

Efficacy And Complications of Levonorgestrel Intrauterine System in Heavy Menstrual Bleeding

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Abstract

Aim of study: To study the efficacy and complications of Levonorgestrel intrauterine system (LNG IUS) in heavy menstrual bleeding. The study was a prospective study conducted at Government general Hospital Vijayawada.

Material & Methods : Study design :- Prospective study .The study was conducted in Government general Hospital Vijayawada .Patients recruited for study were selected from the O.P patients .Total 35 patients were recruited for the present study . Study period is from November 2016 to November 2017 .Eligible women were below 45 years with at least one child ,and chief complaint for all women being heavy menstrual bleeding with pictorial menstrual blood loss assessment chart score of above 100.All patients had initial screening with blood tests ,ultrasound scan , and premenstrual dilatation and curettage in 1st visit. Levonorgestrel intrauterine system was inserted in 2nd visit in O.T after 1 day admission .All patients recruited were followed after 1 week ,1 month ,3 months ,6 months and 1 year .Reduction in menstrual blood loss was noted in all participants.

Results: Initial mean PBAC score at first visit was 206 ± 104 and Mean PBAC (pictorial blood loss assessment chart) score were reduced to 110 ± 94 at 3 months; 68.2 ± 72.6 at 6 months and 40.1 ± 20 at the end of 1 year. With a P value of $<.001$ at 6 months; p value of <0.002 at the end of 1 year . In 5.71%(n=2) LNG IUS expelled . 5.71% (n=2) patients were opted for removal of uterus after 6 months due to poor satisfaction in reduction of menstrual blood loss .No serious side effects were reported at the end of 1 year.

Conclusion: Levonorgestrel intrauterine system significantly reduced the menstrual blood loss and decreased the need to go for hysterectomy in patients with heavy menstrual bleeding .

Keywords: LNG IUS, Heavy menstrual bleeding , PBAC scores.

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I. Introduction

Abnormal uterine bleeding is one of the most common bleeding symptom in gynecological outpatient especially in premenopausal age group¹. Heavy menstrual bleeding is very common presentation. 30% of women in reproductive age group suffer from menorrhagia (heavy menstrual bleeding) and they contribute to 60% of gynecological O.P consultations ².Medical management is the first line of management in heavy menstrual bleeding (H.M.B) .Drugs for medical management include oral contraceptive pills, progestins, tranaxamic acid , non steroidal anti inflammatory drugs , gestrinone. If medical therapy fails patients had a choice for minimally invasive surgery. Minimally invasive surgeries for A.U.B include thermal Balloon ablation; Laser , cryo therapy, transcervical resection of endometrium .These procedures are costly and not available for rural people in India .Additionally repeat surgeries are also common .As many as 30% women undergoing endometrial resection or Laser ablation are opting for hysterectomy ³.Approximately 30% of hysterectomies in India are considered to be performed due to abnormal uterine bleeding , that to below 35 and 40 years of age.Levonorgestrel intrauterine system is considered to be the most effective medical management treatment option for AUB ⁴.The LNG IUS was introduced for contraception in the year 1990 and currently there are an estimated 4 million LNG IUS users world wide ⁵ . The US food and drug authority has approved LNG IUS use both for contraception and for treatment of menorrhagia ⁶.The use of LNG IUS in India is not very much popular ,the reasons being poor availability ,cost ,bias of foreign body in the uterus .Fear of failure of treatment. canbero phobia .Most of the Indian women feel that at any point of time they may need hysterectomy ,because of AUB and it is the final solution. That is why they prefer hysterectomy as first line permanent solution to AUB. Fear of cancer is an Important predetermining factor because of which most of the patients are in favour of hysterectomy . In India most of the women are anemic and in addition menorrhagia worsens the condition .When medical management fails many women are faced in opt for removal of uterus in view of non availability of other options and cost of other modalities.

Now a days the cost of LNG IUS was also reduced and its availability improved. Educational programmes regarding complications of hysterectomy at young age were going. LNG IUS is being accepted as

first line treatment in heavy menstrual bleeding if medical treatment fails in reproductive and premenopausal women .LNG IUS was approved in October 4, 2011 by drugs controller and licensing authority of India, and it was launched in Indian market on 18th October 2012. From them on wards it has reduced the number hysterectomies due to heavy menstrual bleeding.LNG IUS consists of ‘M’ snapped flexible plastic arm with drug reservoir. It has a covering membrane length of horizontal arm 19.5 mm, length of vertical arm 36 mm .cone length 23.5 mm .Drug content 52 mg and daily release 20 micro grams in /day

1.1Material &Methods:

The present study was conducted in the Government general Hospital Vijayawada in India. In the period of November 2016 to November 2017 that is a period of 1 year .Total 35 patients were recruited in the present study .All patients have heavy menstrual bleeding and selected from O.P patients.

