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Quantitative Evaluation of Clinical Outcomes of Levonorgestrel-Releasing IUCD (LNG-IUS) in Heavy Menstrual Bleeding: a Comparative Study

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Abstract. One of the widespread diseases affecting the reproductive system in women is heavy menstrual bleeding, causing many complications such as iron deficiency anemia and fatigue, and lowering the quality of life of women significantly. In this paper, the efficacy of hormonal intrauterine contraception is evaluated in order to meet the demand for efficient treatment methods that have long-lasting effects without surgeries. The purpose of the current work is to perform a quantitative analysis of the clinical effectiveness in terms of decrease in menstrual blood loss, improvement in blood indicators, pain relief, menstruation disappearance, and patients' satisfaction. It is necessary to analyze the results of randomized clinical trials, prospective cohorts, and systematic reviews on the subject matter. The obtained data suggest the presence of a significant decrease in menstrual blood loss, improvement in hemoglobin level, and pain symptoms. Many patients stopped having menses while using the new method. It proved to be more efficient, satisfactory, and easier to continue compared to conventional therapies. Thus, this article offers a unique analysis combining quantitative measures and comparative evaluation of the effect of the therapy on patients' health.
Keywords: *LNG-IUS, Menorrhagia, Contraception, Efficacy, Hemoglobin.*

Introduction

Heavy menstrual bleeding is among the most common gynecological conditions affecting reproductive-age women and presents a significant clinical problem. It is characterized

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by heavy flow of blood during menstruation to an extent that adversely affects the overall physical, psychological, and social well-being of the individual. Historically, it was considered a condition where the blood loss during menses exceeded 80 milliliters. However, in current practice, the main consideration for diagnosis is the patient's self-report of excessive bleeding and the impact of this condition on her quality of life (National Institute for Health and Care Excellence, 2018)

Heavy Menstrual Bleeding Aetiology Is Multidimensional. According to the International Federation of Gynaecology and Obstetrics (FIGO) PALM-COEIN criteria, there are two main categories of heavy menstrual bleeding: structural and non-structural. The former entails endometrial polyp, adenomyosis, uterine fibroids, or malignancy/hyperplasia. In contrast, the latter involves coagulopathy, ovarian dysfunction, endometrial disorders, and iatrogenic causes, including drug therapy and use of intrauterine devices (Munro et al., 2011).

The pathophysiology of heavy menstrual bleeding is based on the imbalance in the usual process of haemostasis in the endometrium. The major mechanisms behind this condition are excessive endometrial proliferation due to high estrogen levels, delayed or inadequate progesterone action, higher prostaglandin production that causes vasodilation, and an increase in endometrial fibrinolysis. Furthermore, defects in the process of angiogenesis cause dilated spiral arterioles in the endometrium, causing excessive bleeding. Studies conducted on molecular analysis have shown increased expression of vascular endothelial growth factor, matrix metalloproteinases, and inflammatory cytokines (Fraser et al., 2007; Maybin & Critchley, 2015).

The burden of heavy menstrual bleeding among patients is considerable as it goes beyond the physical aspects of the condition. Blood loss that is constant and high often causes anemia due to iron deficiency, where the patient feels fatigued, is intolerant to exercises, experiences light headedness, poor concentration, and low productivity levels. The condition can also cause stress on the cardiovascular system. Psychological impacts include experiencing anxiety, feeling embarrassed, socially withdrawn from interactions, and lower engagement in work-related and everyday tasks.

The approaches used to manage cases of excessive menstrual flow depend on the cause of the condition, degree of

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discomfort, patient's preferences, and reproductive plans. The management approach is primarily through medical intervention. Nonsteroidal anti-inflammatory medications decrease the bleeding volume through their inhibition of prostaglandin production, whereas antifibrinolytics, like tranexamic acid, work by avoiding the breakdown of fibrin fibers. Hormonal medications include combined oral contraceptives, as well as oral and injectable progestogens, and function by controlling the lining of the uterus. Unfortunately, these methods have shown to be inconsistent and may result in systemic adverse reactions (American College of Obstetricians and Gynaecologists, 2021).

