

Evaluating the Efficacy of Levonorgestrel-releasing Intrauterine System in the Management of Menorrhagia: A Prospective Cohort Study

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ABSTRACT

Introduction: Although heavy menstrual bleeding rarely poses a life-threatening risk, it significantly disrupts women's lives, causing discomfort and inconvenience. The term "menorrhagia" encompasses the notion of heavy menstrual bleeding. Despite effective conservative surgical solutions, a substantial number of women still choose hysterectomy. Preserving patient autonomy in selecting treatments for menstrual disorders is essential for sustainable care. The Levonorgestrel-releasing Intrauterine System (LNG-IUS), infused with progesterone, emerges as a promising surgical alternative due to its potential to decrease blood loss during menstruation.

Aim: To evaluate the effectiveness of LNG-IUS in controlling heavy menstrual bleeding in women with menorrhagia.

Materials and Methods: The present prospective cohort study was conducted in the Department of Obstetrics and Gynaecology at Vinayaka Mission's Kirupananda Variyar Medical College and Hospital, Salem, Tamil Nadu, India, for 1 year. Fifty women experiencing heavy menstrual bleeding (>80 mL per cycle) underwent LNG-IUS treatment. Menstrual blood loss was assessed using modified imaging assessment of blood loss Pictorial Blood Loss Assessment Chart (PBAC) at three, six, and nine months postinsertion. Efficacy markers encompassed the

observation of increased haemoglobin (Hb) levels, the reduction of PBAC scores both before and after LNG-IUS insertion. Further evaluation encompassed parameters such as the regularity of menstrual cycles and the monitoring of adverse effects after LNG-IUS implantation. Continuous variables were expressed in terms of means, standard deviations (SD), while categorical variables were expressed in terms of frequency and percentage. Analysis of Variance (ANOVA) test was used. A p-value of less than 0.05 was considered statistically significant.

Results: The mean age of the subjects was 35.16 years. The analysis revealed a significant reduction in menstrual blood loss, reflected by a decrease in PBAC score from an average of 198.86 before treatment to 8.78 after nine months of supplementation. Furthermore, haemoglobin percentage (Hb%) improved notably, increasing from an initial average of 9.1% to 10.6% after nine months. About 32% of patients achieved amenorrhoea after nine months. Spontaneous device expulsion occurred in one patient during the sixth month, while another requested removal in the ninth month.

Conclusion: As a non-surgical avenue for menorrhagia, LNG-IUS offers a practical alternative. Positive feedback and sustained adherence highlight its potential as a substitute for managing heavy menstrual bleeding.

Keywords: Menstrual blood loss reduction, Sustainable conservative care, Patient satisfaction, Non-surgical alternative

INTRODUCTION

Excessive menstrual bleeding, while seldom life-threatening, exerts a profound toll on women, inflicting discomfort and disrupting their daily lives. This pervasive issue constitutes a recurrent concern within Gynaecology Clinics, significantly contributing to their caseload. The ensuing financial implications and resource requirements of consultations and treatments substantially burden the broader national healthcare system [1]. In the clinical context, heavy menstrual bleeding (HMB) is defined by the National Institute for Health and Care Excellence (NICE) as an abnormal monthly blood loss that detrimentally impacts a woman's physical, emotional, social, and material well-being. This encompasses either a marked blood loss exceeding 80 mL or protracted bleeding episodes extending beyond five days [1,2].

Amidst this landscape, the pursuit of effective interventions becomes paramount. While the efficacy of various pharmacological approaches remains a topic of debate, and adherence to oral contraceptive regimens is known to fluctuate, oral contraceptive pills persist as a viable avenue for HMB management [3]. Simultaneously, surgical interventions such as hysterectomy and transuterine entrapment Transcervical Resection of Endometrium

(TCRE) remain frequent strategies, albeit often accompanied by considerable financial and physical burdens on patients [4].

