

# Are women satisfied when using levonorgestrel-releasing intrauterine system for treatment of abnormal uterine bleeding?

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## ABSTRACT

**Aim:** To determine the efficacy of levonorgestrel intrauterine system (LNG IUS) in treatment of abnormal uterine bleeding (AUB) in women over 35 years and to determine satisfaction of users of LNG IUS in case of AUB.

**Materials and Methods:** This was a multicentric, retrospective, and observational study. Case records of patients with AUB from the hospitals in Pune, Delhi, and Gurgaon for the last 6 years were examined. Records of 80 women who had an LNG IUS inserted were included. The chief complaints and their duration were recorded. Investigation results, histopathology reports, and date of LNG IUS insertion were noted. The incidence of spotting, heavy menstrual bleeding, pain, expulsion, and amenorrhea were recorded at 3, 6, 12, and 18 months following treatment. Following this a telephonic interview was conducted to determine the efficacy of LNG IUS in treating the symptoms. Patients' satisfaction in percentage was also noted and they were asked if they would recommend the LNG IUS to other women.

**Results:** The mean age of women was 42.3 years. 77.5% of the women had menorrhagia as the chief complaint, and the mean duration was 12 months. Fibroids and adenomyosis were the most common pathology, present in 21.3% and 20% of the patients respectively. At 3 months, spotting seemed to be the predominant symptom (59.4%) and only 15% women had heavy bleeding. 49.3% of women were asymptomatic at 6 months. 27.5% had amenorrhea by the end of 18 months. 14 women in whom the device was expelled or removed due to persistent symptoms, underwent hysterectomy at various stages during the study period. Overall patient satisfaction was high at about 80%. Furthermore, 73.8% patients agreed to recommend it to other women.

**Conclusion:** LNG IUS seems to be a viable and effective treatment option for AUB in women after 35 years. There is a high rate of patient satisfaction in appropriately selected patients.

**Key Words:** Menorrhagia, non-surgical options, peri-menopausal women

## INTRODUCTION

Abnormal uterine bleeding (AUB) is the commonest symptom among women of reproductive age group presenting to the gynecologic out-patient department (OPD). Many women may present, after many years of suffering in silence. Once menopause sets in, this is known to resolve. Women, therefore, need some therapy to tide over this difficult time. Although, there are several hormonal and non-hormonal medications for treatment,

some have serious side-effects while others are unpopular because they are ineffective and temporary in nature.<sup>[1]</sup> Many women, therefore, resort to hysterectomy due to lack of compliance and low efficacy of the medication much against their desire. There has been a constant search for a suitable alternative to hysterectomy that can treat this midlife problem until the woman attains menopause.

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Levonorgestrel intrauterine system (LNG IUS) is one such feasible option in these women. It is known to reduce the amount of bleeding by over 90% due to its continuous progestogenic effect on the endometrium.<sup>[2]</sup> LNG-IUS has also been used in patients having fibroids,<sup>[3]</sup> adenomyosis<sup>[4]</sup> and endometriosis.<sup>[5]</sup> Such usage can reduce the need for hysterectomy, with its morbidity, and mortality. Here, we endeavored to study the satisfaction among users of LNG IUS in terms of reduction in symptomatology.

## AIMS

1. To determine the efficacy of LNG IUS in treatment of AUB in women over 35 years.
2. To determine the satisfaction of users of LNG IUS in case of AUB.

## MATERIALS AND METHODS

This was a multicentric, retrospective, and observational study. Case records of patients with AUB presenting to Gynecology OPD of hospitals in Pune, Delhi, and Gurgaon for the last 6 years were examined. Women over 35 who had an LNG IUS inserted for AUB were included in the study. Records of 80 women who fulfilled the inclusion criteria were scrutinized for the chief complaints, duration of complaints, and ultrasound findings. Complete blood count, Thyroid Stimulating Hormone (TSH) levels, and Pap smear if carried out were noted down. Women were excluded from the study if they were found to have a uterus larger than 12 weeks as recorded in the case file, clinical suspicion of malignancy, adnexal masses, and pelvic inflammatory disease. Malignancy was excluded by clinical examination, cervical cytology, and endometrial sampling report. Histopathology reports and date of LNG IUS insertion was noted.