If treatment through medication proves unsuccessful or unsuitable, surgery can become an option, including endometrial ablation and hysterectomy. Although they work effectively, they are not without risks since they are expensive and invasive procedures that can result in side effects like infection, bleeding, and infertility. Thus, there is a great need for alternative treatments.

Levonorgestrel-releasing intrauterine system has been found to be an extremely efficacious method of treatment that overcomes several weaknesses of traditional treatments. It is because this system allows for the release of levonorgestrel into the uterine cavity with a steady rate, resulting in high concentrations locally and low levels systemically. The way in which it acts includes endometrial hyperproliferation inhibition, stromal decidualization, decreased secretion from glands, vascularity reduction, and local inflammation control (Kaunitz et al., 2010).

One of the major advantages of this contraceptive technique is that it acts for a very long duration, up to five years, without requiring any active participation from the user. Thus, there are no concerns associated with patient compliance, and its effectiveness remains unchanged. Gradual endometrial atrophy leads to significant decrease in menstrual flow, and a large number of women using this method eventually attain amenorrhea. From the perspective of menorrhagia, amenorrhea can be viewed as an ideal goal of therapy, since it indicates successful inhibition of the endometrium.

There is solid clinical proof for its effectiveness in comparison with other approaches used in medicine. Several randomized clinical trials and systematic reviews have shown that this approach leads to a decrease in menstrual bleeding

by more than 90% after 6 to 12 months of use. There has been an improvement in such indicators as hemoglobin level and ferritin. It is also characterized by decreased pain intensity and an increase in quality of life indicators (Endrikat et al., 2012; Cochrane Collaboration, 2020).

In addition, this treatment technique has proven to be effective in substantially lowering the need for surgery. Studies conducted have revealed that it is equally effective as, if not more effective than, the surgical approach in several instances. In addition, unlike the surgical approach, this technique does not affect a woman's fertility and involves minimal risk (Gupta et al., 2013).

Although these benefits exist, variations in clinical outcomes will be encountered based on the patient's age, pathology, and uterine anatomy. In addition, some patients might develop some form of irregular bleeding or spotting, which could influence the early compliance rate. Hence, a systematic analysis of the clinical outcomes will help ensure that there is proper patient selection and counselling to support evidence-based practice.

In this study, an overall quantitative analysis of the clinical outcomes related to the use of the levonorgestrel releasing intrauterine system in the management of menorrhagia has been provided. In addition, the study provides a comparison between this intrauterine device and standard medication treatments in terms of efficacy in reducing blood loss, improving haematological status, decreasing pain, inducing amenorrhea, and increasing patient satisfaction levels.

Materials and Methods

Study Design and Framework

As such, this study constitutes a complete analytical overview with quantitative methodology based on randomized controlled trial evidence, prospective cohort studies, and systematic reviews assessing the efficacy of the levonorgestrel-releasing intrauterine system (LNG-IUS) in managing women with heavy menstrual bleeding (Endrikat et al., 2012; Gupta et al., 2013; Cochrane Collaboration, 2020).

This paper uses an extensive, multiple variable analysis technique, akin to standard techniques employed in clinical studies where various variables are analyzed for their effectiveness within particular treatment settings and compared in terms of functionality and effectiveness (Munro et al., 2011). The aim of such a study would be to compare

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quantifiable results with traditional medicinal therapy.

Literature Search Strategy and Data Sources

An extensive literature search has been performed using major biomedical databases, such as PubMed, PMC, Cochrane Library, and Google Scholar. In addition, the guidelines published by various international organizations were explored for relevant information, including those published by World Health Organization and ACOG (2021).

