment allocation.

The table 2 shows both the groups began with very high and statistically similar PBAC scores (Group A: 163.67, Group B: 160.81;  $p=0.550$ ), indicating severe menstrual blood loss at enrollment. At 3 Months (1<sup>st</sup> follow up visit): Both groups showed a substantial reduction in PBAC scores. However, Group A demonstrated a significantly greater reduction (to 88.67) compared to Group B (to 124.59), a difference that was highly statistically significant ( $p<0.001$ ). At 6

Months (2<sup>nd</sup> follow up visits): The PBAC scores for both groups remained low and were not statistically different from each other (Group A: 87.00, Group B: 91.62;  $p=0.5$ ), suggesting a similar long-term effect on reducing menstrual blood loss.

The table 3 shows both the groups started with statistically similar low haemoglobin levels (Group A: 8.10 g/dL, Group B: 7.92 g/dL;  $p=0.278$ ), confirming anemia at enrollment. At 3 Months (1<sup>st</sup> follow up visit); Both groups showed a marked improvement in haemoglobin levels. The difference between the groups (Group A: 9.87 g/dL, Group B: 10.27 g/dL) was not statistically significant ( $p=0.057$ ), though Group B's mean was slightly higher. At 6 Months (2<sup>nd</sup> follow up visit) : Haemoglobin levels continued to improve in both groups. At this point, Group B had a statistically significant higher haemoglobin level (11.84 g/dL) compared to Group A (10.90 g/dL), with a  $p$ -value of 0.005.

The table 4 shows both the groups had similar low hematocrit levels at enrollment (Group A: 24.63%, Group B: 24.05%;  $p=0.231$ ), consistent with anemia. At 3 Months (1<sup>st</sup> follow up visits); Both groups showed a significant and similar improvement in hematocrit (Group A: 29.80%, Group B: 30.97%). The difference between them was not statistically significant ( $p=0.064$ ). At 6 Months (2<sup>nd</sup> follow up visits); While both groups improved from their baseline, Group A achieved a statistically

significant higher hematocrit (35.43%) compared to Group B (32.70%), with a  $p$ -value of 0.006. This is the opposite trend to what was observed with Haemoglobin at 6 months.

## DISCUSSION

This study aimed to compare the effectiveness of GnRH agonists (Group A) and LNG-IUS (Group B) in managing heavy menstrual bleeding (HMB), anemia, and hematocrit (Hct) levels over a 6-month period. The study initially enrolled 42 participants in each group, but due to loss to follow-up, the number of participants in the final analysis was reduced. In Group A (GnRH agonist), 12 participants were excluded, while in Group B (LNG-IUS), 5 participants were excluded. Among the excluded participants, one from each group required surgical intervention after failing to respond to medical management, highlighting the limitations of medical therapy in certain cases. The final analysis included 37 participants in Group B and 30 participants in Group A.

The higher dropout rate in Group A may reflect differences in treatment tolerability, side effects, or patient preferences. GnRH agonists are known to cause systemic side effects such as hot flashes, mood changes, and bone density loss, which may lead to loss to follow-up, as reported by Sriprasert et al. [1]. Group B (LNG-IUS) had better retention rates, suggesting higher patient acceptability, which

**Table IV: Haematocrit (Hct) Level Over Time**

Group	At Enrollment	p-value	At 3 Months	p-value	At 6 Months	p-value
	Mean $\pm$ SD		Mean $\pm$ SD		Mean $\pm$ SD	
<b>Group A (n=30)</b>	24.63 $\pm$ 1.73 %	0.231	29.80 $\pm$ 2.91 %	0.064	35.43 $\pm$ 4.78 %	0.006
<b>Group B (n=37)</b>	24.05 $\pm$ 2.11 %		30.97 $\pm$ 2.18 %		32.70 $\pm$ 2.01 %	

is consistent with studies showing that LNG-IUS is well-tolerated and associated with high patient satisfaction due to its dual benefits of contraception and menstrual bleeding control, as reported by Kaunitz et al. and Gemzell-Danielsson et al. [7,8].

Regarding age, both groups had similar mean ages (Group A: 33.63 years; Group B: 34.14 years), indicating that age was not a confounding factor in the present study. This is supported by Donnez et al., who reported age as a risk factor for fibroid uteri, while Hashad reported that HMB is more common in a slightly younger age group ( $28.3 \pm 6.46$  to  $29.7 \pm 6.57$ ), likely due to the different pathology of adenomyosis in the present study. At the same time, Pleun Beelen reported a higher age for HMB ( $44.7 \pm 4.4$ ) [9-11].

