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# Title: A PROSPECTIVE STUDY OF LEVONORGESTREL INTRAUTERINE SYSTEM FOR CONSERVATIVE MANAGEMENT OF AUB; EXPERIENCE IN A TERTIARY CARE HOSPITAL

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## ABSTRACT

**Background**: AUB is a common problem in the reproductive age group. In India prevalence is 17.9%. AUB patterns include menorrhagia, metrorrhagia, polymenorrhea, dysfunctional uterine bleeding and heavy menstrual bleeding. Excessive menstruation is often incapacitating and can severely affect woman's quality of life both personal as well as social**. Objectives:** The objective of this study is to observe the efficacy of Levonorgestrel Intrauterian system (Mirena) in AUB patients. **Methods**: The study was conducted at a teritary care hospital over a period of 12 months. 25 women between the age of 30 and 45 years with AUB were included in the study. Pre and Post insertion patients were asked to maintain a PBAC and were followed after 1 month, 3 months and 6 months post insertion. **Results:** LNG-IUS was found to be effective in 23 out of 25 patients suffering from AUB. Relief in dysmenorrhoea was seen in 78.27 %, amenorrhoea was seen in 13% and irregular spotting was seen in 21.73% at the end of 6 months.**Conclusion**: LNG-IUS is a safe, effective acceptable mode of treatment for women with AUB. It can be a good alternative to hysterectomy for heavy menstrual bleeding dueto many beningn etiologies.

**Keywords**: AUB, causes of AUB, LNG-IUS ,Dysmenorrhoea, PBAC score.

## INTRODUCTION

AUB is defined as bleeding from uterine corpus that is abnormal in regularity, volume, frequency and duration and occurs in the absence of pregnancy. It can be acute or chronic, chronic if it is present for more than 6 months. It's a common problem in the reproductive age group. In India prevalence is 17.9%. AUB patterns include menorrhagia, metrorrhagia, polymenorrhea, Dysfunctional uterine bleeding and Heavy menstrual bleeding. To standardize nomenclature of AUB, FIGO(Federation of International of Gynaecologists and Obstetricians) in 2011 came forward with a new classification system to define its cause. This classification is named as 'PALM-COEIN' system. It stands for polyp, adenomyosis, leiomyoma, malignancy, coagulopathy, ovulatory dysfunction, endometrial, iatrogenic, and not yet classified. The first four are structural uterine abnormalities that can be measured visually with imaging modalities and by histopathological study. The others are non-structural. Excessive menstruation is often incapacitating and can severely affect woman's quality of life both personal as well as social. Nearly 30% of all hysterectomies are performed to alleviate heavy menstrual bleeding. Mirena is a hormonal intrauterine device classified as a long acting reversible contraceptive method. T shaped polyethylene frame with a steroid reservoir made of a mixture of levonorgestrel and silicone (polydimethylsiloxane), containing a total of 52mg LNG around the vertical stem. The device releases the hormone at an initial rate of 20mcg/day and declines to a rate of 14mcg after 5yrs, which is still in the range of clinical effectiveness. It causes a local foreign body reaction characterized by an increase in inflammatory cells including neutrophils, lymphocytes, plasma cells and macrophages. These changes are finalized within 3 months of insertion.

## AIMS AND OBJECTIVES

To study the efficacy of Levonorgestrel Intrauterine system (MIRENA) in the conservative management of AUB.

## MATERIAL AND METHODS

Study design: Prospective Observational study . Study setting: This study was conducted in the department of Obstetrics & Gynaecology, SSIMS and RC, Davanagere. Study Subjects: Women between the age of 30 to 45yrs with AUB, attending Gynaecology OPD at SSIMS and RC, Davanagere. Sample Size: 25. Duration of the study: 12months

**Inclusion Criteria**

• Age : 30- 45yrs

• Suffering from various menstrual complaints like menorrhagia, Polymenorrhea, Menometrorrhagia, Dysmenorrhea for a duration more than 6 months.