For this purpose, a systematic approach was adopted with the use of relevant keywords combined with the Boolean operators. Specifically, the following were identified as search terms:

• "Levonorgestrel intrauterine system heavy menstrual bleeding"

• "LNG-IUS clinical outcomes PBAC score"

• "Hormonal IUCD effectiveness in HMB"

• "Comparative treatment heavy menstrual bleeding LNG-IUS vs medical therapy"

This search was limited to literature that was published during the years 2010 and 2025. This ensured that contemporary sources could be reviewed to identify the best available evidence (NICE, 2018).

Additionally, the references cited in the selected articles have also been checked to locate further sources.

Criteria for Study Selection

Inclusion Criteria

The inclusion criteria used were:

• Clinical trial of LNG-IUS for the management of women suffering from heavy menstrual bleeding

• Provided quantifiable outcomes like menstrual blood flow, hemoglobin content, and pain level assessment

• Follow-up period was three to six months or more

• Comparative studies between medical treatments including NSAIDs, tranexamic acid, and birth control pills

• RCTs, cohort studies, and systematic reviews (Gupta et al., 2013; Endrikat et al., 2012)

Exclusion Criteria

Criteria for excluding a study were:

• Studies that assessed solely contraceptive outcomes without measuring any clinical symptoms

• Small-sized samples with low statistical strength

• Lack of quantified measures or follow-up data

• Case reports and other non-peer reviewed studies

Population Under Study and Clinical Setting

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In the study population, patients under investigation were reproductive-aged females suffering from heavy menstrual bleeding regardless of their parity. In the clinical setting, primary HMB, as well as secondary causes of HMB such as adenomyosis and endometrial dysfunction, were considered (Munro et al., 2011).

Variables that were considered in the studies at the baseline stage included:

- Patient age
- Intensity of the bleeding
- Hemoglobin concentrations
- Other symptoms accompanying the condition such as fatigue

The extraction of these variables reflects the typical epidemiological profiling in gynaecology.

Outcome Measurements and Variables Measured

The outcome measurements measured were those that could be quantitatively evaluated. This made possible the objective evaluation of results from different research sources (Cochrane Collaboration, 2020).

Primary Outcome Variables

- Decrease in amount of blood loss during menses (based on PBAC score)
- Changes in hemoglobin and ferritin levels
- Decrease in pain intensity (VAS score)

Secondary Outcome Variables

- Amenorrhea
- Change in bleeding patterns
- Satisfaction with therapy
- Continued use
- Improved quality of life

Variables were compared longitudinally after 3 months, 6 months, 12 months, and more.

Data Extraction and Analysis

Data extraction was done in a methodical way with the use of a set standard format. Important components extracted from the various researches include:

- Research design and sample size
- Follow-up period
- Pre and post treatment measurements
- Percentage change in outcomes

The data extracted were arranged under thematic categories for analysis purposes. Thematic categorization is common practice in systematic reviews (Cochrane

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Collaboration, 2020).

A qualitative analysis was done to determine any common pattern, whereas quantitatively, percentage change and mean were used for comparisons.

Statistical Analysis and Interpretation

While the current research represents a review-based analysis, statistical interpretations were used to increase its clinical significance.

• Mean values and percent changes were computed for all relevant factors

• Relative effectiveness was evaluated by comparing differences in LNG-IUS compared to other treatment options

• Time-related trends were identified to establish the pattern of development in clinical results

Statistical significance (p-value, confidence interval) from initial research papers (Gupta et al., 2013) was taken into account where available for validation purposes.

Correlation analysis was used theoretically to identify connections between:

• Change in blood loss and improvement in hemoglobin content

• Time span of usage and cases of amenorrhea

• Symptom reduction and satisfaction rate

Comparative Analysis Model

The analysis between LNG-IUS and standard methods was carried out on the basis of a comparative framework. The parameters that were compared included:

• Degree of reduction in blood loss

• Periodic effectivity

• Patient compliance

• End results

This method ensured that a holistic approach was undertaken (Kaunitz et al., 2010).

Ethical Considerations

Since this research utilizes information from already existing literature, there is no need for direct contact with patients in any way. All sources of information were taken from articles published in journals and other public databases.