The incidence of spotting heavy menstrual bleeding, pain, expulsion, and amenorrhea were recorded at 3, 6, 12, and 18 months following treatment. Following this, telephonic interview was conducted to determine the efficacy of LNG IUS in treating the symptoms. Spotting was said to be present if patient needed to use sanitary protection following insertion of LNG IUS. Heavy menstrual bleeding was defined as passage of clots or use of double protection, soiling of underclothes despite using protection or passage of clots in toilet bowl. Amenorrhea was defined as complete absence of bleeding. A follow-up sonography report 6 months after LNG IUS insertion was noted down wherever it was performed, specifically with reference to the thickness of the endometrial lining and size of fibroid when present. Patients' satisfaction in percentage was also noted and she was asked whether she would recommend the LNG IUS to other women.

## Statistical analysis

Statistical analysis was carried out by using SPSS 13.  $P < 0.5$  was taken as significant. Results were obtained using frequencies, cross tabs and Chi-square test.

## RESULTS

Out of a total of 80 patients in our study, majority of the women belonged to the age group between 35 and 40 followed by 41-45. The mean age of women in this study was 42.3 years.

## COMPLAINTS

Seventy seven percent of patients presented with menorrhagia. Average duration of complaints was 12 months [Figure 1].

## ETIOLOGY

Pre-treatment ultrasound revealed fibroids and adenomyosis as the commonest pathology present in 21.3% and 20% of the patients respectively. This was followed by thick endometrium in 18.8%, probably denoting endometrial hyperplasia. 18.8% of women did not have any abnormal ultrasound finding, indicating dysfunctional uterine bleeding as the etiology. 5% of the women had endometriosis. Another 16% women had a bulky uterus on ultrasound.

## Symptom relief

Evaluating symptomatic relief post-treatment we found that at 3 months, spotting seemed to be the predominant symptom (59.4%), and only 15% women had heavy bleeding. Twenty five percent of patients had significant reduction in bleeding and they felt significantly better ( $P = 0.00$ ) [Table 1]. At 6 months, the number of women with spotting reduced considerably to 30.7% as did heavy bleeding, which reduced to 6.7%. Most patients (49.3%) were asymptomatic at 6 months.

Both spotting and heavy bleeding reduced remarkably by 12 months to 17.1% and 1.4% respectively and 22.9% patients had amenorrhea by this time. Amenorrhea rate went up to 27.5% by the end of 18 months.

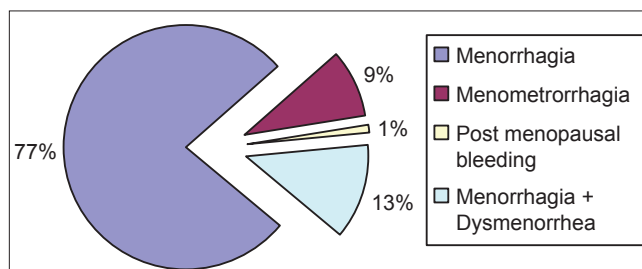


Figure 1: Frequency of symptoms

Patients symptoms were correlated with pathology detected on ultrasound. Table 2 shows how patients' symptoms improved gradually. Significant reduction in bleeding was noted in patients with adenomyosis.

Thirteen patients (56.8%) with simple hyperplasia without atypia had symptom relief by the end of 6 months whereas only 33% patients with proliferative endometrium had a reduction in bleeding. Patient with secretory endometrium did not respond to LNG IUS [Table 3]. For 23 patients, histopathology report was not available.

### Failure rate

In the present study, the expulsion rate was 7.5%, one of which happened during the 1<sup>st</sup> month after insertion, two within 3 months, two at 12 months and one at 18 months. It was found that patients with thick endometrium had maximum expulsion and removal of LNG IUS [Figure 2].

Eight patients had to have the LNG IUS removed due to heavy bleeding or persistence of irregular and frequent bleeding/spotting at 18 months. All of them underwent hysterectomy.

