ORIGINAL ARTICLE

LEVONORGESTREL RELEASING INTRAUTERINE SYSTEM (MIRENA) FOR ABNORMAL UTERINE BLEEDING- A USEFUL TOOL IN THE COVID TIMES

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ABSTRACT

Objectives: To assess the effectiveness of the Levonorgestrel-releasing intrauterine system (LNG-IUS) in improving heavy menstrual bleeding (HMB) and evaluate satisfaction rates among women with heavy menstrual bleeding, treated with LNG–IUS.

Material and methods: This prospective observational study with a one-year follow-up included 73 women of reproductive age 20 – 50 years with complaints of heavy menstrual bleeding (HMB). They presented to the Gynae ward and the outpatient department (OPD) of Khyber Teaching Hospital, Peshawar, Pakistan. Patients with more than 3 cm fibroids, pelvic inflammatory disease, bleeding of unknown cause, and any known pelvic malignancy were excluded. LNG-IUS (Mirena) was inserted in OPD routinely and in Operation Theater under anesthesia where the cervix could not be dilated. Patients were followed up in OPD at one month, 3 months, six months, and one year. Improvement in symptoms, satisfaction level, and Hemoglobin (Hb) before and after the procedure was documented on a Proforma.

RESULTS: There was a progressive resolution in the amount of bleeding in patients followed at 1-month, 3-month, six months, and one year. The satisfaction rate was 92%. There was an improvement in Hb in 97% of patients. Only 04 out of 73 patients needed a hysterectomy.

CONCLUSION: Levonorgestrel-releasing intrauterine system (LNG-IUS) is an effective and tolerated treatment option for abnormal uterine bleeding. In the Covid times, it proved to be an effective first-line management of AUB. We recommend its use after careful selection of patients and also recommend a good counseling session before its use.

Keywords: Abnormal uterine bleeding, heavy menstrual bleeding, LNG – IUS.

INTRODUCTION

As a team working in the Department of Obstetrics and Gynecology, we get a large number of patients of all ages with abnormal bleeding and their treatment ranges from medical to surgical depending on the severity of the problem. In the Covid times, there were continuous directives from the hospital administration to control elective admission and keep beds vacant for the Covid load. However, there was no decrease in the number of patients coming to the OPD for treatment of Abnormal Uterine Bleeding. This heavy and irregular bleeding harms the quality of life of a woman, affecting her physically and psychologically. There is anemia with all its effects if this loss goes unchecked.

We need Mirena, the LNG – IUS to check this bleeding and avoid major surgery. However, large masses and extended pelvic pathology were dealt with through surgery like hysterectomy. Mirena is a device categorized as a long-acting reversible contraceptive, FDA-approved for the treatment of Abnormal Uterine Bleeding. It contains the hormone levonorgestrel, which is released at a dose of 20 micrograms/ day to thin out the endometrial lining and stop the proliferation of the endometrium by estrogens. This not only affects the endometrium inside the uterine cavity but also elsewhere, hence adenomyosis and endometriosis are also affected. The fibroid is also a tumor responsive to estrogen and a small fibroid may also shrink on prolonged use of Mirena.

The procedure can be done as an outpatient, at any time of the cycle, and under anesthesia for those with a closed cervix or with previous surgeries. It is not contraindicated in previous cesarean sections or previous history of myomectomy. Its use decreases bleeding, pain, and suffering and over some time will lead to improvement of Hb, thus improving the quality of the patient’s life. With this mode of conservative treatment, hysterectomy is avoided. In a normal routine, 30% of hysterectomies are done due to abnormal uterine bleeding. The objectives of this research are 1) to assess the effectiveness of the

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Levonorgestrel-releasing intrauterine system (LNG-IUS) in improving heavy menstrual bleeding (HMB), and 2) to evaluate satisfaction rates among women with heavy menstrual bleeding, treated with Mirena (LNG–IUS).

MATERIAL AND METHODS

This prospective observational study was conducted in the Gynae “A” Unit of MTI Khyber Teaching Hospital for two years with effect from 01/07/2019 to 30/06/2021. The sampling technique was non-probability purposive sampling. seventy-three women of reproductive age 20-45 years who presented to the Gynae outpatient department and OPD with abnormal menstrual bleeding, were included. Patients with fibroids larger than 3 cm, pelvic inflammatory disease, known pelvic malignancy, bleeding of unknown cause, poorly controlled diabetes, or cardiac disease were excluded. Before the start of the study, ethical approval was taken from the Hospital’s ethical approval committee. Written informed consent was taken from the patients. After history taking, a pelvic examination to exclude infection and transvaginal ultrasound were done in all patients. Hemoglobin levels (Hb%) were done in all patients. After careful selection, Mirena insertion was carried out by a consultant gynecologist or postgraduate resident (under supervision). It was carried out under aseptic conditions, routinely in OPD and a few in OT under anesthesia where the cervix could not be dilated, especially in those with previous multiple cesarian sections. Hysteroscopy and endometrial biopsy were done in 8 cases where ultrasound reported increased endometrial thickness or irregular growth of the endometrium.

