

# A Study to Analyze the Efficacy of Levonorgestrel Intrauterine System in the Management of Abnormal Uterine Bleeding among Urban Indian Women

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## ABSTRACT

**Objective:** The study tried to analyze the efficacy of levonorgestrel intrauterine system (LNGIUS) for the treatment of heavy menstrual bleeding in the urban and suburban Indian women.

**Materials and methods:** The present study was conducted in the Department of Gynecology and Obstetrics, Vivekananda Institute of Medical Sciences, Ramakrishna Mission Seva Pratishthan, Kolkata, over a period of 1 year. A total of 20 patients suffering from abnormal uterine bleeding in the age group of 20 to 45 years were recruited in this study. The LNGIUS was inserted in all the women and they were followed up at the end of 3, 6, and 12 months. All subjects completed 1 year duration of follow-up. We used the Student's paired t-test to evaluate the reduction in the menstrual blood loss, passage of clots, and increase in hemoglobin concentration at each point from the baseline.

**Results:** At the end of 6 months, most (90%) of the women had an acceptable bleeding, with 10% having amenorrhea (pictorial blood-loss assessment chart score 0). Statistically significant improvement in the hemoglobin level was observed at the end of 3, 6, and 12 months postinsertion. The level of satisfaction increased steadily with time.

**Conclusion:** Levonorgestrel intrauterine system is an effective reversible treatment for menorrhagia. Levonorgestrel intrauterine system can be used as an effective alternative to hysterectomy in the future in the urban and suburban affluent Indian women.

**Keywords:** Abnormal uterine bleeding, Hysterectomy, Levonorgestrel intrauterine system.

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## INTRODUCTION

In most countries, the levonorgestrel intrauterine system (LNGIUS) is licensed both for contraception and treatment of menorrhagia.<sup>1</sup> The LNGIUS is an effective and reversible treatment modality for menorrhagia. Abnormal uterine bleeding (AUB) exerts a significant burden to the society. Women suffer from a significant reduction in quality of life. There is no consensus about how best these women could be treated and that uncertainty is reflected by variations in hysterectomy rates both nationally and internationally. Menorrhagia is in fact the commonest cause for performing a hysterectomy; indeed it is the definitive treatment modality but hysterectomy being a major surgical procedure entails substantial morbidity, even mortality, and also affects the psychological aspect of women. Over the past few years, there has been a declining trend in the rate of hysterectomy performed for menorrhagia. This is attributable to greater acceptance of different modalities including minimally invasive procedures like endometrial ablation, balloon hydrotherapy, and transcervical resection of endometrium. These are becoming popular because of their minimal hospital stay, low complication rate, and good efficacy. In AUB, it is associated with a significant reduction in the number of days of bleeding and menstrual blood loss (MBL). Comparative trials from various studies suggest that use of LNGIUS can be a therapeutic alternative to hysterectomy in menorrhagia.<sup>2</sup> This study is a humble attempt to assess the suitability and applicability of the device in Indian perspective for treatment of excessive uterine bleeding.

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## MATERIALS AND METHODS

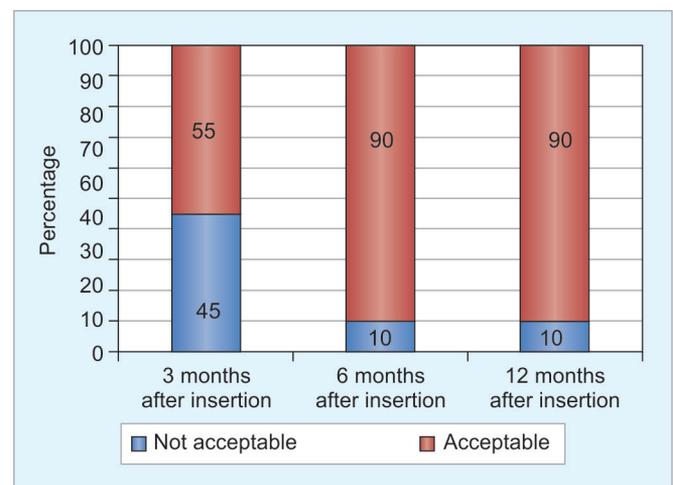
This study was carried out in Department of Obstetrics and Gynecology at Ramakrishna Mission Seva Pratishthan, Kolkata, India. A total of 20 women with AUB were recruited and they were studied for age, parity, education, socioeconomic status, control of menorrhagia, adverse effects, etc. Of the 20 women fitted with LNGIUS, all of them continued with the follow-up period of 1 year. The aims and objectives of this study were to evaluate the following: The efficacy of the LNGIUS in controlling excessive MBL in menorrhagia due to AUB; impact of device on hemoglobin status of subjects as menorrhagia commonly leads to anemia; menstrual pattern following LNGIUS use; common side effects associated with its use; incidence of failure leading to surgical intervention; women satisfaction and acceptability of device. The study is a prospective noncomparative study.

