

## A Non- surgical lifeline for Abnormal uterine bleeding (AUB) - the LNG IUS

Garg Seeru<sup>1,\*</sup>, Soni Anita<sup>2</sup>

<sup>1</sup>Junior Consultant Obstetrician and Gynecologist, <sup>2</sup>Consultant Obstetrician and Gynecologist, Dr LH Hiranandani Hospital, Hillside Avenue, Hiranandani Gardens, Powai, Mumbai-400076, Maharashtra, India.

\*Corresponding Author:  
E-mail: drseeru@yahoo.co.in

### Abstract

**Objective:** To study effectiveness of LNG IUS (levonorgestrel releasing intrauterine system) insertion for patients with Abnormal uterine bleeding and to assess whether the LNG IUS can provide a conservative alternative to hysterectomy in the treatment of AUB. To correlate the cost effectiveness, symptomatic relief and psychological relief achieved with LNG IUS insertion.

**Materials and methods:** It was a prospective non-comparative study with patients who had heavy menstrual bleeding and/or dysmenorrhea and diagnosed as adenomyosis or Idiopathic AUB (According to the FIGO PALM-COEIN Classification of AUB<sup>1</sup>). Thirty patients had LNG IUS insertion whereas another thirty patients opted for hysterectomy. We analyzed them in terms of symptomatic relief, cost effectiveness and psychological relief.

**Results:** After LNG IUS insertion 93.33% of patients had significant decrease in blood loss and 76.6% had significant decrease in pain analyzed on visual analog score (VAS). Forty % of patients complained of inter-menstrual spotting but only 6.6 % had irregular heavy bleeding and only 2 patients out of 30 requested hysterectomy post LNG IUS insertion. 90% patients developed amenorrhea after 1year and only 1 woman required removal of LNG IUS as she was dissatisfied due to vaginal discharge. Hospital stay for LNG IUS was only 6-8 hours while it was 48-72 hours for patients who underwent hysterectomy.

**Conclusion:** There is a significant relief in symptoms along with significant decrease in cost with LNG IUS insertion with a psychological satisfaction of conserving the uterus. Thus the LNG IUS is an excellent and cost effective alternative to surgical management in AUB.

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<b>Quick Response Code:</b> 	<b>Website:</b> <a href="http://www.innovativepublication.com">www.innovativepublication.com</a>
	<b>DOI:</b> 10.5958/2394-2754.2016.00005.9

### Introduction

Heavy menstrual bleeding (HMB) is defined as excessive menstrual blood loss which interferes with a woman's physical, social, emotional and/or material quality of life. It can occur alone or in combination with other symptoms.<sup>2</sup> It is objectively defined as prolonged (>7 days) or excess blood loss of more than 80ml per menstrual cycle.<sup>3</sup>

Idiopathic menorrhagia (IM) or idiopathic AUB is characterized by heavy menstrual bleeding without identifiable pathology. Approximately 30% of women of reproductive age experience excessive blood loss during menstruation.<sup>4</sup> While in nearly half of all cases no organic pathology is found, a number of risk factors may contribute to the development of HMB.<sup>4</sup> Adenomyosis is a common problem affecting five percent of women in the reproductive age<sup>5</sup> and is one of the commonest causes of dysmenorrhea and menorrhagia.

Conservative medical treatment for IM has been disappointing. Conservative surgical methods like

endometrial ablation or resection became popular to avoid hysterectomy. In past years, the only definitive treatment for adenomyosis was hysterectomy.

One minimally invasive procedure for control of IM is insertion of LNG-IUS. Levonorgestrel is released from this system at a rate of 20 mcg/24 hours. It suppresses endometrial growth, the glands of the endometrium become atrophic and the epithelium becomes inactive. This system has been shown to decrease the amount and duration of normal menstrual flow and its efficacy in IM is well documented. According to clinical practice guidelines on menorrhagia, 2010, placement of LNG IUS is recommended in idiopathic AUB.<sup>6</sup> Along with the high contraceptive efficacy, LNG-IUS has shown benefits and improvement of symptoms in adenomyosis and endometriosis.<sup>7, 8</sup>

Hence this study was undertaken to study the effectiveness of LNG IUS insertion for patients with idiopathic abnormal uterine bleeding and adenomyosis and to assess whether the LNG IUS can provide a conservative alternative to hysterectomy in the treatment of idiopathic abnormal uterine bleeding and adenomyosis.

