

CLINICAL EFFICACY OF LEVONORGESTREL-RELEASING INTRAUTERINE DEVICE IN THE MANAGEMENT OF HEAVY MENSTRUAL BLEEDING: A PROSPECTIVE STUDY

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ABSTRACT

Background: Heavy menstrual bleeding (HMB) is a common gynecological problem affecting women's physical health, emotional well-being, and quality of life (1, 2). Medical therapy often provides only partial relief, while surgical options carry higher morbidity. The levonorgestrel-releasing intrauterine device (LNG-IUD) offers a minimally invasive and reversible alternative. The objective is to evaluate the clinical efficacy, safety, and patient satisfaction of the levonorgestrel-releasing intrauterine device in women with heavy menstrual bleeding and to assess its role as an alternative to hysterectomy. **Materials and Methods:** This prospective study included 65 women with clinically diagnosed HMB attending the gynecology outpatient department of a tertiary care hospital over 18 months. After thorough evaluation, eligible participants received the LNG-IUD (Mirena®) and were followed up at 3, 6, and 12 months. Outcomes assessed included changes in menstrual blood loss using the pictorial blood loss assessment chart (PBAC) score, hemoglobin levels, uterine volume, side effects, and patient satisfaction. **Result:** The mean age of participants was 38.7 ± 5.2 years, with 70.8% being multiparous. The mean PBAC score reduced significantly from 276.3 ± 84.5 at baseline to 58.4 ± 22.1 at 12 months ($p < 0.001$). The mean hemoglobin improved from 9.4 ± 1.1 g/dL to 11.6 ± 0.9 g/dL after one year. Amenorrhea or scanty menstruation occurred in 72.3% of women at the end of one year. Common side effects included spotting (18.5%), breast tenderness (10.8%), and mild abdominal pain (9.2%), all of which subsided spontaneously. Overall satisfaction rate was 90.7%, and only four women (6.1%) opted for hysterectomy due to persistent bleeding. **Conclusion:** The LNG-IUD is a highly effective, safe, and well-tolerated therapy for heavy menstrual bleeding. It significantly reduces menstrual blood loss, improves hemoglobin levels, and enhances quality of life, offering a conservative alternative to hysterectomy in most women.

INTRODUCTION

Heavy menstrual bleeding (HMB) affects nearly 20–30% of women of reproductive age and is one of the most common indications for gynecological consultation.^[1-3] Defined as menstrual blood loss exceeding 80 mL per cycle or perceived as excessive by the patient, HMB can lead to anemia, fatigue, and reduced productivity.^[4] Conventional medical therapies—such as tranexamic acid, combined oral contraceptives, and oral progestins—are often limited by poor compliance and side effects.^[5] Hysterectomy, though definitive, is associated with surgical risks and longer recovery time.^[6]

The levonorgestrel-releasing intrauterine device (LNG-IUD) has emerged as a promising conservative option for managing HMB.^[7] It delivers 20 µg of levonorgestrel per day directly into the endometrial cavity, resulting in endometrial atrophy, decreased prostaglandin synthesis, and reduced menstrual blood loss.^[8,9] This study aimed to assess the clinical efficacy, safety, and acceptability of LNG-IUD in women with HMB and to evaluate its potential as a substitute for hysterectomy.

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of Obstetrics and Gynecology at a tertiary care hospital over a period of 18 months (January 2023 – June 2024). Ethical approval was obtained prior to initiation.

Inclusion criteria:

- Women aged 30–50 years with heavy menstrual bleeding for ≥ 6 months
- Willing for intrauterine device insertion and follow-up

Exclusion criteria:

- Pregnancy or suspected pregnancy
- Uterine anomalies or fibroids >10 cm
- Malignancy or endometrial hyperplasia with atypia
- Active pelvic infection or unexplained vaginal bleeding

After detailed history, examination, and investigations (CBC, pelvic ultrasound, thyroid profile, and endometrial sampling), LNG-IUD (Mirena®) was inserted during the proliferative phase of the menstrual cycle. Follow-up evaluations were performed at 3, 6, and 12 months.

