Effect of MIRENA on abnormal uterine bleeding: A study of 30 patients from a private hospital in Tamil Nadu

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Abstract Background: Abnormal Uterine Bleeding is a commonly observed complaint in Ggynaecology OPD. It is annoying. It affects physical, social and economic life of patients. **Aim and objective:** To study the effect of MIRENA on Abnormal Uterine Bleeding in patients at a private hospital **Methodology:** Present study is a prospective study carried out in 30 women with Abnormal Uterine Bleeding at a private hospital. Data was collected with pre tested questionnaire. Data included sociodemographic data, clinical history and clinical examination. MIRENA was inserted on day 5-7 of menstrual cycle. Data was collected from menstrual calendar maintained by the patients about spotting and bleeding. Patients were followed up at 1 month, 4 month and 2 years. The efficacy of Mirena was measured in the form of bleeding pattern, level of HB and satisfaction of the patients. **Results and discussion:** Mean age of the patients was 39.26±2.8 years. Majority of the patients were multipara 24(80%). Abnormal uterine bleeding reduced over time. At the end of 2 years all (100%) patients became amenorrohic. Total bleeding score was 27.94 before insertion and it was significantly reduced to 3.46 after insertion (p<0.05). Mean Hb significantly improved over period of 2 yyears after insertion (p<0.05) **Key Word:** xxxx, xxxxx

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INTRODUCTION

Abnormal uterine bleeding (AUB), defined as a change in any or a combination of frequency, duration, or amount of bleeding. Abnormal uterine bleeding affects 10 - 30% of women of the reproductive age group and about 50% of women in the perimenopausal age group. It accounts for 15% of OPD visits and almost 25% of gynecologic operations.¹ Structural abnormalities such as fibroid, polyp or endometrial hyperplasia present as heavy menstrual bleeding. Adenomyosis and endometriosis mainly present with dysmenorrhea, but can also present with menorrhagia. There are various treatment modalities for abnormal uterine bleeding which includes the medical management with NSAIDs, tranexamic acid, progesterones, oral contraceptives, Danazol, GnRh analogues and Levonorgestrel-releasing intrauterine system. Levonorgestrel-releasing intrauterine system (Mirena), was initially developed as a device for contraception. It is a T shaped intrauterine device. The initial release is 20µ gms per day till 5 years. This rate decreases to half after 5 years.² There is a rapid absorption of locally released levonorgestel from the uterine cavity, via the capillary network in the basal layer of the endometrium, into the systemic circulation. It prevents endometrial proliferation and thereby reduces the duration and the quantity of bleeding.^{3,4} Nearly 30% of all hysterectomies are performed for heavy menstrual bleeding. ⁵ Mirena can be used to prevent hysterectomies as hysterectomy is

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associated with surgical morbidities. AUB affects physical and social quality of life of women Present study is conducted to see the effect of MIRENA on abnormal uterine bleeding.

Aim and objective: To study the effect of MIRENA on Abnormal Uterine Bleeding in patients at a private hospital

MATERIAL AND METHODS

Present study is a prospective study carried out in a private hospital. Study population was 30 women between the ages of 25 to 55 with abnormal uterine bleeding. Patients visiting OBGY OPD in a private hospital were studied.

Inclusion criteria: 1. Patients in age group 25-55 years with abnormal uterine bleeding. 2. Patients with uterine size <12 weeks with no cervical, vaginal pathology and a negative pap smear

Exclusion Criteria: 1. Patients above 55 years and below 25 years 2. Patients with congenital uterine anomaly 3. Patients with fibroids, PID 4. Patients with Haematological disorders 5. Patients with endometrial cancer

Study was approved with ethical committee. A valid written consent was taken from patients after explaining study to them. Data was collected with pre tested questionnaire. Data included sociodemographic data, clinical history and clinical examination. Clinical history included abnormal bleeding pattern like polymenorrhagia , menometrorrhagia and dysmenorrhea. A through clinical examination (general, systemic and pelvic) examination. Transvaginal ultrasound was done and pathologies like fibroids, adenomyosis, endometriosis, endometrial polyps, ovarian cysts, or any other adnexal pathology were diagnosed. Premenstrual dilatation and curettage (D and C) hysteroscopy was done in women above 40 years of age. Patients were started with norethisterone therapy for 3 months depending on phase of menstrual cycle. When patient showed good response to norethisterone, MIRENA was inserted. MIRENA was inserted on day 5-7 of menstrual cycle. Patients were explained about amenorrhea and abnormal bleeding pattern of MIRENA for 3-6 months.

Data was collected from menstrual calendar maintained by the patients about spotting and bleeding. Patients had follow up visits at 1 month, 4 month and 2 years. At every visit location of MIRENA was checked. New changes in pelvic pathology were noted. Data regarding relief of symptoms were recorded.

The efficacy of Mirena was measured in the form of

 1. 1.bleeding score/month. Bleeding score was calculated as sum of daily scores per month. (Score 0 No bleeding, Score 1 Spotting (1 pad/day), Score 2 Mild bleeding (2 pads/day), Score 3 Moderate bleeding (3-4 pads/day), Score 4 Severe bleeding (5-6 pads/day).

- 2. Subjective symptomatic improvement along with improvement in quality of life using Likert's scale.
- 3. Improvement in mean Hb levels.

Statistical analysis will be carried out with the help of SPSS (version 20) for Windows package (SPSS Science, Chicago, IL, USA).