Inclusion criteria include women of reproductive age group (20–45 years); diagnosed with AUB; MBL > 80 mL/cycle in the absence of pregnancy and lactation, with acceptable contraception. Exclusion criteria included history of (h/o) undiagnosed uterine bleeding; nulliparity with no h/o acute fatty liver of pregnancy, breast Ca, pelvic inflammatory disease, postmenopausal bleeding, active thromboembolic disorder, used injectable hormones in last 1 year, fibroid, adenexal tumor, and malignancy.

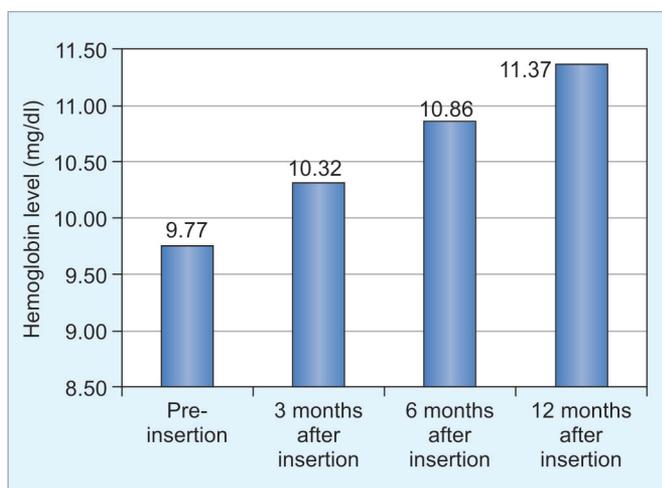
## RESULTS AND ANALYSIS

We used the Student's paired t-test to evaluate the reduction in the MBL, passage of clots, and increase in hemoglobin concentration at each point from the baseline. A p-value of <0.05 was considered significant for all the tests performed. In all cases, a detailed history was taken and physical examination was done and noted on a proforma. The age of patients in the study population ranged from 20 to 45 years. Maximum number of patients belonged to the age group of 40 to 45 years (45%) and minimum in 25 to 30 years of age. The mean age of patients presenting with the complaints of menorrhagia was  $39.95 \pm 5.02$  years (mean  $\pm$  standard deviation). Maximum number of women (90%) belonged to the higher monthly family income group, i.e., Rs. 5,000 and above. Only 10% of women had monthly family income Rs. <5,000. The largest proportion of women had completed their secondary education. Only 5% of women were illiterate. Maximum number of women (65%) was of urban origin, followed by 30% patients from suburban locality. Only 5% of women coming from rural area opted for this treatment. Most of the women participating in the study were para<sub>2or3</sub> (75%). Maximum number of women (75%) had excessive menstrual flow along with increase in duration of bleeding. Only 25% of subjects had only