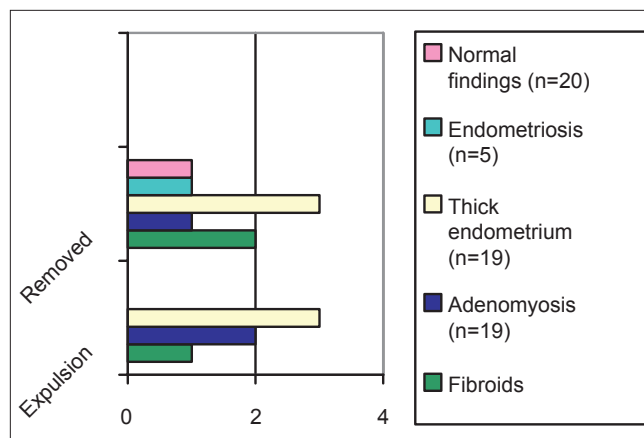


Figure 2: Correlation of ultrasound pathology with expulsion/removal

Table 1: Symptoms after LNG IUS insertion

Symptoms/ months	3 months n=79* (%)	6 months n=75** (%)	12 months n=70*** (%)	18 months n=69**** (%)	P value
No complaints/ bleeding reduced	19 (24)	37 (49.3)	41 (58.6)	45 (65.2)	0.004 Significant
Spotting	47 (59.4)	23 (30.7)	12 (17.1)	4 (5.8)	0.007 Significant
Heavy bleeding	12 (15.2)	5 (6.7)	1 (1.4)	1 (1.5)	0.000 Significant
Amenorrhea	1 (1.2)	10 (13.3)	16 (22.9)	19 (27.5)	0.003 Significant

LNG IUS: Levonorgestrel-releasing intrauterine system, P value <0.5 Significant

Table 2: Correlation of pathology with patient symptoms

Symptoms (over 3, 6, 12, 18 months)	No complaints/ symptomatically improved				Spotting				Heavy bleeding				Amenorrhea			
	3	6	12	18	3	6	12	18	3	6	12	18	3	6	12	18
Fibroids (n=17)	6	7	8	10	8	7	5	2	3	1	1	1	0	1	2	3
Adenomyosis (n=19)	5	10	10	10	10	2	1	1	1	1	0	0	0	5	6	6
Thick endometrium (n=19)	4	9	10	9	13	6	4	1	1	1	0	0	0	0	0	3
Endometriosis (n=5)	2	2	3	3	2	1	0	0	1	1	0	0	0	1	1	1
Normal findings (n=20)	5	8	10	13	14	7	2	0	1	1	0	0	0	3	7	6

P value at 3 months=0.63, P value at 6 months=0.48, P value at 18 months=0.8, USG: Ultrasonography

Table 3: Correlation of histopathology with patient symptoms

Symptoms (over 3, 6, 12, 18 months)	No complaints/ symptomatically improved				Spotting				Heavy bleeding				Amenorrhea			
	3	6	12	18	3	6	12	18	3	6	12	18	3	6	12	18
Proliferative (n=30)	4	10	16	19	22	12	5	3	4	3	1	0	1	4	6	5
Secretory (n=1)	0	0	0	1	0	1	1	0	1	0	0	0	0	0	2	0
Simple hyperplasia without atypia (n=23)	5	13	15	17	15	6	3	0	2	1	0	0	0	1	1	3
Complex hyperplasia without atypia (n=3)	0	1	2	1	3	1	0	0	0	0	0	0	0	1	0	2

For 23 patients, histopathology report was not available

### Patient satisfaction

Patients who were found to have thick endometrium were most dissatisfied ( $60 \pm 43$ ;  $P = 0.04$ ) and had maximum removal of LNG IUS [Table 4]. Patients with adenomyosis, bulky uterus, and normal ultrasound findings responded well to treatment and were highly satisfied (82%). These were the ones who would also highly recommend this treatment modality to other patients (more than 80%).

### DISCUSSION

AUB is a common symptom among women of both reproductive age group and perimenopausal women. Fibroids, adenomyosis, and endometriosis are common gynecological pathologies causing AUB. Together with dysfunctional uterine bleeding these pathologies account for AUB which leads to loss of quality of life in many women and several times leads to a hysterectomy which itself is not without side effects and is many a time avoidable. LNG IUS is an effective and reversible treatment option for benign lesions causing menorrhagia, which has been well-documented in literature.<sup>[6,7]</sup>

LNG IUS reduces mean blood loss more than tranexemic acid, non-steroidal anti-inflammatory drugs, danazol, oral progestogens and combined oral contraceptives.<sup>[8]</sup>

Majority of the women in this study belonged to the reproductive age group as is expected for women with AUB. Since these women still have several years prior to menopause, it becomes relevant to offer them an effective and long-term option besides hysterectomy.

