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Original Research Article

## Acceptability and clinical outcomes of levonorgestrel-releasing intrauterine system in the management of abnormal uterine bleeding among perimenopausal women: a prospective interventional study

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### ABSTRACT

**Background:** The objective of the study was to evaluate the acceptability and clinical outcomes of the levonorgestrel-releasing intrauterine system (LNG-IUS) in the management of abnormal uterine bleeding (AUB) among perimenopausal women.

**Methods:** This prospective single-arm interventional study without a comparator group study was conducted in a tertiary care teaching hospital from March 2022 to March 2025. A total of 120 perimenopausal women aged 40-55 years presenting with AUB and opting for conservative management were enrolled. LNG-IUS was inserted following appropriate clinical evaluation and counselling. Participants were followed up at 1, 3, 6, and 12 months. Outcomes assessed included bleeding pattern, dysmenorrhea, continuation rate, expulsion, and need for hysterectomy. Data were analyzed using SPSS version 26.

**Results:** The mean age of participants was 49.21 years, and the majority were multiparous (82.5%). Adenomyosis (53.3%) and fibroid uterus (45.0%) were the predominant etiologies. A progressive reduction in breakthrough bleeding was observed during follow-up. At one year, 30.0% of women achieved amenorrhea, while 69.2% reported light menstrual bleeding. The continuation rate of LNG-IUS at one year was 64.2%, whereas 35.8% of participants opted for hysterectomy. Device expulsion occurred in 2.5% of cases.

**Conclusions:** LNG-IUS may serve as an effective and acceptable conservative treatment option for perimenopausal women with AUB. It significantly improves bleeding patterns and may reduce the need for surgical intervention in appropriately selected patients.

**Keywords:** Abnormal uterine bleeding, Levonorgestrel intrauterine system, Perimenopausal women, Menorrhagia, Conservative management

### INTRODUCTION

Abnormal uterine bleeding (AUB) is one of the most frequently encountered gynecological complaints among women in the reproductive and perimenopausal age groups. It is defined as bleeding from the uterine corpus that is abnormal in volume, duration, frequency, or regularity in the absence of pregnancy. Globally, AUB affects nearly 10-30% of women, and the prevalence

increases during the perimenopausal transition due to fluctuating hormonal patterns and the higher incidence of structural uterine pathologies.<sup>1</sup> Indian studies have reported prevalence ranging between approximately 17% and 32%, highlighting the considerable burden of disease in our setting.<sup>2,3</sup> Beyond menstrual disturbance, AUB has substantial clinical implications. Chronic heavy bleeding often leads to iron deficiency anemia, generalized fatigue, reduced work productivity, and significant impairment in

physical, social, and emotional well-being. In many tertiary care centers, AUB continues to be one of the leading indications for hysterectomy, underscoring the need for effective conservative management strategies.<sup>4,5</sup>

The etiological spectrum of AUB is diverse and has been standardized under the FIGO PALM-COEIN classification, which categorizes causes into structural (polyps, adenomyosis, leiomyoma, malignancy and hyperplasia) and non-structural (Coagulopathy, Ovulatory dysfunction, Endometrial, Iatrogenic, and Not yet classified) groups.<sup>6</sup> This classification has improved diagnostic clarity and guided individualized treatment approaches. Management is determined by the underlying cause, severity of symptoms, patient age, and reproductive preference. Although medical therapy with combined oral contraceptives, systemic progestogens, nonsteroidal anti-inflammatory drugs, and antifibrinolytics remains the initial line of treatment in many cases, long-term use may be limited by systemic side effects, contraindications, irregular compliance, and recurrence of symptoms.<sup>7</sup> Surgical options such as endometrial ablation and hysterectomy offer definitive control of bleeding; however, they are invasive, associated with perioperative risks, financial burden, and psychological implications. Particularly in perimenopausal women who may have associated comorbidities or prefer uterine preservation, less invasive alternatives are desirable.<sup>8</sup>

The levonorgestrel intrauterine system (LNG-IUS) has emerged as an effective and reversible conservative modality for the management of AUB.<sup>9</sup> By delivering a continuous low dose of levonorgestrel directly to the endometrium, it induces endometrial suppression, reduces glandular proliferation, and results in significant reduction in menstrual blood loss, often up to 80-90% within six months of insertion.<sup>10</sup> In addition to improvement in bleeding patterns, LNG-IUS has been shown to reduce dysmenorrhea, improve quality of life, and decrease the need for hysterectomy. Its long-acting nature and minimal systemic hormonal exposure make it particularly suitable for perimenopausal women.<sup>11</sup> However, despite well-established efficacy, the success of LNG-IUS in routine clinical practice depends largely on patient acceptability, continuation rates, and satisfaction. Initial altered bleeding patterns, misconceptions, socio-economic factors, and counselling quality may influence acceptance and long-term use. Data evaluating its acceptability among perimenopausal women in tertiary care settings remain limited.

Therefore, the present study was undertaken to evaluate the acceptability and clinical outcomes of the levonorgestrel intrauterine system in the management of abnormal uterine bleeding.

