THERAPEUTIC EFFICACY OF LEVONORGESTREL INTRAUTERINE SYSTEM AS AN ALTERNATIVE TO HYSTERECTOMY FOR MANAGEMENT OF HEAVY MENSTRUAL BLEEDING IN PERIMENOPAUSAL WOMEN

SUDERSHAN DASH1, JAGANNATH MISHRA1*, SHASHIS SHANKAR BEHERA1, SUBHASHREE ROUT2

1Department of Obstetrics and Gynecology, PBMH, KIMS, Bhubaneswar, Odisha, India. 2Department of Obstetrics and Gynecology, AIIMS, Bhubaneswar, Odisha, India. Email: shashibehera1971@gmail.com

Received: 04 September 2017, Revised and Accepted: 09 December 2017

ABSTRACT

Objective: This prospective observational study has been conducted to find out the efficacy and patient satisfaction of levonorgestrel intrauterine system (LNG-IUS), and it was compared with results of hysterectomy in perimenopausal Indian women with heavy menstrual bleeding (HMB).

Methods: It was a prospective study conducted on 135 cases after taking consent. Patients were inserted with LNG-IUS, and the outcome in terms of further bleeding and quality of life was compared to that of hysterectomy.

Results and Conclusion: Levonorgestrel containing-IUS is a highly effective treatment of HMB in perimenopausal women. It is a safe, effective, and quality of life after treatment makes it a good alternative to hysterectomy for HMB.

Keywords: Production of chloroform by fresh water chlorella species and blue green alga Anabaena flos-aquae has also been reported by Wachter and Andelman, 1984.

INTRODUCTION

Heavy menstrual bleeding (HMB) is menstrual blood loss (MBL) that is subjectively considered to be excessive by the woman, defined as prolonged (>7 days) or excessive MBL ≥80 ml per menstrual cycle [1] and interferes with her physical, emotional, social, and material quality of life. HMB is an important cause for anemia in perimenopausal women. In general, HMB is a symptom of ovulatory disorders, primary endometrial disorders, fibroid, adenomyosis, and endometriosis, or genital malignancies [2]. Medical treatment for benign lesions includes non-hormonal or hormonal oral medications for a prolonged period of time. When medical treatment is ineffective or unacceptable to the patient, surgical treatment such as hysterectomy or endometrial ablation is the choice. The levonorgestrel-releasing intrauterine system is a nonsurgical, long-acting, and alternative to the traditional medical and surgical treatments for HMB [3].

NICE guideline has stated that while Mirena levonorgestrel intrauterine system (LNG-IUS) is preferable to other medical treatments (triamcinolone acid, nonsteroidal anti-inflammatory drugs (NSAIDs), and COC); this recommendation is based on indirect evidence [4].

The effectiveness and cost-effectiveness of levonorgestrel-containing intrauterine system in Primary Care against Standard Treatment for Menorrhagia (ECLIPSE [5]) trial was a pragmatic, multicenter, and randomized trial that compared the clinical effectiveness of the levonorgestrel IUS with that of usual medical treatment in the primary care setting. Indirect comparison has shown that LNG-IUS generates more quality-adjusted life years than other medical treatments (triamcinolone acid, NSAIDs, and COC) and at a lower cost. Therefore, LNG-IUS is the recommended first-line treatment for HMB.

METHODS

A prospective observational study was conducted to study the efficacy of LNG-IUS in comparison to hysterectomy in perimenopausal women with HMB.

In this study, 135 cases volunteered for taking LNG-IUS. LNG-IUS was inserted as per guidelines, after excluding cases of fibroid >5 cm, adenexal mass, submucosal fibroid or polyp and uterine anomaly by hysteroscopy, clinical and suspicious cases of malignancy, any active liver disease, and coagulopathy.

These patients were followed up at 1 month, 3 months, 6 months, and 12-month post-insertion.

Factors observed at follow-up:

1. Number of pads used per day
2. Duration of bleeding
3. Hemoglobin (Hb%) level
4. Objective sense of wellbeing.

RESULTS

Table 1 summarizes majority of cases attending OPD were from age group 15–39 years (62%) and 38% of cases belong to age group 40–45 years. Out of 2165 cases of HMB, 866 cases were found to have no obvious structural pathology, i.e., around 40% cases.

Out of 537 cases of HMB in perimenopausal group, only 135 (25.14%) cases gave consent for LNG-IUS insertion, and it was inserted as per guidelines for insertion of LNG-IUS [6].

All cases were using more than 5 pads per day before insertion of LNG-IUS.

None of the cases were using more than 8 pads per day 1 month after insertion of LNG-IUS while only 28 patients were using 5–8 pads per day, i.e., 78.6% attained desired MBL after 1 month post-insertion.

Graph 4 shows 89.3% attained desired MBL after 3 months of LNG-IUS insertion.

While none of the cases were using more than 6 pads per day 6-month post-insertion of LNG-IUS, 90% achieved desired MBL.