Ethics were upheld through:

• Use of reliable information sources

• Non-repetition of data

• Interpretation of results without errors

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Methodological Advantages and Disadvantages

Advantages

• Selection of high-quality studies (randomized controlled trials, systematic reviews)
• Multivariate quantitative research
• Comparative study of treatment approaches
• Long-term evaluation of results

Disadvantages

• Heterogeneity of study design and sample
• Different approaches to measuring the results
• Lack of consistent statistical information in studies

Nevertheless, the similarity of results in several studies increases the validity of the results obtained.

Results

Thematic Section 1: Quantitative Reduction of Menstrual Bleeding

Based on the analysis of several randomized clinical trials and observational cohort studies, it can be concluded that the administration of the LNG-IUS results in a fast, gradual, and continuous reduction in menstrual bleeding, which makes the intrauterine device one of the most efficient conservative methods of managing heavy menstruation (Endrikat et al., 2012; Gupta et al., 2013; Cochrane Collaboration, 2020). As it happens, the reduction does not occur immediately and depends on the passage of time, showing a gradual improvement from month to month.

In the period of the first three months since the application of the treatment, about 65–75% of women report a decrease in the volume of menstrual bleeding (Endrikat et al., 2012). The reduction is associated with a suppression of the endometrium proliferation process and decreased glandular activities. However, during this period, spotting might occur because of the insufficient atrophy of the endometrium (Bahamondes et al., 2015).

By the end of six months, the level of reduction reaches 85–90%. It is associated with a considerable thinning of the endometrial layer and its vascularity. By 1 year and after, most individuals are able to have almost complete inhibition of their periods, with declines surpassing 90%-95%. In some instances, amenorrhea ensues, which is the target treatment result for severe HMB (Gupta et al., 2013; Bahamondes et al., 2015).

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Table 1

Progressive Reduction in Menstrual Blood Loss

Duration of LNG-IUS Use	Mean Reduction (%)	Clinical Interpretation
0–3 months	65–75%	Initial suppression; irregular spotting common
3–6 months	85–90%	Significant endometrial thinning
6–12 months	90–95%	Near-complete control of bleeding
>12 months	>95%	Amenorrhea in many patients

Thematic Section 2: Thematic: Effects on Haematology and Treatment of Anemia

The decrease in the amount of blood loss during menstruation corresponds to a significant increase in hemoglobin and serum ferritin values (Fraser et al., 2007; Gupta et al., 2013). Heavy menstrual blood loss often results in iron deficiency anemia and should be treated.

Hemoglobin values of 8–10 g/dL are observed at baseline. Over the course of treatment, these patients have increasing values of hemoglobin by 1–2 g/dL at six months and by 12 months, most patients reach normal values of 12–13 g/dL (Endrikat et al., 2012).

Serum ferritin levels are increased significantly. Initially, low iron levels improve over six months, and normalization occurs when treatment continues (Cochrane Collaboration, 2020).

There is a positive correlation between the amount of blood loss and hemoglobin levels.

Table 2

Haematological Improvement Over Time

Parameter	Baseline	6 Months
Hemoglobin (g/dL)	8.5–10	10.5–11.5
Ferritin	Low	Moderate

Thematic Section 3: Comparative Efficacy with Standard Medical Treatment

The comparative analysis indicates that the LNG-IUS is considerably more efficacious than the standard medical treatments in terms of decreasing the volume of menstrual flow and enhancing outcomes (Gupta et al., 2013; Cochrane

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Collaboration, 2020).

NSAIDs and tranexamic acid treatment allows for achieving only a partial decrease in bleeding and is conditional upon the constant administration of the drug throughout each menstrual period (ACOG, 2021). The effectiveness of combined oral contraceptives is moderate but entails compliance problems and systemic hormonal impact.

On the contrary, LNG-IUS provides continuous, local administration of the medication and guarantees the efficacy of therapy regardless of patient adherence (Kaunitz et al., 2010). Therefore, the efficacy in practice is higher.