### Materials and Methods

Sixty women who presented with heavy menstrual bleeding and /or dysmenorrhoea and were diagnosed as adenomyosis or idiopathic AUB and had no contraindication to IUS insertion or hysterectomy were

recruited for the study after deciding their management option. This was a prospective comparative study conducted at our tertiary care hospital over a period of two years from June 2013 to May 2015 after approval from the hospital Scientific and Ethics committee.

The diagnosis of adenomyosis or Idiopathic AUB was made according to the FIGO PALM-COEIN Classification of AUB. Adenomyosis was diagnosed on the basis of trans-vaginal ultrasound criteria by Duelohm et al<sup>9</sup>: Globular uterus or asymmetric thickening of the anterior or posterior uterine wall; a poorly defined endometrial-myometrial junction or a focal or diffuse heterogeneous myometrial echotexture without a discrete mass to suggest a myoma. A myometrial cyst was defined as a round anechoic area of 1-7 mm diameter. Heterogenous myometrium was defined by the presence of an indistinctly marginated myometrial area with decreased or increased echogenicity. Heavy menstrual bleeding without identifiable pathology was diagnosed as Idiopathic AUB. Thirty women were in the LNG IUS insertion group and thirty had opted to undergo hysterectomy after discussing with them.

**Exclusion criteria:** Suspicion of pregnancy; congenital or acquired uterine anomaly like fibroid uterus which can distort the uterine cavity; acute pelvic inflammatory disease (PID) or history of PID; post-partum endometritis or infected abortion in the past three months; untreated acute cervicitis or vaginitis; suspected uterine or cervical neoplasia or abnormal Pap smear; previously inserted IUD that hasn't been removed; acute liver disease or liver tumour and known or suspected carcinoma of breast.

We excluded malignancy by complete clinical examination, Pap smear and post-menstrual ultrasonography to check endometrial thickness (<8 mm). Pre-anaesthesia checkup after routine investigations was done for all. The LNG IUS group underwent hysteroscopy with LNG IUS insertion under general anaesthesia as a day care procedure and were discharged on the same day. The other thirty women were admitted to the ward and underwent Laparoscopic hysterectomy. They were discharged after 48-72 hours of surgery.

All women were followed up for 1 year post-operative. The women in the IUS group were asked to mark the days of bleeding and spotting in the menstrual diary and the amount of bleeding in the pictorial blood assessment chart provided with the IUS.

We analyzed them in terms of symptomatic relief (bleeding and pain), cost-effectiveness of the procedure and psychological relief (overall satisfaction). This was assessed by using the menstrual diary and a visual analog scale (VAS) at inclusion in the study, after six months and after 12 months of use. VAS is a 10 cm long scale.

**VAS for dysmenorrhoea:** The left end of the scale, that is score 0, corresponded to no pain and the right end, that is score 10, corresponded to unbearable pain.

**The severity of pain was graded as:** 1-4 as mild pain, 5-8 as moderate pain and 9-10 as severe pain.

**The menstrual pattern was assessed by the menstrual diary and classified as:** normal menses, absent bleeding, infrequent bleeding, scanty regular bleeding, heavy regular bleeding, frequent heavy bleeding, irregular bleeding or irregular spotting.

**Women were asked to mark VAS for overall satisfaction:** The left end of the scale, that is score 0, corresponded to not at all satisfied and the right end, that is score 10, corresponded to very satisfied.

## Results

The women in the study belonged to the age group 38-44 years. All women had completed family and reproductive function was not a concern for them. The etiological distribution is mentioned in Table 1.