In response to this complex challenge, the utilization of the levonorgestrel intrauterine device (LNG-IUS) as a therapeutic option for menorrhagia has emerged with prominence. Initially developed for contraception [4-6], the LNG-IUS comprises a T-shaped polyethylene body measuring 32 mm in diameter. This encloses a silicone membrane-covered reservoir containing 52 mg of levonorgestrel (LNG). Following insertion, the device maintains a plasma concentration of 150-200 pg/mL, releasing LNG at a controlled rate of 20 µg/24 hours [6]. Leveraging its progestin (LNG) release mechanism, the LNG-IUS effectively mitigates menorrhagia by inducing endometrial involution, stromal degradation, bolstering cervical mucus viscosity, and modulating endometrial estrogen responsiveness [7, 8]. By harnessing its ability to harmonize hormonal imbalances and address excessive bleeding with precision, this approach can revolutionize menorrhagia management and restore women's quality of life. In light of the multifaceted challenges posed by heavy menstrual bleeding, this study endeavours to delve into the efficacy of the LNG-IUS as a tailored and less invasive solution. The study aimed to evaluate the effectiveness of the LNG-IUS in

managing menorrhagia in terms of symptom relief, reduction in menstrual blood loss.

MATERIALS AND METHODS

The present prospective cohort study was conducted at the Department of Obstetrics and Gynaecology, Vinayaka Mission's Kirupananda Variyar Medical College and Hospital, Salem, Tamil Nadu, India, from January 2014 to June 2015. Institutional Ethical Committee approval (VMKVMC/EC/14/57) was obtained.

Inclusion criteria: Women aged 20 to 50 afflicted with menorrhagia, without an immediate need for medical intervention, devoid of any history of medication-induced vaginal bleeding, and free from vulvar, vaginal, or cervical pathologies. Initial ultrasounds were performed to rule out the presence of adnexal masses.

Exclusion criteria: Pregnant women, those currently facing genital infections, individuals with severe anaemia (Hb<7 gm%), abnormal cervical cytology, and benign/malignant endometrial histology. Individuals with a prior history of endometrial resection or ablation, a history of thromboembolism, liver disease, fibroids (size > 2.5 cm or > 3 counts), adnexal tumours or cysts, and thyroid dysfunction were also excluded from the study.

Participant enrollment: A total of 50 women aged 20 to 50, who had experienced substantial menstrual bleeding for a minimum of three months, were enlisted for participation. The levonorgestrel intrauterine system (LNG-IUS) was administered as an outpatient procedure, post obtaining informed consent.

Study Procedure

Assessment of menstrual blood loss: The quantification of menstrual blood loss employed a modified PBAC [9]. Scores were computed by multiplying pad usage, flow duration, and staining degree (assigned values of 1, 5, and 20 for light, moderate, and heavy contamination, respectively). A PBAC Score above 100 indicated the presence of menorrhagia, signifying menstrual blood loss exceeding 80 mL.

Follow-up and outcome measures: After the insertion of LNG-IUS, participants underwent visual assessments at three, six, and nine months. Efficacy markers encompassed the observation of increased haemoglobin (Hb) levels, the reduction of PBAC scores both before and after LNG-IUS insertion. Further evaluation encompassed parameters such as the regularity of menstrual cycles and the monitoring of adverse effects after LNG-IUS implantation.

STATISTICAL ANALYSIS

The data were analysed and tabulated using the trial version of Statistical Package for Social Sciences (SPSS), version 16. Continuous variables were expressed in terms of means, Standard Deviations (SD), while categorical variables were expressed in terms of frequency and percentage. ANOVA test and Chi-square test were used. Statistically significant findings were determined by considering p-values less than 0.05.

RESULTS

The mean age of the participant group was calculated to be 35.16 years [Table/Fig-1]. Among the diverse age groups, the highest frequencies emerged in the 31-35 and 36-40 ranges, constituting 26% and 30% of the cohort, respectively.

Histology of Endometrium

Endometrial histological profiles: The prevalent histological patterns within the participants were unveiled through an investigation of endometrial histology, as presented in the majority, constituting 34 (68%) patients of the cases, displayed the proliferative phase of the menstrual cycle. Following this, 14 (28%) patients exhibited the secretory phase, while a smaller subset 2 (4%) patients displayed simple hyperplasia without atypia.

Age group (years)	Frequency	Percentage	Mean	Standard Deviation
20-25	4	8%	35.16	5.72
26-30	7	14%		
31-35	13	26%		
36-40	15	30%		
41-45	10	20%		
46-50	1	2%		
Total	50	100%		

[Table/Fig-1]: Age-wise distribution of the study population

PBAC score dynamics: Before the intervention, the mean PBAC score was 198.86. This score substantially declined to 76.66 after the 3-month interval. Following this trend, PBAC scores diminished to 30.38 at 6 months and reached their lowest point of 8.78 at the 9-month mark [Table/Fig-2]. At the initiation of the study, the mean Hb% was registered at 9.1 gm%, representing the baseline haemoglobin status. As the study progressed, a notable improvement in Hb% was observed, accentuating the positive impact of the LNG-IUS intervention [Table/Fig-3].

