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Original Research Article

Role of levonorgestrel releasing intrauterine device in management of heavy menstrual bleeding: a conservative approach

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ABSTRACT

Background: Heavy menstrual bleeding (HMB) is defined as prolonged (>7 days) or excessive menstrual blood loss greater than or equal to 80 ml per menstrual cycle. The objective of the study was to assess the efficacy, acceptability and side effects of LUS IUS in women with heavy menstrual bleeding.

Methods: 42 women with heavy menstrual bleeding with or without associated dysmenorrhoea or chronic pelvic pain and had no contraindication to IUS insertion were included in the study. Patients having active genital tract infection, suspicion of pregnancy, uterine fibroids >2.5 cm in size or sub mucosal distorting the uterine cavity, uterine size >12 weeks, atypical endometrial hyperplasia or malignancy, abnormal cervical cytology, coagulopathy or liver disease were excluded from the study. Preliminary endometrial biopsy was done to rule out malignancy and LNG IUS was inserted under anaesthesia. Women were followed for 3,6,12 and 24 months post insertion.

Results: In first 3 months, 20% patients achieved normal menstrual cycle, and at 6 months 44.44% had scanty menstrual flow and after 1 year of use 81.5% achieved amenorrhoea. In initial 3 months 37.5% patients had irregular heavy bleeding, which reduced to 13.89% at 6 months and 0% at 1 year follow up. Irregular spotting was second most complaint in 32.5% patients in initial 3 months that persisted in 7.4% patients at 1 year follow up. In 5.0% patients, there was spontaneous expulsion of the device in first 3 menstrual cycles. After 3 months of use 57.5% patients were satisfied with the device and at the end of 1 year 92.5% were satisfied.

Conclusions: LNG IUS is highly effective in controlling blood loss, well tolerated and better alternative for hysterectomy with higher user satisfaction in all age group of women.

Keywords: Adenomyosis, Endometrial hyperplasia, Endometriosis, Fibroid, Heavy menstrual bleeding, LNG IUS

INTRODUCTION

Heavy menstrual bleeding (HMB) is defined as prolonged (>7 days) or excessive menstrual blood loss greater than or equal to 80 ml per menstrual cycle.¹ It interferes with a woman's physical, social, emotional and/or material quality of life. Abnormal uterine bleeding is a common reason for consulting a gynecologist and hysterectomy is often used to treat women with menorrhagia but medical therapy may be a successful alternative.² Levonorgestrel-releasing intrauterine device (LNG-IUS) has become one of the most acceptable medical treatments for menorrhagia, reducing referrals to

specialists and decreasing the need for operative gynaecological surgery.³ 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. Along with the high contraceptive efficacy, LNG-IUS has shown benefits and improvement of symptoms in menorrhagia, adenomyosis and endometriosis.^{4,5} LNG-IUS device has also been found to be cost-effective with less side effects and to increase the quality of life (QOL).⁶ The QOL of women treated with the LNG-IUS is markedly improved, causing high levels of patient satisfaction.⁷ Hence, this study was conducted to evaluate

the efficacy, acceptability and side effects of LNG-IUS in women with heavy menstrual bleeding.

METHODS

It was a prospective interventional study conducted over a period between september 2013 to august 2015 in Department of reproductive biology, obstetrics & gynaecology, IGIMS, Patna, Bihar, India. 42 women with heavy menstrual bleeding with or without associated dysmenorrhoea or chronic pelvic pain, fibroid uterus not distorting the endometrium, adenomyosis or endometriosis, having young age or medical or surgical high risk factors making unsuitable for surgery and had no contraindication to IUS insertion were included in the study.

Patients having active genital tract infection, suspicion of pregnancy, uterine fibroids >2.5 cm in size or sub mucosal distorting the uterine cavity, uterine size >12 weeks, atypical endometrial hyperplasia or malignancy, abnormal cervical cytology, coagulopathy or liver disease were excluded from the study.

All patients underwent a complete general physical, systemic and gynecological examination. CBC, TSH, FBS, LFT, RFT, coagulation profile, ultrasound pelvis, pap smear and endometrial biopsy was done to rule out any malignancy. LNG-IUS was inserted in post menstrual phase under intravenous anesthesia. Follow up was done at 3, 6, 12, 24 months. At each visit menstrual pattern,

blood loss and opinion of women for satisfaction was recorded.

RESULTS

Forty two women with abnormal uterine bleeding were enrolled in the study with mean age of 38.2 + 6.85 years. Majority (76.2%) of the patients belonged to 30-50 years of age. 69% patients had dysfunctional uterine bleeding, 14.3% had fibroid uterus, 9.5% patients had adenomyosis and rest patients had menorrhagia associated with endometriosis and severe dysmenorrhoea.