The procedure of hysteroscopy with LNG IUS insertion was described as easy by the women and was well tolerated by them. There was no post-operative pain associated with the procedure and they were discharged within two to three hours of procedure.

Post operative pain relief was required by all in the laparoscopic hysterectomy group for about one week. There were no post-operative complications and they were discharged after 48-72 hours of surgery. The cost of hysteroscopy with LNG-IUS insertion at our hospital was about Rs 15,000 whereas the minimum cost involved in laparoscopic hysterectomy was Rs. 70,000.

There was a change in bleeding pattern observed by all patients in the LNG IUS group. There was irregular vaginal spotting for first three to six months but reduced bleeding. The bleeding pattern has been described in Table 2. Bleeding reduced significantly in 93.3% of women whereas irregular heavy bleeding was seen in 6.6% women. Twenty three of the 25 (92%) women with adenomyosis who complained of dysmenorrhea were significantly relieved of the pain and their pain scores are mentioned in Table 3.

Six women complained of disturbing irregular spotting and bleeding, 2 patients required additional progesterone only pills to control the irregular bleeding and 2 patients required additional Selective Estrogen Receptor Modulator pills to control the irregular bleeding. Total 27 patients developed amenorrhoea after 1 year. Two patients opted for hysterectomy after LNG IUS insertion and only one patient opted for removal of IUS due to irregular vaginal spotting. Most women reported reduced menstrual blood loss and spotting after six months and eventually 90 % of women developed amenorrhoea after 1 year of insertion. Amenorrhoea was acceptable to all 90% women as they were counseled regarding the same before the procedure. Twenty seven women that is 90% women

continued the LNG-IUS till 1year follow up and intended to continue as per our survey.

Only one woman reported a petty weight gain of about two kgs by the end of one year. The incidence of other progestational side effects like mood changes, headaches, breast tenderness was negligible. In the hysterectomy group ten (33.33%) women complained of backache post surgery which they attributed to the surgery.

Five women complained of menopausal symptoms which was more psychological due to loss of an organ and the red badge of femininity (menstruation) which is important for the Indian women. As far as the overall

satisfaction scoring is concerned, 90 percent women in the LNG IUS group gave the scores between 8-10 which meant very satisfactory scores with the average score being nine. They were very satisfied with the conservation of their uterus and did not report any psychological or sexual disturbances. But in the hysterectomy group at least six women (20%) reported dyspareunia, another six(20%) reported vasomotor menopausal symptoms in the postoperative period. Fifty percent were satisfied with the surgery and fifty percent were not satisfied with the average satisfaction score being 5. VAS score for overall satisfaction is recorded in Table 4.

**Table 1: Etiology of AUB**

	LNG IUS group	Hysterectomy group
Adenomyosis	22	3
Idiopathic AUB	08	27

**Table 2: The menstrual bleeding patterns at recruitment, 6 months and 12 months of LNG-IUS insertion**

Menstrual pattern	At Recruitment	6 months	12 months
Normal menses	0	0	0
Absent bleeding	0	3	27
Infrequent bleeding	0	7	0
Scanty regular bleeding	0	6	0
Heavy regular bleeding	15	0	0
Frequent heavy bleeding	10	0	0
Irregular heavy bleeding	05	2	2
Irregular spotting	0	12	1

**Table 3: VAS scores of dysmenorrhea**

VAS scores	Before IUS insertion	6 months post LNG IUS	12 months post LNG IUS
0 no pain	0	17	23
1-4 mild pain	02	05	02
4-8 moderate pain	13	03	0
8-10 severe pain	10	0	0

**Table 4: VAS scores for overall satisfaction at 12 months**

Degree of satisfaction with score	LNG-IUS group	Hysterectomy group
Not at all satisfied (0-2)	0	12(40%)
Not satisfied (2-4)	3(10%)	3 (10%)
Uncertain (4-6)	0	0
Satisfied (6-8)	0	12(40%)
Very satisfied (8-10)	27(90%)	3(10%)

## Discussion

Due to the local effects of levonorgestrel on the endometrium, all women experience a change in their bleeding pattern. First few months irregular spotting or bleeding continues but blood volume is reduced and number of days of bleeding reduce gradually and hence the total menstrual blood loss decreases. After 1 year of use, menstrual blood loss is drastically reduced and about 80% experience amenorrhoea.