Outcome measures:

1. Menstrual blood loss: Assessed by PBAC score at each visit.
2. Hemoglobin levels: Measured at baseline and 12 months.
3. Uterine volume: Evaluated by ultrasound.
4. Adverse effects and expulsion rate.
5. Patient satisfaction: Assessed using a structured questionnaire.

Statistical analysis: Data were analyzed using SPSS version 25.0. Mean \pm SD values were calculated, and significance was determined using paired t-test and Chi-square test. A p-value < 0.05 was considered significant.^[10]

RESULTS

Table 1: Demographic profile of participants

Parameter	Number (n=65)	Percentage (%)
Age (years)		
30–35	18	27.7
36–40	21	32.3
41–45	17	26.2
46–50	9	13.8
Parity		
Multiparous	46	70.8
Nulliparous	19	29.2

Mean BMI was 25.6 ± 2.7 kg/m². The most common presenting complaint was menorrhagia (76.9%), followed by polymenorrhea (15.4%) and continuous spotting (7.7%).

Table 2: Changes in menstrual blood loss (PBAC score) and hemoglobin

Parameter	Baseline	3 months	6 months	12 months	p-value
PBAC score	276.3 ± 84.5	142.1 ± 48.7	85.9 ± 30.4	58.4 ± 22.1	<0.001
Hemoglobin (g/dL)	9.4 ± 1.1	—	10.6 ± 0.9	11.6 ± 0.9	<0.001

The reduction in PBAC scores and increase in hemoglobin levels were statistically significant ($p < 0.001$).

At 12 months, 47 women (72.3%) achieved amenorrhea or scanty menstruation, 13 (20%) had

normal flow, and only 5 (7.7%) continued to have heavy bleeding.

Uterine volume decreased from a mean of 110.3 ± 28.5 mL to 87.4 ± 22.8 mL at one year ($p < 0.05$).

Table 3: Adverse effects and continuation rate

Side effect	Number	Percentage (%)
Spotting/irregular bleeding	12	18.5
Breast tenderness	7	10.8
Lower abdominal pain	6	9.2
Expulsion	2	3.1
None	38	58.4

Side effects were generally mild and self-limiting. No cases of pelvic inflammatory disease or uterine perforation occurred. Four women (6.1%) opted for hysterectomy due to persistent bleeding.

DISCUSSION

This study demonstrates that LNG-IUD is a highly effective and well-tolerated method for the

management of heavy menstrual bleeding, consistent with previous studies.^[11–13] The significant reduction in PBAC score and improvement in hemoglobin levels corroborate findings by Hurskainen et al. and Gupta et al.^[14,15]

The device acts locally by inducing endometrial suppression and reducing menstrual blood flow without causing systemic side effects.^[16] The majority of women in the present study reported

high satisfaction, paralleling outcomes reported by Kaunitz et al. and Varma et al.^[17,18]

Our study observed a 72.3% rate of amenorrhea or scanty flow, similar to international trials that documented 70–80% rates after one year of LNG-IUD use.^[19] Minor adverse effects like spotting and breast tenderness were transient and manageable.^[20] Importantly, the hysterectomy conversion rate was only 6.1%, indicating that LNG-IUD can effectively avoid unnecessary surgical interventions in most cases.^[21]

Overall, the device offers a convenient, reversible, and long-term solution for HMB with excellent safety and patient satisfaction profiles.

CONCLUSION

The levonorgestrel-releasing intrauterine device is a safe, effective, and patient-friendly option for managing heavy menstrual bleeding. It significantly reduces menstrual blood loss, improves hemoglobin concentration, and minimizes the need for hysterectomy. Owing to its reversibility, ease of use, and low complication rate, LNG-IUD should be considered a first-line therapy in women seeking a conservative alternative to surgery.

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