1.2Inclusion criteria : -

1. .Parous women with atleast 1child
2. Age group below 45 years
3. Failed medical management to a period of 6 months prior to insertion of LNG IU
4. Heavy Menstrual bleeding for 6 months prior to inclusion in present study.

Exclusion criteria :

1. Not Reliable for follow up
2. Abnormal endometrial or cervical biopsy
3. Delivery or abortion in less than 1 year
4. Patients with gross pelvic pathology
- 5.

Total 35 patients were recruited for present study .All patients had heavy menstrual bleeding with PBAC score of least 100 and suffering since last 1 year and took medical treatment to 6 months prior to the present study .All patients were investigated with Blood investigative like Hb% LFT, RFT, thyroid function test, haemogram and urine analysis, ultrasound for pelvic pathology and endometrial thickness was taken. Premenstrual Endometrial Biopsy was taken. Both malignant and premalignant lesions were excluded. Patients were taken for LNG IUS insertion after explaining the advantages and complications .Consent was taken and LNG IUS inserted in O.T under sedation and patients were kept in ward to observation for 1day and then discharged .At the time of discharge all patients were advised to come after 1 week to verification of threads and position LNG IUS. Patients were asked to come back after 1, month, 3 months, 6 months and after, 1 year. At each visit a questionnaire was given to patients regarding menstrual blood loss relief from other symptoms, palpation of threads and any other complaints. All patients were given education regarding counting of pads and noting down of pad soakage as per PBAC chart score:

II. Results

Table-1

| Age –wise distribution of cases | | |
|---------------------------------|-----------|-------------|
| <30 Yrs | 2 | 5.71% |
| 30-35 Yrs | 5 | 14.28% |
| 35-40 Yrs | 8 | 22.87% |
| 40-45 Yrs | 20 | 57.14% |
| Total(n) | 35 | 100% |

Total 35 women were recruited in the present study 5.71% of patients (n=2), were below 30 Years of age 14.28% (n=5), were between 30 to 35 years 22.87% (n=8), were between 35 and 40 years 57.14% (n=20), were 40 and 45 years, mean age of patients were 40.1 years ±(28 to 44).

Table-2

| Party wise distribution of cases | | | |
|----------------------------------|----------|-----------|-------------|
| 1 | Child | 2 | 5.71% |
| 2 | Children | 32 | 91.42% |
| 3 | Children | 1 | 2.75% |
| Total | | 35 | 100% |

In present study 91.42% of patients have 2 children and taken up for LNG, IUS

Table-3 Initial PBAC scores

| PBAC score | Number | Percentage |
|------------|--------|------------|
| 100-150 | 6 | 17.4% |
| 150-200 | 24 | 68.32% |
| >200 | 5 | 14.28% |
| | N=35 | 100% |

Mean PBAC scores was 206 ±104

| Factor | Count | Percentage |
|---------------------------|-------|------------|
| Only HMB | 27 | 77.1% |
| Adenomyosis dysmenorrhea | 2 | 5.71% |
| HMB+contraception | 1 | 2.85% |
| Fibroid <3cm dysmenorrhea | 3 | 8.57% |
| Cirrhosis of liver | 1 | 2.85% |
| Budd chiari syndrome | 1 | 2.85% |
| | n=35 | 100% |

Most of patients showed normal uterus on ultrasound (n=2) 5.71% of cases of HMB were associated with Adenomyosis, 8.57% (n=3) patients were having a fibroid of less than 3cm, one patient with HMB wanted contraception also. After explaining the risk patients accepted to the LNG IUS. 2 patients with medical disorders were recruited in the study.

| Biopsy Type | Count | Percentage |
|---------------------------|-------|------------|
| Proliferative Endometrium | 21 | 60% |
| Secretory | 9 | 25.71% |
| Pill Endometrium | 2 | 5.71% |
| Hemorrhage & Necrosis | 2 | 5.71% |
| Simple hyperplasia | 1 | 2.87% |

Table-6 complications reported after 1 week

| Complication | Count | Percentage |
|--------------|-------|------------|
| Pain | 4 | 11.4% |
| Cramps | 2 | 5.71% |
| Spotting | 2 | 5.71% |
| Expulsion | 10 | 28.5% |

All 35 patients were asked to report after 1 week unfortunately in 5.71% (n=2) patients LNG IUS expelled. 28.5% complained of spotting. Even though the percentage is high its significance is questionable because of small sample size (n=35)