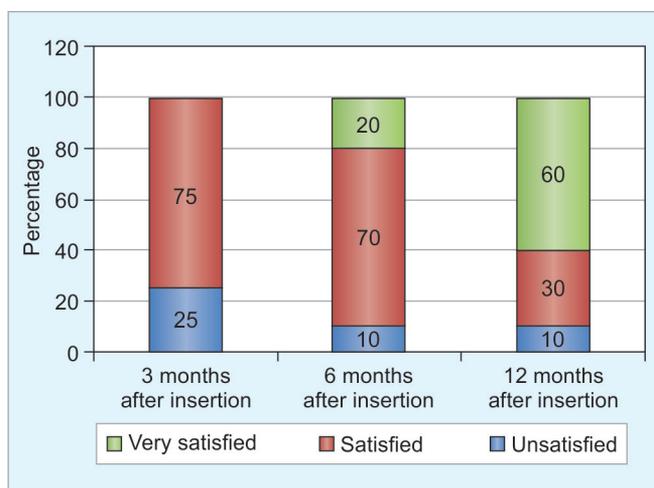
increase in flow. Most women (85%) were suffering from their symptoms for 6 to 12 months before they came for treatment. Mean duration of the symptoms was  $8.15 \pm 4.16$  months. Maximum number of women (90%) had proliferative endometrium. Only 5% subjects had secretory endometrium and another 5% had simple hyperplasia. All the 20 women completed 1 year follow-up at the end of 3 months following insertion of LNGIUS. Most of the women (55%) had acceptable bleeding, i.e., pictorial blood-loss assessment chart (PBAC) score between 0 and 100 (MBL <80 mL); 35% had moderate bleeding, i.e., PBAC score of 100 to 200 (MBL 80–160 mL). Persistent heavy bleeding, i.e., PBAC score >200 (MBL >160 mL) was seen in 10%. At the end of 6 months, most women (90%) had acceptable bleeding, out of which 10% had amenorrhea. Persistent heavy bleeding was seen in none of the women. At 12 months follow-up, 35% of women has amenorrhea (PBAC score 0). None of the women had persistent heavy bleeding at 12 months. A total of 90% of women had acceptable bleeding and 10% had moderately acceptable bleeding (Graph 1). Only 30% of women at 3 months and 15% of women at 6 months postinsertion complained of passage of clots. None of the subjects had passage of clots at 1 year postinsertion. Thus, the reduction in passage of clots at the end of 3, 6, and 12 months was statistically significant with p-value <0.001 for each of 3 periods of follow-up. The percentage of amenorrhea following insertion at 3, 6, and 12 months were nil, 10%, and 35% respectively. Statistically significant improvement in the hemoglobin level was observed at the end of 3, 6, and 12 months postinsertion. The preinsertion mean hemoglobin level was  $9.77 \pm 0.70$  gm/dL. The postinsertion mean hemoglobin level at 3, 6, and 12 months was  $10.32 \pm 0.65$ ,  $10.86 \pm 0.52$ ,  $11.37 \pm 0.49$  gm/dL respectively. Maximum improvement was seen at the end of 12 months, showing an increase of 16% from the preinsertion level (Graph 2).



**Graph 1:** Distribution of cases according to the menstrual pattern following insertion of the LNGIUS



**Graph 2:** Improvement in the hemoglobin following insertion of the LNGIUS



**Graph 3:** Evaluation of patient satisfaction according to subjective assessment of MBL

**Table 1:** Complications following the insertion of LNGIUS

Complication	No. of patients (at 12 months)	Percentage
Spotting/irregular vaginal bleeding	3	15
Expulsion	1	5
Perforation	0	0
Pelvic pain	1	5
Excessive weight gain	0	0
Acne	0	0
Headache	0	0
Edema	0	0
Breast tenderness	0	0

At the end of 3 months, 75% women were satisfied and 25% were not satisfied with the treatment results. At the end of 12 months, number of women who were satisfied was 30%, 60% were very satisfied, and only 10% were not satisfied. The level of satisfaction increased steadily with time and even though 10% of women were not satisfied, 100% of the women wanted to continue with the treatment (Graph 3). The most common complication was irregular vaginal bleeding in 15% of women at 1 year of use. Systemic progesterone side effects were seen in none of the women. These complications resolved without treatment (Table 1).

**DISCUSSION**

This is a prospective study including 20 women, mean age of presentation was 39.95 ± 5.02 years, i.e., perimenopausal age group. A total of 90% women in the study belonged to the higher monthly family income group of Rs. 5,000 or more. This is because the device being costly was affordable by the women belonging to higher socioeconomic status. Most of the women (50%) in the study group had completed their education up to higher secondary