Moreover, LNG-IUS proves to be more efficient over time, lowering the incidence of surgical interventions, including endometrial ablation or hysterectomy (Gupta et al., 2013).

Table 3

Comparative Effectiveness

Parameter	**LNG-IUS**	**Tranexamic Acid**	**NSAIDs**	**OCPs**
Blood loss reduction	>90%	40-60%	20-40%	50-60%
Compliance dependency	None	High	High	Very High
Long-term effectiveness	Excellent	Limited	Limited	Moderate
Need for surgery	Low	Moderate	Moderate	Moderate

Thematic Section 4 - Themes: Decrease in Dysmenorrhea and Pain Intensity

The efficacy of LNG-IUS in decreasing dysmenorrhea is due to its impact on the synthesis of prostaglandins and the activity of the endometrium (Kaunitz et al., 2010). Prostaglandin concentration is high when there is uterine hyperactivity and ischemic pain during HMB.

After the use of LNG-IUS, there will be a decrease in endometrial activity, which decreases prostaglandin synthesis, hence the decrease in uterine contractions and pain (Bahamondes et al., 2015).

Like bleeding, pain decreases gradually. There will be moderate pain after three months, and after six to twelve months, pain will be minimal (Endrikat et al., 2012).

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Table 4

Pain Score Reduction (VAS Scale)

Duration	Mean VAS Score	Clinical Interpretation
Baseline	7–8	Severe dysmenorrhea
3 months	4–5	Moderate improvement
6 months	2–3	Significant relief
12 months	1–2	Minimal or no pain

Thematic Section 5: Alterations in Menstrual Bleeding and Development of Amenorrhea

The most prominent feature of using LNG-IUS therapy involves the gradual change in menstruation that eventually results in amenorrhea in many patients (Bahamondes et al., 2015; Cochrane Collaboration, 2020).

In the first phase of the treatment course, irregular spotting takes place because of insufficient endometrial suppression. Later on, menstrual bleeding becomes less in amount and duration. By one year of therapy, a considerable number of patients develop amenorrhea (Gupta et al., 2013).

It should be regarded as a positive result of the treatment course, especially when treating women with HMB.

Table 5

Bleeding Pattern Changes

Duration	Bleeding Pattern	Duration
0–3 months	Irregular spotting	0–3 months
3–6 months	Reduced flow	3–6 months
6–12 months	Minimal bleeding	6–12 months
>12 months	Amenorrhea common	>12 months

Thematic Section 6: Patient Satisfaction, Adherence, and Acceptability

Satisfaction rates are typically very high, combining the advantages of symptom alleviation, convenience, and sustainability (Endrikat et al., 2012). Patients generally report marked improvements in their quality of life, lower fatigue levels, and greater ability to function in everyday life.

Adherence rates are also quite high, indicating both efficacy and safety (Bahamondes et al., 2015). Withdrawal from therapy is normally because of early irregular bleeding.

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Table 6

Satisfaction and Continuation

Outcome	Percentage	Interpretation
Satisfaction Rate	80-95%	High acceptance
1-year continuation	85-90%	Good tolerability
3-year continuation	70-80%	Sustained effectiveness

Thematic Section 7: Functional Outcomes and Quality of Life Improvement

One of the outcomes that cannot be neglected but is frequently overlooked is functional improvement and quality of life enhancement. The reduction in menstrual bleeding helps enhance patients' energy, eliminate fatigue, increase productivity, and reduce absence from work (Shankar et al., 2004; NICE, 2018).

Improved mental health, diminished anxiety regarding menstruation, and more active participation in society have been observed by patients (Cochrane Collaboration, 2020).

Discussion

From the current study, it can be concluded that the LNG-IUS device effectively helps in controlling the symptoms of heavy menstrual bleeding by providing excellent clinical advantages. It reduces menstrual blood loss in a progressive manner along with improved haematological status, lower pain intensity, and high patient satisfaction. All these observations have been supported by various large-scale clinical trials and systematic reviews, further strengthening the use of LNG-IUS as a treatment of choice (Gupta et al., 2013; Cochrane Collaboration, 2020).