Time	PBAC score Mean	PBAC score SD	ANOVA F value	p-value
Preinsertion	198.86	39.39	4.368	<0.0001
3 months of follow up	76.66	37.07		
6 months of follow up	30.38	21.16		
9 months of follow up	8.78	7.95		

[Table/Fig-2]: Mean and standard deviation of PBAC Scores in the study population. PBAC score: Pictorial blood loss assessment chart; ANOVA: Analysis of variance

Time	Haemoglobin Percentage % Mean (grams %)	Haemoglobin Percentage % SD	ANOVA F value	p-value
Preinsertion	9.1	0.59	<0.0001	<0.0001
3 months of follow up	9.9	0.56		
6 months of follow up	10.7	0.40		
9 months of follow up	10.6	2.77		

[Table/Fig-3]: Mean and standard deviation of Haemoglobin Percentage % in the study population.

A substantial proportion of participants (66%) underwent irregular menstruation upon inserting the LNG-IUS. Over the time, a discernible shift was observed, with a reduction to 42% after three months and a significant decline to 10% after six months. The 9-month follow-up revealed a notable transformation, resulting in irregular periods reaching 0% [Table/Fig-4], however, regular periods were seen in 64% and amenorrhoea in 32% and One patient (2%) wanted to remove the device in the ninth month [Table/Fig-4].

Time	Menstrual pattern	Frequency	Percentage	p-value
Preinsertion	Irregular periods	33	66%	<0.0001
	Regular periods	17	34%	
	Amenorrhoea	0	0	
3 months of follow-up	Irregular periods	21	42%	
	Regular periods	28	46%	
	Amenorrhoea	1	2%	
6 months of follow-up*	Irregular periods	5	10%	
	Regular periods	36	72%	
	Amenorrhoea	8	16%	
9 months of follow-up	Irregular periods	0	0	
	Regular periods	32	64%	
	Amenorrhoea	16	32%	

[Table/Fig-4]: Distribution of the study population based on menstrual pattern. *One patient had a spontaneous device expulsion. Chi square test was used.

A sole occurrence of spontaneous LNG-IUS expulsion was recorded during the initial six-month period across the entire participant pool. Furthermore, within the study population, only one patient opted for the voluntary removal of the LNG-IUS after the ninth month, citing amenorrhoea as the reason [Table/Fig-5].

Visits	No. of Spontaneous Expulsion LNG-IUS	No. of Removal LNG-IUS	Percentage
3 months	0	0	0%
6 months	1	0	2%
9 months	0	1	2%

[Table/Fig-5]: Study population based on the Spontaneous expulsion of the LNG-IUS and Instances of Voluntary LNG-IUS Removals.
LNG-IUS: Levonorgestrel releasing intrauterine system

Common side effects included abdominal cramps, intermenstrual spotting, vaginitis, weight gain, headache, and breast tenderness, with the highest incidence in the first three months. These gradually declined over time, with 30% reporting no adverse events at three months, 80% at six months, and 98% by nine months. Expulsion occurred in 2% of cases at six months, while weight gain and breast tenderness initially affected 4%, both showing a decreasing trend [Table/Fig-6].

Adverse events	Visits 3 months Frequency (%)	Visits 6 months Frequency (%)	Visits 9 months Frequency (%)
Nil Adverse events	15 (30%)	40 (80%)	49 (98%)
Expulsion	0	1 (2%)	0
Abdominal cramps	17 (34%)	0	0
Intermenstrual spotting	6 (12%)	6 (12%)	1 (2%)
Weight gain	2 (4%)	2 (4%)	0
Vaginitis	5 (10%)	1 (2%)	0
Headache	3 (6%)	0	0
Breast tenderness	2 (4%)	0	0

[Table/Fig-6]: Distribution of the study population based on the adverse events due to LNG-IUS.

DISCUSSION

The study findings underscored the efficacy of LNG-IUS in reducing menstrual blood loss. This reduction persisted through 3, 6, and 9 months of usage and extended into the following 3-month interval.

The dataset includes diverse sample sizes, encompassing the present study with 50 participants, Gmal.H. Sayed et al.,'s [10] study in 2011 with 29 participants, Soysal M et al.,'s [11] research in 2005 involving 32 participants, Vera Grigorjeva et al.,'s [12] investigation in 2003 with 69 participants, and F. Mercurio et al.,'s [13] study in 2003 with 32 participants, all spanning nine months.