• Uterus size < 12weeks.

• Fibroids <3cm in diameter

• Negative pap smear.

• For those above 40yrs of age D & C report negative for malignancy.

**Exclusion Criteria**

• Uterus size >12weeks

• Women with uterine anomaly

• Multiple fibroids distorting the uterine cavity (intramural and subserosal fibroids of >3cm and submucous fibroids distorting the uterine cavity).

• Atypical endometrial hyperplasia

• Genital bleeding of unknown etiology

• Acute pelvic inflammatory disease

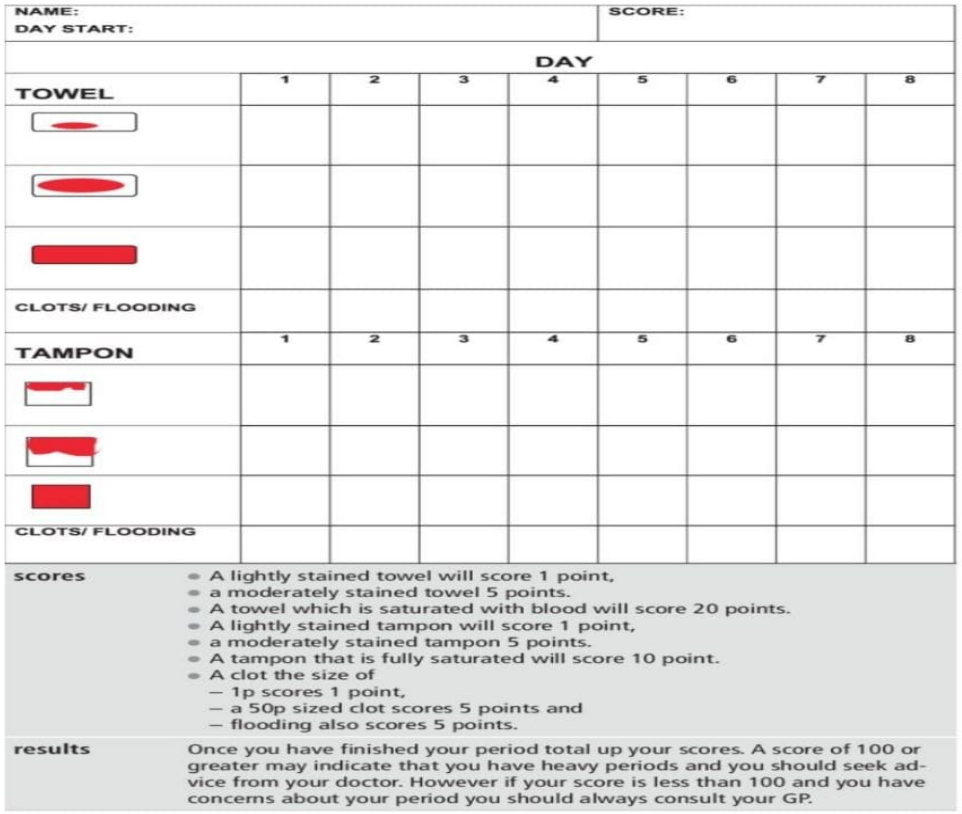
• Untreated abnormal cervical cytology.

• Any coagulopathy

## METHODOLOGY

After approval by the ethics committee, after taking written and informed consent, 25 women between the age of 30 and 45yrs with AUB were included in the study conducted over a period of 12 month from December 2022 to November 2023 in SSIMS and RC hospital, Davanagere- a tertiary care hospital. A detailed history was taken followed by a complete examination. Previous month PBAC was noted for statistical analysis. PBAC score was calculated by assigning score of 1, 5, 20 to a lightly, moderately or heavily soaked pad. 1,5,10 to lightly, moderately or heavily soaked tampon. Passage of clots score1 for small clot size of 5 rupee coin and 5 for 2 rupee coin size clot has been noted.