## METHODS

This prospective single-arm interventional study without a comparator group hospital-based study was conducted in

the Department of Obstetrics and Gynecology at a tertiary care teaching hospital from March 2022 to March 2025. A total of 120 perimenopausal women aged 40-55 years presenting with abnormal uterine bleeding were enrolled using consecutive sampling after obtaining written informed consent. Women opting for conservative management with a uterine size  $\leq 12$  weeks and no evidence of premalignant or malignant pathology were included. Patients with active pelvic infection, suspected or confirmed genital tract malignancy, distorted uterine cavity, significant submucous fibroids altering the cavity, unexplained vaginal bleeding, contraindications to hormonal therapy, or unwillingness for follow-up were excluded. Baseline evaluation included detailed clinical history, examination, complete blood count, pelvic ultrasonography, and endometrial assessment where indicated.

After appropriate counselling regarding benefits, expected changes in bleeding pattern, and possible adverse effects, the levonorgestrel intrauterine system was inserted under aseptic precautions during the post-menstrual phase. Participants were followed up at 1, 3, 6, and 12 months post-insertion. At each visit, bleeding pattern, dysmenorrhea, adverse effects, device expulsion, and continuation status were assessed and documented.

The primary outcome measure was acceptability of LNG-IUS as a conservative treatment modality for abnormal uterine bleeding. Secondary outcomes included reduction in menstrual blood loss, development of amenorrhea, continuation rate, expulsion rate, and requirement of hysterectomy during follow-up. Data were analyzed using SPSS version 26, with categorical variables expressed as frequencies and percentages and continuous variables as mean  $\pm$  standard deviation. A p value  $< 0.05$  was considered statistically significant. Ethical approval was obtained from the Institutional Ethics Committee and conducted in accordance with the Declaration of Helsinki.

## RESULTS

A total of 120 perimenopausal women were included in the study. The baseline demographic characteristics are presented in Table 1. The mean age of the study population was 49.21 years, and the mean body mass index (BMI) was 24.61 kg/m<sup>2</sup>. The majority of participants were multiparous (82.5%), and 70.0% had a history of previous vaginal delivery. Approximately 28.3% of women belonged to the lower socioeconomic class.

The clinical profile of the participants is summarized in Table 2. Heavy menstrual bleeding (62.5%) and dysmenorrhea (75.0%) were the predominant presenting complaints. Comorbidities were present in 66.7% of participants, with hypertension being the most common (27.5%). A substantial proportion of women (64.2%) had received prior medical therapy for abnormal uterine bleeding.

The etiological distribution of abnormal uterine bleeding is shown in Table 3. Adenomyosis (53.3%) and fibroid uterus (45.0%) were the predominant underlying causes in the study population.

**Table 1: Baseline demographic characteristics (n=120).**

Variables	Values
Mean age (years)	49.21
Mean BMI (kg/m <sup>2</sup> )	24.61
Multiparous	99 (82.5%)
Previous vaginal delivery	84 (70.0%)
Lower socioeconomic status	34 (28.3%)

**Table 2: Clinical profile and presenting complaints.**

Variables	N (%)
Heavy menstrual bleeding	75 (62.5)
Dysmenorrhea	90 (75.0)
Comorbidities present	80 (66.7)
Hypertension	33 (27.5)
Prior medical therapy for AUB	77 (64.2)

**Table 3: Etiological distribution of abnormal uterine bleeding.**

Etiology	N (%)
Adenomyosis	64 (53.3)
Endometriosis	2 (1.7)
Fibroid uterus	54 (45.0)
Total	120 (100)

**Table 4: Change in bleeding pattern after LNG-IUS insertion.**

Parameters	3 months N (%)	6 months N (%)	12 months N (%)
Breakthrough bleeding	24 (20.0)	6 (5.0)	—
Amenorrhea	—	—	36 (30.0)
Light menstrual bleeding	—	—	83 (69.2)

**Table 5: Treatment outcomes and device-related events at 1 year.**

Variables	N (%)
Continued LNG-IUS	77 (64.2)
Opted for hysterectomy	43 (35.8)
Expulsion	3 (2.5)

Changes in menstrual bleeding pattern following LNG-IUS insertion are detailed in Table 4. A progressive reduction in breakthrough bleeding was observed during follow-up, decreasing from 20.0% at 3 months to 5.0% at

6 months. At one year, 30.0% of women achieved amenorrhea, while 69.2% reported light menstrual bleeding.

Treatment outcomes at one year are presented in Table 5. A total of 64.2% of participants continued LNG-IUS therapy, reflecting good acceptability, while 35.8% opted for hysterectomy. Device-related complications were minimal, with expulsion occurring in 2.5% of cases.