Among all the results, the one regarding the reduction of blood loss due to menstruation is considered very important. The gradual decrease in the loss is attributed to the mechanism through which the LNG-IUS acts, i.e., the gradual reduction in the thickness of the endometrium through glandular proliferation and vascularity. According to other clinical studies, this reduction was seen in the range of 90%, within 6-12 months (Endrikat et al., 2012; Kaunitz et al., 2010). In light of this observation, patients should be counselled appropriately to prevent misunderstanding about the efficacy of LNG-IUS.

An additional key aspect of the effectiveness of the procedure under consideration refers to the improvement of the haematological indices of the patients (the level of

hemoglobin and ferritin), which also needs to be taken into account. Iron deficiency anemia caused by heavy menstrual bleeding represents a serious problem for patients, and its elimination is crucial to improve the patients' general health state. The strong positive correlation between the decrease in the amount of menstrual blood flow and the rise in hemoglobin levels was observed in this study, supporting the direct physiological connection between these indices (Fraser et al., 2007; Shankar et al., 2004).

A comparative analysis clearly shows that the use of the LNG-IUS method is significantly more effective compared to standard medical treatment using such drugs as nonsteroidal anti-inflammatory drugs (NSAIDs), tranexamic acid, or combined oral contraceptives. Although these therapies have a certain effect in alleviating the symptoms, their effectiveness is limited by low compliance among patients and a relatively short duration of action. In comparison with these drugs, the LNG-IUS system provides continuous local drug administration without patient participation (Kaunitz et al., 2010).

Other interesting findings are the decrease in pain caused by the heavy menstrual bleeding. It has been explained by the lowered production of prostaglandins and uterine contractility (Bahamondes et al., 2015).

Amenorrhea development in some patients may be considered an additional effect rather than a negative side effect of treatment. While patients may consider amenorrhea unpleasant, they will be convinced otherwise after appropriate counselling about the benefits of amenorrhea and the prevention of anemia. It has been shown that there is a high amenorrhea rate of 50-60% after long-term use (Bahamondes et al., 2015; Endrikat et al., 2012).

High satisfaction and continuation rates in the present study can be attributed to the efficacy and safety of LNG-IUS. Convenience and user-independence in using this drug contribute to the high patient satisfaction. High continuation rates mean that the patients enjoy the drug's benefits without suffering any serious side effects (Gupta et al., 2013).

From a functional perspective, the improvement in clinical symptoms translates into enhanced quality of life. Patients report increased energy levels, reduced fatigue, improved daily functioning, and decreased absenteeism (National Institute for Health and Care Excellence, 2018).

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This highlights the broader impact of effective HMB management beyond purely clinical parameters.

Despite these advantages, certain limitations must be considered. Variability in study designs, differences in outcome measurement methods, and heterogeneity in patient populations may influence the generalizability of results. Additionally, initial side effects such as irregular bleeding may affect early continuation rates. However, these effects are usually transient and resolve with continued use (Bahamondes et al., 2015).

Conclusion

LNG-IUS can be regarded as an extremely efficacious and reliable form of therapy for heavy menstrual bleeding. In this case, LNG-IUS proved to produce a profound decrease in menstrual blood loss, considerable improvements in haematological factors, satisfactory pain relief, and high rates of patient satisfaction. The superior performance compared to traditional medical treatments is manifested not only in its effectiveness but also in its long-term outcomes. The local mode of action and low dependence on patient cooperation make LNG-IUS a favourable choice in practical applications. The appearance of amenorrhea and enhancement of QoL constitute additional evidence of the therapy's efficiency. Also, the reduced incidence of surgical procedures indicates the treatment's economic benefits and invasiveness. In summary, LNG-IUS may be recommended as the first-choice treatment for heavy menstrual bleeding among eligible women.

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