92% of the cases achieved desired MBL at 1 year post-insertion of LNG-IUS.
Table 1: Demographic characters of total patients (14432)

<table>
<thead>
<tr>
<th>Age in years</th>
<th>HMB (n=2165)</th>
<th>Without obvious pathology (n=866)</th>
<th>Fibroid (n=541)</th>
<th>Others (n=758)</th>
<th>Total (n=14432)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15–39</td>
<td>876 (40)</td>
<td>329 (38)</td>
<td>447 (80.2)</td>
<td>224 (30)</td>
<td>9048 (62)</td>
</tr>
<tr>
<td>40–45</td>
<td>1289 (60)</td>
<td>537 (62)</td>
<td>94 (19.8)</td>
<td>534 (70)</td>
<td>5348 (38)</td>
</tr>
</tbody>
</table>

HMB: Heavy menstrual bleeding

Graph 1: Total patients counseled for insertion of levonorgestrel intrauterine system

Graph 2: Menstrual blood loss 1 month before insertion of levonorgestrel intrauterine system/hysterectomy

Graph 3: Menstrual blood loss after 1 month of levonorgestrel intrauterine system insertion

All cases were selected for LNG-IUS insertion were anemic. Most (74.3%) were mildly anemic while 25.7% were moderately anemic.

Graph 4: Menstrual blood loss after 3 months of levonorgestrel intrauterine system insertion

Graph 5: Menstrual blood loss after 6 months of levonorgestrel intrauterine system insertion

Graph 6: Menstrual blood loss after 1 year of levonorgestrel intrauterine system insertion

Graph 8 shows a continuous increased trend in hemoglobin level after use. 88.2% achieved hemoglobin level more than 10 g/dl after 1 year of use.

Graph 9 shows a continuous increased trend in hemoglobin level after use. 90% achieved hemoglobin level more than 10 g/dl 1 year posthysterectomy (Table 2).

Although spotting and intermenstrual bleedings per v were a problem initially for few after 1 year of insertion none of them were having these problems at 1 year. Oligomenorrhea/amenorrhea was seen in 19 cases after 1 year.
Pelvic pain and mood changes were seen only in 4 and 2 cases, respectively, and at 1 year 91.9% cases were satisfied with the procedure. 23 cases did not come for follow-up.

**DISCUSSION**

Approximately 30% of women with perimenopause experience heavy bleeding during menstruation [7]. While in nearly half of all cases no organic pathology is found, a number of risk factors may contribute to the development of HMB [7].

- 60% of women presenting with complaint of HMB were perimenopausal and 41% were not having any major organic pathology. All cases were using >5 pads/day before any procedure.

At 1 month post-insertion 78.6% cases were using <5 pads/day. Irvine et al. found mean MBL of 85.1% at 1 month post-insertion [8] whereas Tang and Lee [9] found a reduction of 54% MBL at 1 month.

- At 3 months post-insertion 89.3% cases achieved normal MBL which is nearer to Anderson and Rybo [10] who found 86% reduction in MBL but Barrington and Simpkins [11] got only 74% cases of normal menstruation at 3 months.

- At 6 months and 1 year post-insertion 92.9% cases achieved normal MBL which is higher than Fedele et al. [12] and Milson et al. who found 80% and 88% achieved normal menstruation.

- Hb% level shows an increased trend both after LNG-IUS and hysterectomy at 1, 3, 6, and 12 months without supplementing any hematinic and there was no significant difference between the two (p=0.534). The same was also noticed by Crosignani et al. [13], Anderson and Rybo [10], and Schulen et al. [14].

- Spotting and intermenstrual bleeding was seen in no case after 1 year though it was a problem in early months.

- Oligo/Amenorrhea was noticed by 19 cases in our study (p=0.035)

- Pelvic pain was seen in both conditions very rarely.

- Most patients were happy with LNG-IUS except 4 cases out of 112 opt for hysterectomy later due to persistent bleeding.

- In a study by Garg et al. [15] at 6 months post-IUS insertion 10% had amenorrhea, 40% had irregular spotting (decreased flow), 23.3% had infrequent bleeding, 20% had scanty regular bleeding and only two women (6.6%) had irregular heavy bleeding.

- In the study by Yazbeck et al. [16] 86.1% women with dysfunctional uterine bleeding were very satisfied with the treatment with LNG-IUS as an alternative to hysterectomy.

**CONCLUSION**

There is the high effectiveness of LNG-IUS in the treatment of HMB in perimenopausal women. Significant cases were having oligomenorrhea/amenorrhea after 1 year of LNG-IUS insertion. The patient satisfaction and acceptance were comparable to hysterectomy. It is a safe, effective, and acceptable mode of treatment and can be a good alternative to hysterectomy for HMB due to much benign etiology. A Cochrane meta-analysis of 8 trials comparing medical treatment to all surgical methods found that although endometrial destruction, and especially hysterectomy, more effectively reduces MBL, the LNG-IUS provides an equivalent improvement in the quality of life [17].

**REFERENCES**


3. Usman K, Antony ZK, Mohindra V, Kapur A. Therapeutic use of LNG intrauterine system (Mirena) for menorrhagia due to benign lesions-an