Histological analysis of endometrial samples revealed that 68% were in the proliferative phase, 28% were in the secretory phase, and 4% exhibited simple hyperplasia without atypia, reflecting diverse menstrual patterns among participants. In a study by Doraiswami S et al.,' study, 20% were in the proliferative phase, 28.4% were in the secretory phase, and 6.1% exhibited simple hyperplasia without atypia [14].

Mean and Standard Deviation of PBAC Score provides a clear view of the reduction in menstrual blood loss achieved through continuous usage of the device in the present study-approximately 95.6% at the end of nine months. This contrasts with the findings of other studies by Endrikat et al., [15] and Bilian Xio et al., [16], reporting reductions of around 94% and 84% after nine months of usage.

Notably, Hb% increased from 9.1% preinsertion to 9.9 gm% after three months, indicating a substantial improvement. This trend continued, with Hb% increasing to 10.7 gm% at six months and sustaining at 10.6 gm% by the end of nine months throughout

regular menstrual cycles as compared to Kaunitz AM et al., [17] who reported with baseline preinsertion Hb% was 12.4gm% and increasing to 13.4 gm% at six months and sustaining at 13.6 gm% by the end of nine months throughout regular menstrual cycles.

In the present study, 66% of participants had irregular periods at LNG-IUS insertion, which decreased to 42% at three months and further declined to 10% and 0% at six and nine months, respectively. In contrast to the present findings, Rafique N et al., [18] reported that irregular bleeding was observed in 89% of participants following LNG-IUS insertion. In their study, although irregular periods were initially common, a gradual improvement in bleeding patterns was noted over subsequent follow-up visits, with a significant proportion of women eventually achieving regular or amenorrhoeic cycles by the end of the observation period.

Regarding the distribution of the study population based on spontaneous expulsion of LNG-IUS and instances of voluntary LNG-IUS removal rates, the present research found a notably low rate of 1% throughout nine months. This contrasts with findings from other studies by Gmal.H. Sayedin et al., [10], Soysal M. et al., [11], Vera Grigorieva Jt. [12], and F. Mercurio et al., [13] reported expulsion rates of 10%, 31%, 5.79%, and 12.5% at the end of the nine months.

In the present study, by the culmination of the nine-month monitoring period, a significant proportion of the study population (98%) reported no adverse events, underscoring the favorable safety profile of the intervention. Gupta Taru et al [19] observed that approximately 85% of women reported no significant adverse effects, with the most common complaints being mild abdominal cramping (10%) and transient spotting (5%). Kaunitz AM et al [20] reported that fewer than 10% of participants experienced adverse effects, primarily limited to intermenstrual bleeding and breast tenderness, which tended to diminish over time.

In the study by A. Kriplani et al [21], adverse events such as irregular bleeding patterns were noted in 12% of users, while other events such as weight gain or headache were rare and generally self-limiting. Similarly, Peter C. Reid et al [22] documented that adverse effects were infrequent, with less than 15% of women reporting complaints, chiefly limited to initial spotting and mild pelvic discomfort.

The findings of this study carry profound and far-reaching implications for both primary care and gynaecological practice. Moreover, these findings call for the strengthening of collaborative frameworks between primary care providers and gynaecological specialists. Establishing clear referral pathways, shared care models, and continuous professional development programs will ensure that patients receive coordinated, high-quality care across the continuum of health services.

Limitation(s)

Several limitations are evident in this research. Firstly, the minimal sample size of 50 participants may have restricted the generalisability of the findings to the local community. To enhance the study's validity and applicability, a more significant number of participants from a more diverse population could have been advantageous. Secondly, multicentric research, with its broader range of patient characteristics, is known to provide more comprehensive insights than studies conducted in other medical environments. Thus, the analysis across multiple centers could have enriched the study's outcomes. Lastly, it is important to have a comparison group in the study to enhance the results. Comparative data would have allowed for a more robust evaluation of the intervention's effectiveness.

CONCLUSION(S)

The study findings underscored the efficacy of LNG-IUS in reducing menstrual blood loss. This reduction persisted through 3, 6, and 9 months of usage. Due to its reversibility and contraceptive properties, LNG-IUS could be a favoured intervention for contraception while

addressing heavy menstrual bleeding. As a non-surgical avenue for menorrhagia, LNG-IUS offers a practical alternative. Positive feedback and sustained adherence highlight its potential as a substitute for managing heavy menstrual bleeding.

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