level and only 5% were illiterate. This confirms the fact that education helps us to counsel the women regarding benefits of conservative treatment and motivate them for using a novel form of treatment. They are also more compliant with the follow-up; 65% of our subjects hailed from urban areas, 30% from sub-urban, and only 5% of them came from rural areas. This distribution reflects the easier motivation of urban people for using conservative management. Like in the study by Hurskainen et al<sup>3</sup> most women participants in our study also were para<sub>2</sub> with completed families. This corroborated with the fact that AUB as a cause of menorrhagia is seen mostly in multiparous women. Most of the women suffering from menorrhagia had both increase in the amount of flow along with increase in duration of bleeding. Only 25% of women had only increase in amount of flow. It was seen that most women in all similar studies had menorrhagia as the primary complaint. All the 20 women completed their whole follow-up period of 12 months. Menstrual blood loss before and after insertion of LNGIUS was assessed by PBAC score.<sup>4</sup> The mean PBAC score for this group was 341 ± 92 with a range of 130–506. The postinsertion mean PBAC score at 3 months range represented a reduction of 67% in MBL, at 6 months represented and decrease of 88% of MBL, similarly at 12 months, a reduction of 94% in MBL after 1 year of insertion of LNGIUS was noted (Graph 1). Xiao et al<sup>5</sup> reported percentage reduction of MBL of 78 and 83.8% from baseline at 6 and 12 months respectively. The p-value in this study was <0.001. Recent results of Nagrani et al<sup>2</sup> of 4 to 5 years long-term follow-up of the women recruited in their original study demonstrated a continuation rate of 50% after a mean 54 months of follow-up. Only 26.4% eventually had surgical treatment and an overall 67.4% avoided surgery, despite 50% not continuing the treatment. The percentage of women having amenorrhea by 3, 6, and 12 months in this study was 0, 10, and 35%

respectively. Amenorrhea is achieved maximally at the end of 12 months of treatment. Cameron<sup>6</sup> reported amenorrhea in 20% of women after 6 months, rising to about 50% after 5 years follow-up. In the current series, mean hemoglobin level increased by 6% from 9.77 gm/dL at preinsertion to 10.32 gm/dL at 3 months after insertions, at 6 months a rise of 11%, which was statistically very significant as analyzed by paired t-test. Similarly at 12 months, a total rise of 16% from preinsertion level was noted (Graph 2). However, Xiao et al<sup>5</sup> observed an increase in mean Hb% levels of 7.24% at 3 months, 8.64% at 6 months and 9.79% at 12 months. In the present study, the level of women satisfaction on subjective assessment increased steadily with time. Only 10% of women remained unsatisfied at the end of 1 year of treatment, but none of them chose to discontinue the treatment (Graph 3). Hurskainen et al<sup>1</sup> conducted a trial where, after 12 months, 20% of women in LNGIUS group underwent hysterectomy and 68% continued to use the system, with 69% experiencing amenorrhea or minimal bleeding. The most common complication was irregular vaginal bleeding mostly in the form of spotting in about 40% patients at 3 months postinsertion. This complaint reduced to about 15% of patient at 6 months. A total of 15% of the women persistently complained of spotting even at 12 months of follow-up (Table 1). In a study by Taru et al,<sup>7</sup> expulsion rate was 4.2%, removal rate was 7.14%, and continuation rate is 88.57%. About 2.28% patients underwent hysterectomy because of continuous bleeding even after 3 to 4 months of insertion. Thus, a longer duration of follow-up is at more conclusive evidence for expulsion rates.

## CONCLUSION

The LNGIUS is a meaningful rationale for reduction of menstrual bleeding in menorrhagia. It also preserves the fertility when desired and is an excellent contraceptive. Studies have shown that LNGIUS reduces the MBL by 80 to 96% over a period of 1 year with a low rate of adverse events; 60% of patients avoid a major surgery. Improvement in quality of life is similar to hysterectomy.

Overall cost of LNGIUS is significantly lower. This study also shows that LNGIUS is an effective reversible treatment for menorrhagia. Satisfaction with treatment is high. Irregular vaginal bleeding is the most common adverse effect, especially in first 3 months following insertion, which can be managed well by preinsertion counseling. Systemic effects are largely absent. The present study also shows that LNGIUS has a potential to replace hysterectomy as a mode of treatment modality in future in a certain group of women as it is easy to insert, has sustained effect, provides contraception, and is well-tolerated, cost-effective, reversible, and may reduce the need for surgery.

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