In patients offered an LNG-IUS, counselling regarding the anticipated changes in the bleeding pattern, particularly in the first few cycles should be done. The changes may last longer than six months and hence sometimes the patient may need to continue treatment for at least six cycles to witness the benefit<sup>2</sup>.

The Cochrane database suggested that the Levonorgestrel releasing intrauterine system results in a significant reduction in baseline menstrual blood loss in heavy menstrual bleeding. According to the ACOG (American college of Obstetricians and Gynecologists), the LNG-IUS appears to reduce menstrual blood loss significantly in women with HMB<sup>10</sup>.

In our study there were 25 women with diagnosed adenomyosis and 35 women with idiopathic AUB. Twenty two of the 25 women with adenomyosis underwent hysteroscopy with LNG-IUS insertion and only three of them opted for hysterectomy whereas 27 women in the idiopathic AUB group opted for hysterectomy and eight women underwent hysteroscopy with LNG-IUS insertion.

As far as the menstrual bleeding patterns were concerned all the 30 women in the LNG-IUS group had heavy menstrual bleeding before recruitment. At six months post IUS insertion 10% had amenorrhoea, 40% had irregular spotting (decreased flow), 23.33% had infrequent bleeding, 20% had scanty regular bleeding and only two women (6.66%) had irregular heavy bleeding. By the end of 12 months 90% of women in this group developed amenorrhoea. Hence we can conclude that there was a significant reduction in menstrual blood loss at the end of six months which was consistent with the results of the study by Kriplani et al and Yazbeck et al and Lahteenmaki et al<sup>11,12,13</sup>. In the study by Kriplani et al HMB was cured in 77.7% patients at 3 months and in all patients at 36 months. There was a significant decrease in the number of bleeding days and decrease continued with increasing duration of treatment. 28.57% women developed amenorrhoea at the end of six months whereas in our study 10% developed amenorrhoea at six months and 90% at 12 months.

In our study there was a significant reduction in the dysmenorrhoea associated with adenomyosis after LNG-IUS insertion and pain reduced further with duration of treatment. 56.6% women had no pain at the end of six months and 76.6% women had no pain at 1 year post LNG-IUS and these results were similar to study by J. Sheng et al<sup>7</sup>.

The overall satisfaction scores were significantly more in the LNG-IUS group as compared to the hysterectomy group with 90% women being very satisfied with the treatment in the IUS group and only 50% being satisfied in the hysterectomy group. The women who underwent hysterectomy complained of backache, sexual problems, menopausal symptoms and psychological disturbances due to loss of an organ. Our results were comparable to previous studies<sup>12,13</sup>. In the study by Yazbeck et al 86.1% women with dysfunctional uterine bleeding were very satisfied with the treatment with LNG-IUS as an alternative to hysterectomy.

Considering the short duration of hospital stay and the low cost involved in LNG-IUS insertion procedure as compared to laparoscopic hysterectomy as mentioned above, it is more cost effective than hysterectomy both in the short term (1 year) and longer term (5 years).

The LNG-IUS was associated with significant decrease in the blood loss, significant decrease in the pain associated with adenomyosis and blood loss. Treatment with IUS improved general well being, efficacy at work; physical, psychological and sexual activity. Hence it provided good symptomatic relief with higher satisfaction rates. Hysterectomy remains a definitive cure but it is a major surgical procedure for the treatment of heavy menstrual bleeding and it has significant anatomical, urological, sexual, psychological and emotional sequel and high cost attached to it.

Hence this prospective non-comparative study provides further evidence of the high efficacy and cost effectiveness of LNG-IUS in AUB as an alternative to hysterectomy. Hence LNG-IUS should be considered for treatment of AUB before taking a decision for hysterectomy.

**Conflict of Interest: None**

**Source of Support: Nil**

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