In terms of caste distribution, Group B had a higher proportion of participants from caste group 4 (54.05%), while Group A had more participants from caste group 1 (23.33%). This may reflect socio-cultural or regional influences on treatment choice. Regarding parity, Group B had more participants with a parity of 3 (48.64%), while Group A included nulliparous women (16.67%). This suggests that LNG-IUS may be preferred for women with moderate parity, while GnRH agonists are more commonly used in nulliparous women or those with higher parity. This aligns with studies suggesting that LNG-IUS is more suitable for women who have completed their families, as it provides contraception benefits in addition to managing HMB, as reported by Tariq et al. [12].

Regarding contraceptive use, most participants in both groups were non-users of

contraception, but Group B had a slightly higher proportion of users (86.48%), likely due to the contraceptive benefits of LNG-IUS. This is consistent with studies showing that LNG-IUS is often chosen for its contraceptive and therapeutic benefits, as reported by Kaunitz et al. and Gemzell-Danielsson et al [7,8].

In relation to clinical diagnoses, fibroids were the most common diagnosis in both groups, with a higher prevalence in Group B (75.67%), suggesting that LNG-IUS may be particularly effective for fibroid-related HMB. This finding is supported by studies indicating that LNG-IUS significantly reduces menstrual bleeding in women with fibroids. In contrast, endometriosis was more prevalent in Group A (23.33%), suggesting that GnRH agonists may be preferred for endometriosis-related symptoms due to their ability to suppress estrogen levels and alleviate symptoms associated with endometriosis, as supported by Bofill Rodriguez et al [13].

**Clinical and Laboratory Outcomes:** When comparing the Pictorial Blood Loss Assessment Chart (PBLAC) at 3 months, Group A showed a significant reduction in menstrual blood loss compared to Group B, indicating faster symptom relief with GnRH agonists. At the same time, at 6 months, both groups achieved similar reductions in blood loss, suggesting that LNG-IUS catches up in effectiveness over time. This is consistent with studies showing that LNG-IUS has a delayed but sustained effect on reducing menstrual bleeding, as supported by Bofill Rodriguez et al. and Chen et al [13,14].

**Regarding Hemoglobin (Hb) Levels:** At 3 months, a trend toward higher Hb levels was

observed in Group B, indicating early improvement in anemia. At the same time, by 6 months, Group B had significantly higher Hb levels, demonstrating better long-term anemia correction. This finding aligns with evidence that LNG-IUS improves anemia by reducing menstrual blood loss over time, as supported by Sriprasert et al., Bianchi et al., and Nidhi et al. [1,15,16].

Regarding Hematocrit (Hct) Levels: After the first visit at 3 months, a trend toward higher Hct levels was observed in Group B, suggesting early improvement in anemia. By 6 months, Group B had significantly higher Hct levels, indicating better long-term anemia correction. This is consistent with findings that LNG-IUS leads to a greater correction of anemia in women with HMB. GnRH Agonists (Group A): These provide quicker relief from heavy menstrual bleeding within the first 3 months; however, they are less effective in correcting anemia over the long term. GnRH agonists can also have significant side effects, such as hot flashes and bone density loss, which may affect their long-term use. The study provides a detailed comparison of two widely used treatments for HMB, highlighting their distinct benefits and limitations. The inclusion of both clinical and laboratory outcomes offers a comprehensive assessment of treatment effectiveness. However, as limitations the higher dropout rate in Group A may introduce bias, as participants who discontinued treatment may have had different outcomes. Also, the study duration of 6 months may not capture the long-term effects or complications of the treatments.

## CONCLUSION

The findings suggest that GnRH agonists are more effective for short-term symptom relief,

while LNG-IUS offers sustained improvements in both bleeding and anemia over time. The choice of treatment should be tailored to individual patient needs, considering factors such as the urgency of symptom relief, the importance of long-term anemia management, and patient preferences. These results underscore the importance of personalized treatment plans and highlight the need for further research to explore long-term outcomes and patient satisfaction with these treatments.

## ACKNOWLEDGEMENT

We are thankful to all the participants involved in this study. We also extend our gratitude to Nepalgunj Medical College Teaching Hospital Kohalpur for all the logistic support.

**Conflict of Interest:** None declared

**Funding:** None

**Author's Contribution:** data collection analysis, reviewed literature and final revision- **BKM, MK.** Both the authors approved the final version of manuscript towards publication.

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