The predominant symptom seemed to be heavy blood loss and only a small number of women had dysmenorrhea, which is interesting because fibroids and adenomyosis were present in a total of 40% of women. Hence in both these categories it becomes apparent that the bleeding was the main reason for seeking medical help. This is comparable to that in a study by Robinson *et al.*<sup>[9]</sup>

Most of the women had actually suffered for a period of

**Table 4: USG findings and satisfaction**

USG findings	Satisfaction (%) mean $\pm$ SD	P value
Fibroids (n=17)	70.3 $\pm$ 3	0.25
Adenomyosis (n=19)	82.3 $\pm$ 30.4	0.25
Thick endometrium (n=19)	60 $\pm$ 43	0.04
Endometriosis (n=5)	69 $\pm$ 41	0.68
Normal findings (n=20)	82 $\pm$ 24	0.37

USG: Ultrasonography

1 year prior to presenting in the OPD, which made it even more necessary for them to have an effective mode of treatment. Several women had in fact tried conservative medical methods of treatment including hormones during this period, with no relief.

LNG IUS seems to be an effective alternative for treatment of AUB related to fibroids. In a systematic review by Zapata *et al.*,<sup>[10]</sup> it was revealed that most women with uterine fibroids using LNG IUS were likely to have less menstrual blood loss after insertion, despite some occurrence of irregular bleeding. LNG IUS may have higher rates of expulsion in these women compared to those without fibroids.

A study by Socolov *et al.*,<sup>[3]</sup> evaluating LNG IUS use in menorrhagia due to fibroids showed that 96% of the patients had achieved oligomenorrhea by 1 year.

We found in the present study that among women with fibroids, spotting seemed to be the predominant symptom at 3 months post-insertion (47%), and continued to be so at 6 months (41.1%). At 12 months, however, 47% of the women were symptom free and by 18 months majority of the patients (76.4%) were asymptomatic and actually achieved amenorrhea.

A total of 70.3% patients with fibroids in the present study were satisfied and 82.4% would recommend this treatment to other users. Similarly, in the study by Socolov *et al.*,<sup>[3]</sup> 89% of women with fibroids considered LNG IUS as a good treatment.

The cases with adenomyosis seemed to respond very well and after the first 6 months most of the patients were asymptomatic (52.63%) and 26.3% had amenorrhea at 6 months and 31.57% at 12 months. Similar was the case with the thick endometrium group. This is comparable to the study by Cho *et al.*,<sup>[4]</sup> where 23% patients had amenorrhea by 12 months. Hence LNG IUS may be a suitable alternative to hysterectomy in adenomyosis.

In the endometriosis group, the number of patients was insufficient to comment definitely on improvement of symptomatology.

In the group with no ultrasound abnormality (dysfunctional uterine bleeding), it took 12-18 months to achieve symptomatic relief (50% at 12 months and 65% at 18 months).

On histological evaluation of the endometrium, most women had proliferative endometrium (37.5%) followed

by simple hyperplasia (28.75%) without atypia. Only 3 (3.75%) women had complex hyperplasia without atypia and 1 patient had a secretory endometrium.

Among the LNG IUS users in the endometrial hyperplasia group (simple and complex), 69.2% of the patients persisted to have spotting at 3 months and 65.3% had resolution of symptoms at 1 year.

In a study by Haimovich *et al.*,<sup>[11]</sup> there was 50% reduction in bleeding at 3 months and complete cessation of bleeding at 24 months in women with simple endometrial hyperplasia.

Expulsion/removal was compared with ultrasound findings. A total of six patients expelled the device and for eight, the LNG IUS was removed. Interestingly, expulsion or removal was not found to be related to uterine pathology ( $P = 0.132$ ). This was found to be more in patients with menorrhagia and menometrorrhagia ( $P = 0.002$ ).

LNG IUS had to be removed in six patients due to persistent heavy bleeding in spite of waiting for 3-12 months. And in the remaining two it was removed due to persistent spotting/bleeding at 18 months. All these patients opted to undergo hysterectomy.

The LNG IUS got expelled within 3 months of insertion for all 6 patients except one. She was 39 years old with fibroid uterus and menorrhagia. She had complete relief from her symptoms for 1 year. Her heavy bleeding returned after a year and at that time, the LNG IUS was found in the cervical canal.

Overall 74% of women would recommend the LNG IUS to other women for treatment of AUB.

## CONCLUSION

LNG IUS seems to be a viable and effective treatment option for AUB in women after 35 years. There is a

high rate of patient satisfaction in appropriately selected patients.

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