Table-7 Reduction in menstrual blood loss

| | 1 month | 3 months | 6 months | 1 year |
|---------------|------------|------------|------------|------------|
| No change | 20(57.16%) | 9(25.71%) | 1(2.85%) | - |
| 30% | 8(22.85%) | 19(54.28%) | 3(8.57%) | - |
| 50% | 5(14.28%) | 5(14.28%) | 10(28.57%) | 3(8.57%) |
| 70% | - | - | 17(48.57%) | 23(65.71%) |
| 90% | - | - | 2(5.71%) | 4(11.42%) |
| Expelled | 2(5.71%) | 2(5.71%) | 2(5.71%) | 2(5.71%) |
| Lost followup | - | - | - | 1(2.87%) |
| Hysterectomy | - | - | - | 2(5.7%) |
| Total | N=35(100%) | 35(100%) | 35(100%) | 35(100%) |

Table-8 PBAC score at each visit

| PBAC score | Mean+/- 2 SD |
|---------------|--------------|
| Initial visit | 206 +/- 104 |
| 1 month | 176 ± 108 |
| 3 months | 110 ± 94 |
| 6 months | 68.2 ± 72.6 |
| 1 year | 40.1 ± 20.1 |

After 3 months 25.71% of patients <30% reduction 54.28% women reported 30% reduction of blood loss, 14.25% of women reported 50% reduction in menstrual blood loss 5.71% (n=2) of patients show expulsion of LNG IUS. These 2 patients were excluded for further follow up. After 6 months 33 patients turned for follow up. No much improvement in 2.85% (n=1), 28.57% (n=10) of patients show 50% reduction in menstrual blood loss; 41.57% (n=17) patients reported 70% reduction, in menstrual blood loss 5.71% (n=2) of patients reported 90% reduction in menstrual blood loss. Estimated P value of <0.002 at time end of 6 months which was statistically significant. After 6 months 5.7% (n=2) women opted by hysterectomy because of unsatisfactory relief. After 1 year (2.85%) n=1 patient lost follow up. Remaining 30 patients were continued for follow up till 1 year, at the end of 1 year 8.57% (n=3) showed 50% reduction 5.71% (n=23) showed 70% reduction, 5.71%

(n=2) showed 90% reduction in menstrual blood loss. No case of amenorrhoea reported. Treatment is said to be failed in case of confirmed expulsion or patients switch over to in other methods of treatment. At the end of one year: - One lost follow up, 2 women opted for hysterectomy, 2 cases excluded for follow up in view of expulsion. Remaining 85.71% (n=30) patients were counselled regarding the further follow up for the LNG IUS, with satisfactory reduction of menstrual blood loss.

III. Discussion

Present study has shown that LNG IUS a good alternative to hysterectomy LNG IUS is preferred treatment to be opted before resorting to hysterectomy in selected patients with heavy menstrual bleeding with out major pelvic pathology. Insertion of LNG IUS has definitely reduced the menstrual blood loss and improved quality of life. In present study 48.67% of patients reported 70% reduction in blood loss. After 6 months this is almost similar to study of Gopi mohan et al in 2014 when they reported 77% and 92% reduction in mean PBAC scores after 3 months and 6 months, respectively⁷. According to the study of Milson .L, they reported 82% reduction in 3 months and 88% reduction on menstrual blood loss after 6 months⁸. In present study 14.1% patients reported dysmenorrhoea. All got relieved from dysmenorrhoea at the end of 6 months. According to study of Sheng.J the VAS of dysmenorrhoea dropped continuously and significantly from base line score of 77.91 ± 14.7 to 11.8 ± 17.9 after 6 months of LNG IUS insertion⁹. In the present study 5.71% (n=2) of expulsion was noted previous report of Bhas field RA. Quoted on expulsion late of 5f. Even though expulsion rate is high. Total member of patients were less. In another study by Gopi mohan et al in 2015 reported 11% (n=7) expulsion rate other 3 months.⁷ In present study pain and cramps were reported by 11.0% and 5.7% of patients and 28.5% of patients reported spoiling. According to the study of Sheng.j et al most common side effect were weight gain in 28.7%, simple ovarian cyst formation 22.5% and abnormal pain in 12.8%⁹. Another study by Lelehci.s reported that acne was significantly increased in patients with LNG IUS.¹⁰ Another study by Dong suo part et al showed that common side effect were Vaginal spoiling in 58.3% LNG IUS expulsion in 3.75% (n=18) 10.4% under went premature removal. 16.6% under went hysterectomy.¹¹

IV. Conclusion

Present study shows that LNG IUS is an important tool in the medical management of heavy menstrual bleeding. Insertion of LNG IUS can avoid hysterectomy in many women with heavy menstrual bleeding and should always be considered before resorting to hysterectomy.

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