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Retrospective observational study to analyse the efficacy of levonorgestrel intrauterine implants to manage abnormal uterine bleeding in a tertiary care center

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Type of Publication: Original Research Article

Conflicts of Interest: Nil

# Abstract

**Introduction:** AUB-Abnormal uterine bleeding is a common gynecological complaint affecting around 10–30% of women during their reproductive years. It adversely affects a woman's life, leading to, and medical, psychological, social, and sexual problems. We aim to study the efficacy of a levonorgestrel intrauterine system (LNG-IUS) in 50 women suffering from AUB.

**Methodology:** A retrospective observational study was carried out at a tertiary care center in Bengaluru over 2 years. A total of 50 patients aged 30 years to 50 years (average age = 42.9 years) who underwent LNG-IUS insertion for abnormal uterine bleeding were studied. Cases were evaluated according to clinical findings, and transabdominal ultrasound. The women were called for follow-up at 1 week, 1 month, 6 months, and 1 year to

analyze the type and amount of bleeding and development of amenorrhea.

**Results**: of the 50 patients included in this study, Menorrhagia was the chief presenting complaint in 48% patients attending the gynaecological OPD. By the end of 6 months, 68% patients experienced decreased menstrual blood loss, 92% reported Amenorrhea at the 1-year followup.

**Conclusion:** A levonorgestrel intrauterine system significantly reduces bleeding in menorrhagia due to benign causes and is found to be highly effective in the management of various gynaecological pathologies such as endometrial polyps, adenomyosis and endometrial hyperplasia when insertion performed after dilatation and curettage/polypectomy. It has proven to be superior to

Dr. Tejaswini HK, et al. International Journal of Medical Sciences and Advanced Clinical Research (IJMACR)

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various surgical and other non-surgical treatment modalities.

**Keywords:** About four key words or phrases in alphabetical order, separated by commas.

#### Introduction

Abnormal uterine bleeding (AUB) is one of the most common reasons why women of the reproductive age group seek medical advice. Dysfunctional uterine bleeding, in the absence of a medical illness or pelvic pathology, is responsible for almost half the cases of abnormal bleeding.The PALM-COEIN recent classification given by FIGO (the International Federation of Gynaecologists and Obstetricians) divides AUB as being caused by either organic lesions (polyp, adenomyosis, leiomyoma, malignancy, and hyperplasia) or functional disturbances (coagulopathy, ovulatory dysfunction, endometrial, iatrogenic, not yet classified). There are various treatment modalities for abnormal uterine bleeding which include medical management with NSAIDs, tranexamic acid, progesterones, oral contraceptives, Danazol, GnRH analogs, and Levonorgestrel-releasing intrauterine system. Levonorgestrel-releasing intrauterine system (Mirena), was initially developed as a device for contraception, which does not suppress ovulation. It is a T-shaped intrauterine device that releases 20 micrograms of levonorgestrel daily. It endometrial prevents proliferation and reduces the duration and the quantity of bleeding. Mirena was also found to be cost-effective compared to hysterectomy. The surgical morbidity associated with hysterectomy is avoided, by using this hormone-releasing intrauterine device. As amenorrhea is expected in patients on Mirena, counseling should always include, the advantages, side effects, and the chances of the expulsion of Mirena. Mirena can also be used in patients with adenomyosis and endometriosis, and the principle behind is probably the atrophy of the endometrial glands and extensive transformation of the decidua, caused by the chronic exposure of the endometrium to progesterones. It is successful in patients presenting with menorrhagia for unknown reasons.

#### **Objectives**

1. To determine the effectiveness of Levonorgestrelreleasing intrauterine system (Mirena), in decreasing menstrual blood loss, at the end of one year after insertion.

2. To follow up with patients who had Levonorgestrel releasing intrauterine system (Mirena) inserted from 2021 to 2023 (2 years), in the Department of Obstetrics and Gynaecology.

## Methodology

**Source of data:** The records on insertion of Mirena, were obtained from the OT Register of out/in-patients Department of Obstetrics and Gynaecology Rajarajeswari Medical College and Hospital, Bangalore, Karnataka, India, who had insertion of Mirena, from the year 2021 to 2023 were collected.

Duration of Study: 24months.

Type of study: Retrospective observational study

Study Center: RRMCH, Bangalore.