### Pictorial assessment of blood loss chart (PBAC)



| NAME: DAY START: | | | | | SCORE: | | | |
|---|---|---|---|---|---|---|---|---|
| | DAY | | | | | | | |
| TOWEL | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| CLOTS/ FLOODING | | | | | | | | |
| TAMPON | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| CLOTS/ FLOODING | | | | | | | | |

**scores**

- A lightly stained towel will score 1 point,
- a moderately stained towel 5 points.
- A towel which is saturated with blood will score 20 points.
- A lightly stained tampon will score 1 point,
- a moderately stained tampon 5 points.
- A tampon that is fully saturated will score 10 point.
- A clot the size of
  - 1p scores 1 point,
  - a 50p sized clot scores 5 points and
  - flooding also scores 5 points.

**results** Once you have finished your period total up your scores. A score of 100 or greater may indicate that you have heavy periods and you should seek advice from your doctor. However if your score is less than 100 and you have concerns about your period you should always consult your GP.

All patients had routine blood investigations- Hb, TLC, platelet count, blood sugars, RFT & thyroid function test. Any obvious pathologies like fibroids, adenomyosis, endometriosis, endometrial polyps, ovarian cysts, were diagnosed by using transvaginal ultrasound. All patients had pap smear, pre-menstrual endometrial biopsy was done if ET was more than 11mm and if the age of the patient is >40yrs. Patients were counselled regarding the altered bleeding pattern for 3-6 months and amenorrhea as possible side effects with LNG-IUS insertion. In patients meeting the above criteria, LNG-IUS was inserted in immediate post menstrual phase, using sterile aseptic technique. Post insertion patients were asked to maintain a PBAC ( Pictorial blood loss assessment chart) and were followed after 1 month, 3months & 6 months post insertion. During each follow up, Patients were asked regarding their menstrual pattern, menstrual symptoms, and the relief they have obtained from the antecedent

menstrual complaints. A detailed general, systemic, pelvic examination ( to see for MIRENA threads) and breast examination was done at every visit, Follow up ultrasound was done at every visit to see for mirena location. ET was measured, and development of a new pathology like ovarian cysts were noted. Hb estimation was done during each visit.

• **TREATMENT FAILURE** was defined as:

➢ PBAC any time more than 100

➢ Expulsion

➢ Patient having any severe side effect and insisting for removal

• **SPOTTING** was defined as: occassional unpredictable bleed requiring minimal or no protection.

• **AMENORRHEA** was defined as absence of bleeding for 3 months or more.

**RESULTS:**

**TABLE-1 AGE WISE DISTRIBUTION OF THE PATIENTS**

| | FREQUENCY | PERCENTAGE |
|---|---|---|
| <39YR | 12 | 48% |
| 40-44YR | 10 | 40% |
| 45YR | 3 | 12% |
| TOTAL | 25 | 100 |

**TABLE-2 : ETIOLOGY WISE DISTRIBUTION OF PATIENTS**

| ETIOLOGY | FREQUENCY | PERCENTAGE |
|---|---|---|
| OVULATORY DISFUNCTION | 12 | 48% |
| ENDOMETRIAL HYPERPLASIA | 5 | 20% |
| ADENOMYOSIS | 4 | 16% |
| LEIOMYOMA | 4 | 16% |
| POLYP | 0 | 0% |
| TOTAL | 25 | 100% |

**Most common cause of AUB was Ovulatory Dysfunction**

**TABLE-3: HB LEVEL AT PRE- TREATMENT AND AT 6 MONTH POST TREATEMENT**

| HEMOGLOBIN | MEAN | STANDARD DEVIATION | PVALUE |
|---|---|---|---|
| PRE TREATMENT | 9.1 | 1.1054 | <0.001 |
| AT6MONTHS | 10.9 | 0.6950 | <0.001 |