Patients were followed up at one month, 3 months, 6 months, and 1 year either in person or through telephone. At every follow-up, improvement in HMB based on the patient’s perception (patient-reported outcome) and satisfaction level (patient-reported outcome) were noted. Hb before and after the procedure was done. All the data were documented on a pre-designed Proforma. The data were analyzed in SPSS. Mean and standard deviation was calculated for quantitative variables like age, parity, and mean Hemoglobin levels. Frequency and percentage were calculated for categorical variables like improvement in symptoms, satisfaction level, and improvement in hemoglobin.

RESULTS

The total number of patients enrolled in this study was 73. The patients’ age range was 25 – 50 years and the mean age was 35.5 (SD: +/- 4.2) years. There was no loss to follow up. Those who could not come for a repeat Hb evaluation at 6 months were asked to get their Hb checked at a laboratory near their locality and communicate the result. The rest of the demographic details are given in Table 1. The types of uterine pathologies are listed in Table 2. There was a progressive decrease in the amount of bleeding and an increase in satisfaction rates, with a considerable positive impact seen after 6 months of use (Figure 1). In our study, 67 out of 73 (92%) patients were satisfied with the decrease in bleeding, by the end of one year. Hb improvement was registered in 71 (97%) patients by the end of one year. Mean Hb levels improved from 8.8g/dl to 10.5 g/dl. 4 out of 73 patients (5.47%) needed a hysterectomy due to non-improvement of symptoms. Two of these had expulsion of Mirena with heavy menstrual bleeding with clots. There was no uterine perforation or misplaced IUCD.

Table 1: Demographic details

<table>
<thead>
<tr>
<th>No. Of patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>25 – 35 Years</td>
<td>2</td>
</tr>
<tr>
<td>35 – 40 Years</td>
<td>43</td>
</tr>
<tr>
<td>40 – 45 Years</td>
<td>21</td>
</tr>
<tr>
<td>45 Years &amp; Above</td>
<td>7</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
</tr>
<tr>
<td>Nullipara</td>
<td>5</td>
</tr>
<tr>
<td>1-3</td>
<td>15</td>
</tr>
<tr>
<td>4-5</td>
<td>32</td>
</tr>
<tr>
<td>&gt;5</td>
<td>21</td>
</tr>
<tr>
<td>No. of previous C sections</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>47</td>
</tr>
<tr>
<td>one</td>
<td>12</td>
</tr>
<tr>
<td>two</td>
<td>8</td>
</tr>
<tr>
<td>More than two</td>
<td>6</td>
</tr>
</tbody>
</table>

Table 2: Distribution of Patients according to pathology

<table>
<thead>
<tr>
<th>No. Of patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Idiopathic HMB</td>
<td>33</td>
</tr>
<tr>
<td>Fibroids (less than 3cm)</td>
<td>22</td>
</tr>
<tr>
<td>Adenomyosis</td>
<td>15</td>
</tr>
<tr>
<td>Simple endometrial hyperplasia</td>
<td>3</td>
</tr>
</tbody>
</table>

Fig 1: Effect of Mirena on the decrease in bleeding and satisfaction rates:
DISCUSSION

Abnormal uterine bleeding not only disturbs the patient psychologically but is often incapacitating, leads to anemia, and can severely affect the women’s quality of life. Woman with menorrhagia (excess of 80 ml) shows iron deficiency and become anemic for which we used LNG – IUS. Cochrane database system review has also discussed this in detail. Ninety-two percent of our patients were satisfied with a decrease in bleeding which was better than another study by Parag M. Hangeker et al. which reported overall satisfaction of 76%. 8

A total of 4 out of 73 patients i.e., 5.47% needed a hysterectomy. Comparable results were reported by other studies. 9, 10 The age range as shown in the diagram is from 25 – 50 years of age with a mean age of 35.5 years in our patients. Other studies have shown use with good effectiveness and similar ranges. 11 Twenty-two out of 73 patients had small fibroids and Mirena was effective in 21 out of 22 patients. Other studies also report the successful use of Mirena in patients with myomas. 12, 13 Fifteen out of 73 of our patients had adenomyosis and were very satisfied with Mirena with good results. Other studies also discuss the use of Mirena in adenomyosis and one monitoring has been done by MRI. 14, 15 Although this study doesn’t compare Mirena with other treatment options used for heavy menstrual bleeding, several studies have suggested that concerning heavy menstrual bleeding and improvement in quality of life, Mirena is better than oral progestogens and almost as good as endometrial ablative techniques. However, as compared to a hysterectomy, it is uncertain which treatment option is better. 16-20

The strength of the study lies in the fact that it is the first study done in the COVID era evaluating the utility of Mirena at times when elective surgeries needed to be grossly curtailed. The limitations of the study include its small sample size, subjective methods of reporting outcomes (patient-reported outcomes/PRO), and being a non-randomized, single-center study. 21 More studies of larger magnitude and involving more centers are needed to get statistically significant results.

CONCLUSION

Mirena is an effective and well-tolerated treatment option for abnormal uterine bleeding. In the Covid times, it proved to be an effective first-line management of AUB. We recommend its use after carefully selecting patients and having a good counseling session before its use.

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AUTHOR’S CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under

Naib JM: Data collection, conceptualization, writing, and overall supervision.
Afridi F: Literature search, Writing
Qadir M: Statistical analysis and bibliography.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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