**Study period:** 2021- 2023

**Study Place:** Department of Obstetrics and Gynecology, Raja Rajeswari Medical College & Hospital, Bengaluru, Karnataka

#### Age Group (Years) n (=50) % 31-40 17 34.0 41-50 25 50.0 51-60 8 16.0 31-56 Min - Max Mean $\pm$ SD 43.9+6.4 Median (Q1-Q3) 43.5 (38-48)

#### Table 1: Age-distribution of study subjects

# Selection Criteria

#### **Inclusion Criteria**

- Married women.
- Age group (30-50 yrs)
- With Mirena inserted for Menorrhagia, Endometriosis, Adenomyosis, Firboid, and Endometrial hyperplasia.

## **Exclusion Criteria**

- Age above 50 yrs
- With a history of malignancy
- Where Mirena was inserted for Contraception alone.

Table 2: Presenting Complaints of study subjects-

Presenting Complaints	n (=50)	%
Menorrhagia (Heavy menstrual bleeding)	24	48.0
Polymerogenic (Frequent menstrual bleeding)	9	18.0
Irregular heavy bleeding	12	24.0
Dysmenorrhea	5	10.0

## Methodology

Those patients who had a contact number were contacted over phone and enquired about insertion of Mirena, the symptoms they presented with, reason for insertion, number of days of bleeding, whether excessive, and whether associated with pain. The survival analysis was done and the patient asked whether Mirena was insitu, removed or expelled. Those patients who had inserted Mirena, and continued to use for one year and above, and were willing to be followed up were followed. Those patients who had inserted Mirena, and continued to use for one year and above, and were willing for a telephonic interview, were explained about the study and an oral consent obtained, for follow up. The general proforma, which includes general information about the patient, including the indication, bleeding pattern, associated symptoms, associated comorbidities, whether ultrasound and endometrial biopsy were done, were analysed.

Table 3: Sonography Findings of Study Subjects

#### **Statistical Analysis**

All the data collected were entered into a Microsoft

Sonography Findings	n (=50)	%
Bulky Uterus	20	40.0
Adenomyosis	14	28.0
Polyp	5	10.0
Fibroids	7	14.0
Thickened endometrium	3	6.0

Excel worksheet and analyzed using the statistical software SPSS 20.0.

#### Results

50 patients included in this study, Menorrhagia was the chief presenting complaint in 48% patients attending the gynaecological OPD.

Table 4: Follow-up status of Study Subjects

Status	Follow-up		
	1 Month	6 Month	1 Year
Heavy Bleeding	12 (24.0)	-	-
Moderate bleeding	4 (8.0)	9 (18.0)	-
Spotting	30 (60.0)	7 (14.0)	4 (8.0)
Amenorrhea	4 (8.0)	34 (68.0)	46 (92.0)

By the end of 6 months, 68% patients experienced decreased menstrual blood loss, 92% reported Amenorrhea at the 1-year follow up.

Dr. Tejaswini HK, et al. International Journal of Medical Sciences and Advanced Clinical Research (IJMACR)

#### Discussion

The term abnormal uterine bleeding is used for both ovulatory and anovulatory bleeding. Abnormal uterine bleeding affects 10 - 30% of women of the reproductive age group, and about 50% of women in the perimenopausal age group. This study highlights both the benefits and side effects to the use of LNG - IUS in the management of AUB. The high rates of amenorrhea and low rates of side effects at the end of 2 years indicate the effectiveness of LNG - IUS, with its minimally invasive insertion technique adding to its superiority over other surgical techniques. The choice of medical treatment is the choice of the individual. Local LNG-IUS ranks much higher than all other medical treatments, when the effectiveness, side effect and acceptability are taken into account. The other forms of treatment include endometrial resection/ablation and hysterectomy. Hysterectomy is a definitive treatment, but the risk of surgical morbidity and the cost involved should be considered. The NICE in the UK, has recommended that Mirena, should be considered as the first line of treatment, if no structural abnormalities are detected. Mirena proved superior to oral treatment in achieving normalization of blood loss and also in frequency of side effects. Menorrhagia was the primary symptom in 48% of patients and irregular heavy bleeding was the secondary symptom in 24% of patients.

## Conclusion

Heavy menstrual bleeding or menorrhagia is a subjective finding that can be caused by various structural and nonstructural pathologies. Heavy bleeding can lead to psychological, social, medical and sexual problems, necessitating appropriate and adequate management. Multiple medical and surgical treatment modalities are available for the same. Treatment of menorrhagia results in substantial improvement in the quality of life. Thus, in addition to being a highly effective reversible contraceptive method, it is an excellent fertility sparing device and is the first choice of treatment for heavy menstrual bleeding as per the NICE guidelines.

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