There is significant (P<0.001) improvement in Hemoglobin levels at 6 months after insertion compare to before treatment

**REDUCTION IN MEAN PBAC SCORE OVER 6 MONTHS**

**TABLE-4: PBAC SCORE(MEAN) AT 1 MONTH,3 MONTHS,6MONTHS**

| | PBACSCORE(MEAN) | % DECREASE |
|---|---|---|
| PRETREATMENT | 1080 | |
| AT1MONTHS | 370 | 65.74% |
| 3MONTHS | 132 | 87.78 |
| 6MONTHS | 90.7 | 91.602 |

**TABLE-5: IRREGULAR SPOTTING**

| | FREQUENCY | PERCENTAGE |
|---|---|---|
| AT3 MONTHS(N=24) | 15 | 62.5% |
| AT6MONTHS (N=23) | 5 | 21.73% |

**DYSMENORRHEA**

**TABLE-6: DYSMENORRHEA AT 3 MONTHS, 6 MONTHS**

| | FREQUENCY | PERCENTAGE |
|---|---|---|
| PRE TREATMENT(N=25) | 14 | 56% |
| AT 3 MONTHS(N=24) | 9 | 37.5% |
| AT 6 MONTHS (N=23) | 4 | 17.39% |

The above table shows prevalence of dysmenorrhoea at 3 months and 6 months of treatment.There is 82.61% reduction in the dysmenorrhoea at 6 months after insertion of LNG-IUS.

**TABLE-7: AMOENORRHEA**

| | FREQUENCY | PERCENTAGE |
|---|---|---|
| At 1 month | 0 | 0 |
| 3 month(N=24) | 1 | 4.16% |
| 6 month(N=23) | 3 | 13.04% |

13% of the women had amoenorrhoea at 6 months after the insertion of LNG-IUS.

**TABLE-8: TREATMENT FAILURE**

| | FREQUENCY | PERCENTAGE |
|---|---|---|
| AT 1 MONTH (N=25) | 01 | 4% |
| AT 3 MONTHS(N=24) | 01 | 4% |
| AT 6 MONTHS(N=23) | 0 | 0 |

The above table shows failure rate of LNG-IUS at 1 month,3 months,6 months post insertion.

## DISCUSSION

LNG-IUS was found to be effective in 23 out of 25 patients suffering from AUB. Most common cause of AUB seen in patients aged 35-39 years.Most common cause of AUB was due to Ovulatory Dysfunction. There was improvement of MEAN HB level from 9.1 to 10.9 after 6 months of post insertion of Mirena. There was 91 % reduction in the mean PBAC Score, 6 months post insertion of Mirena. There was reduction in menstrual blood loss at the end of 6 months. There is significant improvement in the hemoglobin level at 6 months after insertion compared to before treatment. Relief in dysmenorrhea was seen in 78.27% of patients at the end of 6 months. Among 25 patients 3 patients had Amenorrhea at the end of 6 months .Among 25 patients, Irregular spotting was seen in 15 patients at the end 3 months but irregular spotting was seen only in 5 patients at the end of 6 months. Treatment failure was seen in 2 patients,one expelled LNG-IUS after 1 month and the LNG-IUS had been removed due to pain not relieved with analgesics at 3 months in one patient. Proper counselling prior to insertion and after insertion made LNG-IUS well accepted in our study population. Milena insertion had an additional benifit of contraception.

## CONCLUSION

LNG-IUS is a safe, effective and acceptable mode of treatment for women with AUB. It can be a good alternative to hysterectomy for heavy menstrual bleeding due to many benign etiologies. This study has shown that the LNG-IUS results in a significantly lower objectively measured blood loss and over 6 month of follow up, the treatment is associated with high levels of patient satisfaction and significant improvement in the menstrual symptoms. Spotting and irregular cycles are common and troublesome side effects which need counselling and reassurance.

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