## DISCUSSION

Abnormal uterine bleeding (AUB) in the perimenopausal age group remains a common and challenging clinical problem in routine gynecological practice. This is largely attributed to the high prevalence of structural uterine abnormalities, such as adenomyosis and fibroid uterus, along with the hormonal fluctuation's characteristic of the perimenopausal transition.<sup>12,13</sup> In the present study, adenomyosis and fibroid uterus were identified as the predominant etiologies. Similar observations have been reported by Gopinath and Vaidya, who also highlighted these conditions as leading causes of AUB.<sup>14</sup> A higher prevalence of adenomyosis has been documented by Koothan et al, while Renuka R et al, reported comparable findings in their study population.<sup>14-16</sup> Furthermore, the chronic nature of symptoms in this age group is reflected by the fact that a substantial proportion of women in the present study had previously received medical therapy, suggesting that conventional treatments often provide only temporary or suboptimal relief.

Following LNG-IUS insertion, a progressive improvement in menstrual bleeding pattern was observed. Breakthrough bleeding was more common during the initial months but declined steadily with continued use. A similar trend has been reported by Tariq et al, who observed higher rates of spotting in the early phase that decreased over time.<sup>17</sup> Maldonado et al also described a gradual reduction in bleeding and spotting days during the first year of LNG-IUS use.<sup>18</sup> By one year, a considerable proportion of women in the present study achieved amenorrhea, while the majority reported only light menstrual bleeding, indicating a significant reduction in menstrual blood loss. These findings are consistent with those reported by Kriplani et al, who demonstrated marked improvement in bleeding patterns along with favorable clinical outcomes.<sup>19</sup>

The continuation rate observed in the present study further reflects the acceptability of LNG-IUS. Approximately two-thirds of women continued the method at one year, and continuation was considered an indirect indicator of patient satisfaction and treatment effectiveness. Comparable findings have been reported by Blumenthal et al, who observed that many women preferred to continue conservative management when adequate symptom relief was achieved.<sup>20</sup> However, a proportion of women in the present study opted for hysterectomy. This decision does not necessarily indicate treatment failure, but may instead reflect individual expectations, persistence of symptoms,

or a preference for definitive management. A similar trend has been described by Mani et al, where a subset of patients eventually proceeded to surgery despite initial LNG-IUS use.<sup>21</sup> These findings highlight the importance of adequate pre-insertion counselling, particularly regarding expected changes in bleeding patterns, to improve continuation rates.

In addition to improvement in bleeding patterns, a reduction in dysmenorrhea was also observed, indicating an added therapeutic benefit of LNG-IUS. Sheng et al, similarly reported significant improvement in pain, particularly among women with adenomyosis.<sup>22</sup> The expulsion rate in the present study was low, suggesting good device retention and safety. Although higher expulsion rates have been reported by Youm et al, such differences may be related to variations in patient characteristics, underlying uterine pathology, and duration of follow-up.<sup>23</sup>

In the present study, it was also observed that fear of side effects, misconceptions, and lack of awareness were major reasons for refusal. Similar concerns have been highlighted by Black et al, who emphasized the role of myths and misconceptions in limiting acceptance of intrauterine devices.<sup>24</sup> Lete et al, also reported discontinuation due to side effects such as irregular bleeding.<sup>25</sup> Together, these observations highlight the importance of patient education and counselling in improving acceptance and long-term continuation of LNG-IUS.

Although hysterectomy remains the definitive treatment for abnormal uterine bleeding, it is associated with surgical risks, prolonged recovery, and higher overall cost. In contrast, LNG-IUS provides an effective, uterus-preserving alternative that can be offered to a wide range of patients. Health quality Ontario has also recognized LNG-IUS as an effective non-surgical option for the management of abnormal uterine bleeding.<sup>26</sup>

The present study has certain limitations that should be acknowledged. The absence of a comparator group limits the ability to establish a direct causal relationship between LNG-IUS use and the observed clinical improvements. Therefore, the findings should be interpreted as associations observed in a real-world clinical setting rather than definitive comparative efficacy. Being a single-centre study, the findings may not be generalizable to a broader population. The duration of follow-up was limited to one year, which may not fully capture long-term outcomes and complications. Additionally, patient satisfaction was not assessed using a standardized validated tool and was instead inferred indirectly from continuation rates. Further studies involving larger sample sizes and longer follow-up periods are warranted to validate and strengthen these findings.

The results of the current study indicate that LNG-IUS is a practical and successful conservative choice for treating

abnormal uterine bleeding in perimenopausal women. The majority of patients saw a discernible improvement in their menstrual pattern throughout follow-up, and many reported either little bleeding or total amenorrhea by one year. While the low expulsion rate confirms its safety in standard clinical practice, the study's continuation rate shows a satisfactory degree of acceptability. LNG-IUS provides a dependable uterus-preserving option and may lessen the need for surgical intervention in carefully chosen individuals, even though hysterectomy remains the definitive treatment.

## CONCLUSION

This study suggests that LNG-IUS is a useful and effective conservative option for the management of abnormal uterine bleeding in perimenopausal women. Over the course of follow-up, most patients demonstrated a clear improvement in menstrual patterns, with many experiencing either minimal bleeding or complete amenorrhea by one year. The continuation rate observed in the present study indicates good overall acceptability, while the low expulsion rate further supports its safety in routine clinical practice. Although hysterectomy remains the definitive treatment, LNG-IUS offers a reliable, uterus-preserving alternative and may help reduce the need for surgical intervention in appropriately selected patients.

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