Table 1: Age distribution of the cases.

Age (years)	No of patients	Percentage
21-30	8	19.0%
31-40	17	40.5%
41-50	15	35.7%
51-60	2	4.8%
Total	42	100%

In surgical high risk group, we had patients with history of previous 2 LSCS with herniorrhaphy, previous 4 LSCS, previous 2 LSCS with failed attempt of hysterectomy due to frozen pelvis and morbid obesity. In medical high risk group patients had hypertension, diabetes mellitus, rheumatic heart disease, coronary artery disease, hypothyroidism, bronchial asthma and chronic renal failure. All patients were followed till 3, 6, 12 and 24 months.

Table 2: Etiology of heavy menstrual bleeding.

Diagnosis	Number	Percentage	
HMB N= 29 (69%)	HMB in <40 years	13	31.0%
	HMB in >40 years, wants conservative t/t	4	9.5%
	HMB with systemic diseases	8	19.0%
	HMB in surgically high risk patients	4	9.5%
Fibroid uterus with normal cavity	6	14.3%	
Endometriosis	3	7.2%	
Adenomyosis	4	9.5%	
Total	42	100%	

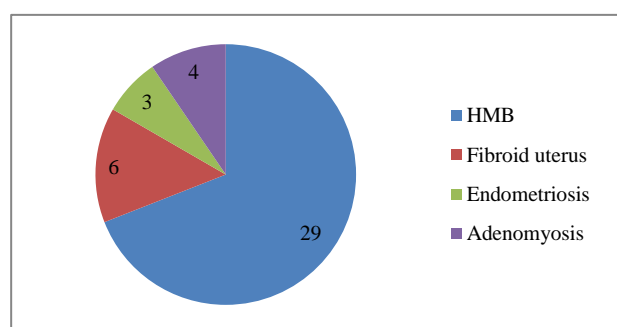


Figure 1: Etiological distribution of cases.

In first 3 months, 21% patients achieved normal menstrual cycle, and at 6 months 44.44% had scanty menstrual flow. After 1 year of use 81.5% achieved amenorrhoea whereas 11.1% had regular scanty bleeding. After 6 months of use there was significant reduction in pain and bleeding in cases of endometriosis, severe dysmenorrhoea and chronic pelvic pain. In cases of adenomyosis there was decrease in uterine size as well as in menstrual bleeding. The most frequent complaint in initial 3 months was irregular heavy bleeding in 37.5% patients which reduced to 13.89% at 6 months and 0% at 1 year follow up. Irregular spotting was second most

complaint in 32.5% patients in initial 3 months that persisted in 7.4% patients at 1 year follow up. In 4.7% patients, there was spontaneous expulsion of the device in first 3 menstrual cycles. 2 patients requested for removal of the device due continued irregular heavy bleeding and opted for hysterectomy. Post insertion pain and vaginal

discharge was a common complaint in many patients in initial 3 months. After 3 months of use 57.5% patients were satisfied with the device and at the end of 1 year 92.5% were satisfied whereas 7.4% patients were not completely satisfied due to irregular spotting. After 2 years all patients who came for follow up were satisfied.

Table 3: Follow up of effects of LNG-IUS.

Duration	3 months N = 40	6 months N = 36	12 months N = 27	24 months N = 12
Irregular heavy menses	15 (37.5%)	5 (13.89%)	0	0
Irregular Spotting	13 (32.5%)	4 (11.1%)	2 (7.4%)	0
Normal menses	8 (20.0%)	6 (16.7%)	0	0
Scanty menstrual flow	2 (5.0%)	16 (44.44%)	3 (11.1%)	1 (8.4%)
Amenorrhoea	0	5 (13.9%)	22 (81.5%)	11 (91.6%)
Dysmenorrhoea	27 (67.5%)	10 (27.78%)	1(2.78%)	0
Expulsion	2 (5.0%)	0	0	0
Lost to follow up	2(5.0%)	4(11.11%)	9	15
Satisfied with device	23 (57.5%)	31 (86.11%)	25 (92.5%)	12 (100%)
Device removed	0	2 (5.55%)	0	0

Table 4: Follow up of side effects.