RESULTS

Total 30 patients were studied. Mean age of the patients was 39.26±2.8 years. Range was from 25-54 years. Maximum patients were in the age group of 35-45 years. Table 1 shows distribution of patients of Abnormal Uterine Bleeding according to parity. Majority of the patients were multipara 24(80%) followed by primipara 05(16.67%). One patient was unmarried. All patients underwent ultrasonography. Majority of the patients had fibroids 13(43.33%). Adenomyosis was observed in 05 (16.67%) patients. Adenomyoma was seen in one patient. Normal ultrasound was observed in 12 (40%) patients. Table 3 showed Bleeding pattern of patients of Abnormal Uterine Bleeding after insertion of MIRENA. Abnormal uterine bleeding reduced over time. At first month after insertion of MIRENA amenorrhoea was seen in 6.67%. At the end of 1 year 30% patients become amenorrohic. At the end of 2 years all (100%) patients became amenorrohic. Heavy bleeding was observed in one patient. This patient was posted for hysterectomy. Moderate flow was reduced over period. Spotting was observed in 80% patients at the end of one month, it was reduced over time and by the end of 2 years in all patients.

The efficacy of Mirena was measured in the form of Subjective symptomatic Bleeding score/month improvement along with improvement in quality of life using Likert's scale and Improvement in mean Hb levels. Total bleeding score was 27.94 before insertion and it was reduced to 3.46 after insertion. This difference was statistically significant (p<0.05).Likert scale was 9.4 before insertion and 4.21 after insertion this difference was statistically significant (p<0.05). Mean Hb improved over period of 2 years it was 7.6 ± 1.3 mg/dl before insertion and 10.23±0.9 after insertion of MIRENA. Improved Hb level was statistically significant (p<0.05).(table5) MIRENA was associated with Side effects. Breakthrough bleeding was most commonly observed (12 cases) side effect. Other side effects were increased body weight (1), increased vaginal discharge (3) and lower backache (10). No side effects were observed which leads to removal of MIRENA.

Table 1: Distribution of	patients of Abnormal Uterine	Bleeding according to parity
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Sr no	Parity	No of patients	Percentage
1	Primipara	05	16.67%
2	Multipara	24	80%
3	Unmarried	01	3.33%
4	Total	30	100%

 Table 2: Distribution of patients of Abnormal Uterine Bleeding according to ultrasound findings

Sr no	Ultrasound findings	No of patients	Percentage
1	Fibroids	13	43.33%
2	Adenomyosis	05	16.67%
3	Adenomyoma	01	3.33%
4	Normal	12	40%

Table 3: Bleeding pattern of patients of Abnormal Uterine Bleeding after insertion of MIRENA

Sr no	Bleeding pattern	1 month	4 month	1 year	2 years
		(n=30)	(n=28)	(n=18)	(n=9)
1	Amenorrhoea	02(6.67%)	09(30%)	10(33.33%)	09(30%)
2	Heavy bleeding	00 (0%)	01(3.33%)	00 (0%)	00 (0%)
3	Moderate flow	04(13.33%)	02(6.67%)	02(6.67%)	00 (0%)
4	Spotting	24(80%)	16(53.33%)	06(20%)	00 (0%)

Table 4: Comparison of variables before and after insertion of MIRENA in patients of Abnormal Uterine Bleeding

Sr no		Before insertion	After insertion	P value
1	Total bleeding score	27.94	3.46	<0.05
2	Likert's scale	9.4	4.21	<0.05
3	Mean Hb	7.6±1.3	10.23±0.9	<0.05

DISCUSSION

Total 30 patients were studied. Mean age of the patients was 39.26±2.8 years. Range was from 25-54 years. Majority of the patients were multipara 24(80%). Majority of the patients had fibroids 13(43.33%). In our study, Abnormal uterine bleeding reduced over time. At first month after insertion of MIRENA amenorrhoea was seen in 6.67%. At the end of 1 year 30% patients become amenorrohic. At the end of 2 years all (100%) patients became amenorrohic. Spotting was reduced over time and by the end of 2 years in all patients. Total bleeding score was 27.94 before insertion and it was significantly reduced to 3.46 after insertion. In a study by Ronnerdag M et al.., Amenorrhea is seen in 17% at the end of one year, increasing to 60% in long term users ⁶. Pallavi C et al...⁷ studied effects of Mirena in abnormal uterine bleeding and after 4 four months of therapy found significant decrease to the extent of eighty percent and an appreciable increase in hemoglobin status. Previous studies also showed significant reduction in abnormal bleeding in women having Abnormal Uterine Bleeding.⁸⁻¹¹ Likert scale was 9.4 before insertion and 4.21 after insertion this difference was statistically significant (p<0.05). Mean Hb improved over period of 2 years it was 7.6 ± 1.3 mg/dl before insertion and 10.23±0.9 after insertion of MIRENA. Improved Hb level was statistically significant (p<0.05). Similar

findings were observed in previous studies where significant improvement was observed in Hb after insertion of MIRENA. ^{12,13}

In our study we found that only one patients required Hystereotomy, so MIRENA can be a replacement for hysterectomy. Similar findings were seen in Marjoribanks J *et al.*, ¹⁴ and Hurskainen R *et al.*, ¹⁵.

CONCLUSION

MIRENA has significant reduction in menstrual blood loss in abnormal uterine bleeding patients.

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