Complaints	At 3 months N=40	At 6 months N = 36	At 12 months N = 27	At 24 months N = 11
Irregular heavy menses	15 (37.5%)	3 (8.3%)	0	0
Irregular spotting	13 (32.5%)	4 (11.1%)	1 (3.7%)	0
Post insertion pain	9 (22.5%)	0	0	0
Post insertion Vaginal discharge	14 (35.0%)	2 (5.2%)	0	0

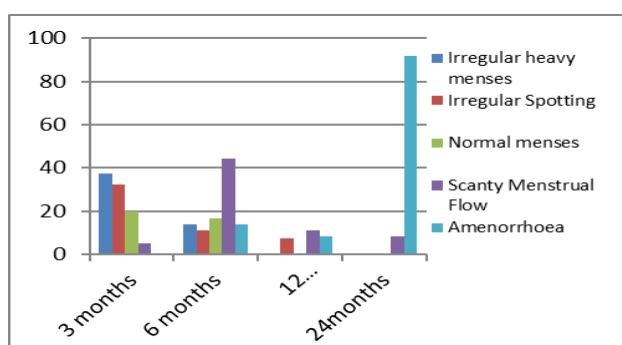


Figure 2: Effects on menstrual blood flow after LNG-IUS insertion.

DISCUSSION

Approximately 30% of women of reproductive age experience heavy bleeding during menstruation.⁸ While in nearly half of all cases no organic pathology is found, a number of risk factors may contribute to the development of HMB.⁸ In present study 69% patients had heavy menstrual bleeding with no identifiable cause. There were

many treatment options including hemostatic drugs, hormones, endometrial ablation, LNG-IUS and the definitive treatment was hysterectomy. Medical management of HMB with hormones was really challenging due to poor compliance, side effects, cost, troublesome breakthrough bleeding and actual failures. According to Value study, a survey of outcomes of 37,000 hysterectomies, operative and postoperative complication was reported in 3.5% and 9% cases.⁹ Postoperative mortality was 0.38/1000 patients and psychological implication was seen in 35-45% patients.⁹ This was a well-recognized and established fact that the LNG-IUS offers potential therapeutic benefits in menorrhagia and symptomatic fibroids etc.¹⁰ However, it frequently produced menstrual disturbances initially that can limit its use by clinicians.

This prospective interventional study was done to evaluate the efficacy, acceptability and side effects of LNG-IUS in women with 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.¹¹

In a study by Garg et al at six months post IUS insertion 10% had amenorrhea, 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.¹² By the end of 12 months 90% of women in this group developed amenorrhea. In present study, at 6 months 13.9% had amenorrhea, 44.44% had scanty menstrual flow 11.1% had irregular spotting, 16.7% had normal menstrual cycle, and only 5 (13.89%) patients had Irregular heavy bleeding. At 1 year of use 81.5% had amenorrhea, 11.1% had regular scanty flow and only 2 (7.4%) had irregular spotting.

In a study by Kriplani et al HMB was cured in 77.7% patients at 3 months and in all patients at 36 months.¹³ There was a significant decrease in the number of bleeding days and decrease continued with increasing duration of treatment. 28.57% women developed amenorrhea at the end of six months whereas in our study 13.9% developed amenorrhea at six months, 81.5% at 12 and 91.6% at 24 months. In a Brazilian study, 44% of women reported amenorrhea at the 6th month of the study.¹⁴ In a study from Austria, 56% subjects experienced an absence of menstruation, either completely from the time of insertion (47%) or temporarily (9%).¹⁵

Lockhat et al found significant improvement ($P < 0.05$) in severity and frequency of pain and menstrual symptoms in 85% of patients.¹⁶ In a study by Garg et al there was a significant reduction in the dysmenorrhea associated with adenomyosis after LNG-IUS insertion and pain reduced further with duration of treatment.¹² 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. In present study also all the patients with severe dysmenorrhea and endometriosis were relieved of their symptoms.

In a study by Tariq et al 38% women experienced vaginal spotting at the end of 3 months, however, at the end of one year it reduced to 3.5% and spontaneous expulsion of device was noticed in 8.8% women within 3 months.¹⁷ In present study 32.5% patients had irregular spotting after 3 months which reduced to 7.4% at the end of 1 year and 5% patients expelled the device within 3 months. Another 5.5% patients requested removal of device due to heavy bleeding even after 3 months.

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.¹⁸ 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. In present study 57.5%, 92.5% and 100% patients were satisfied with the device after 3 months, 1 year and 2 years respectively.

CONCLUSION

LNG-IUS is a safe, effective and acceptable mode of treatment of heavy menstrual bleeding. It can be a good alternative to hysterectomy for heavy menstrual bleeding due to many benign etiologies. It is associated with lesser side effects and higher satisfaction rate. LNG-IUS can be choice of treatment for entire reproductive years and it also helps in smooth transition to menopause. So, hysterectomy should be avoided for inappropriate reasons and femininity must be preserved.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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