ISSN- O: 2458 - 868X, ISSN–P: 2458 – 8687
National Library of Medicine - ID: 101731606

International Journal of Medical Science and Innovative Research (IJMSIR)
IJMSIR : A Medical Publication Hub
Available Online at: www.ijmsir.com
Volume – 7, Issue – 2, March – 2022 , Page No. : 16 - 23

A comparative study to compare the efficacy of lNG-IUD and oral medroxyprogestrone acetate for heavy menstrual bleeding

[1]Suman Bala, Department of Obstetrics and Gynecology, SMS Medical College, Jaipur
[2]Neha Yadav, Department of Obstetrics and Gynecology, SMS Medical College, Jaipur
[3]Asha Verma, Department of Obstetrics and Gynecology, SMS Medical College, Jaipur
[4]Poonam Muhal, Department of Obstetrics and Gynecology, SMS Medical College, Jaipur
[5]Shavya Aggarwal, Department of Obstetrics and Gynecology, SMS Medical College, Jaipur
[6]Vasundhra, Department of Obstetrics and Gynecology, SMS Medical College, Jaipur
Corresponding Author: Neha Yadav, Department of Obstetrics and Gynecology, SMS Medical College, Jaipur.

Citation this Article: Suman Bala, Neha Yadav, Asha Verma, Poonam Muhal, Shavya Aggarwal, Vasundhra, "A comparative study to compare the efficacy of lNG- IUD and oral medroxyprogestrone acetate for heavy menstrual bleeding", IJMSIR- March - 2022, Vol – 7, Issue - 2, P. No. 16 – 23.
Type of Publication: Original Research Article
Conflicts of Interest: Nil

Abstract

Background: To compare the efficacy between levonorgestrel intrauterine device and oral medroxy progesterone acetate for idiopathic heavy menstrual bleeding.

Material and method: A total of 80 cases were included in the study, it is a comparative study that was carried out in department of obstetrics and gynecology, SMS medical college, Jaipur during the period from May 2020 onward till September 2021.

The evaluation of heavy menstrual bleeding done by Higham VBS (VISUAL BLOOD SCORE) The cut of value in VBS is 185.80 women with heavy menstrual bleeding were selected, LNG-IUD was inserted in women, who want IUD and can afford IUD (MIRENA), 40 women will be treated with IUD and 40 women were treated with oral medroxyprogesterone acetate, these were followed up for a period of 6 month, and the total amount of blood loss at 6 month measured and the menstrual pictogram which is a modification of the previous PBAC technique was used to quantify blood loss at end of 6 month. The difference in the blood loss between two groups compared.

Result: Baseline blood loss in Medroxyprogesterone group was 106.23±17.58 ml while blood loss at 6 months is 53±15.35. This difference in blood loss at baseline & 6 months after using Medroxyprogesterone was statistically significant (t=16.499, Df= 39, P value<0.001).

In study subjects with LNG IUD, baseline blood loss was 106.13±19.95 ml while blood loss at 6 months was 33.88±15.25 ml. This difference in blood loss at baseline & 6 months after using LNG IUD was statistically significant (t=19.811, Df= 39, P value<0.001). The mean improvement in blood loss in study subjects taking Medroxyprogesterone was 53.23±20.40 ml while in LNG IUD group, the mean improvement in blood loss was 72.25±23.06 ml.

This difference in mean improvement in blood loss among both groups was statistically significant (p value<0.001).

Conclusions: Our findings concur with NICE guidelines for the use of LNG- IUS as a first-line treatment for menorrhagia [1].

The LNG-IUS should be considered as first-line treatment in patients with menorrhagia if pharmaceutical treatment is indicated, whether or not contraception is needed.

Keyword: menstrual blood loss, LNG-IUD, oral medroxyprogesterone, visual blood score.

Introduction

Heavy menstrual bleeding defined objectively as blood loss 80 ml or more per menstrual cycle is an important cause of iron deficiency anaemia and adversely affect health related quality of life. (1)

Idiopathic heavy menstrual bleeding is defined as bleeding in absence of any pelvic pathology or general bleeding disorder, and has a negative impact on a woman's physical, social, emotional, and material quality of life. [2,3] Quantification of menstrual blood loss also provides an invaluable tool for the assessment of treatment response and disease progression.

The menstrual pictogram is an easy and accurate method for objectively estimating menstrual blood loss. It is suitable for use in the gynae outpatient clinic, as well as in the initial assessment of women in primary care. The menstrual pictogram that is currently in use is a modification of the previous PBAC technique.[4,5]

Although hysterectomy and endometrial ablation provide effective surgical option for heavy menstrual bleeding, both the approaches are associated with perioperative and long-term surgical risks, Algorithms for heavy menstrual bleeding emphasize the use of medical treatment before resorting to surgical options.[6-8]While surgical approaches may be effective, they are associated with perioperative and long-term complication risks. In addition, many women with menorrhagia desire to preserve their potential for childbearing.

Therefore, surgical options should be reserved for women who have pelvic pathology and for those who fail medical treatment. LNG-IUD (brand name MIRENA), contain 52 mg of LNG, it shorten the time of bleeding and blood loss by inhibiting endometrial proliferation. Medroxy progester one acetate is given as 10mg once daily in tablet form for 10 days consecutive days in each cycle, starting on day 16 of menstrual cycle has been found to significantly reduce menstrual blood loss.

Material and method

This is a comparative carried out in department of obstetrics and gynecology, SMS medical college, Jaipur during the period from May 2020 onward till September 2021.It is a multicenter hospital based non-randomized control trial.

A total of 80 cases were included in the study, based on pre-defined inclusion criteria of Parous women aged 20 year or older with idiopathic heavy menstrual bleeding. Any women with Changes in menstrual regularity, hot flushes, sleeping disorder, or mood changes in 3 month preceding study, Breastfeeding, Congenital or acquired uterine abnormality, including fibroids if they distorted the uterine cavity or cervical canal (three or more subserous or intramural fibroids with a total volume of less than 5 cm3 were acceptable),History of organic causes of abnormal uterine bleeding (e.g endometriosis, adenomyosis, endometrial polyps),Use of the levonorgestrel-releasing intrauterine system or a copper intrauterine device during the 30 days before the study, Concomitant use of medication or presence of an

underlying disease or condition known to affect coagulation and menstrual blood loss ,History of or presence of an underlying disease/condition known to affect the metabolism or pharmacokinetics of the study medication, Body mass index greater than 35 kg/m2,History of vascular or coagulation disorder, were excluded from study.

Sample size was calculated as 80% study power and alpha error of 0.05 assuming deviation of 135; 8 ml in absolute change in menstrual blood loss from baseline after 6 months of use of LNG IUD. For a minimum detectable difference of 90 ml in absolute change in menstrual blood loss from baseline, 35 patients in each will be required as sample size, which will be further enhanced and rounded off to 40 patients in each group as final sample size, expecting 15% dropout /loss to follow-up/ attritions.

A written informed consent was taken from each patient. The research protocol was approved by the institutional ethical committee. After applying the inclusion and exclusion criteria for each patient detailed history taken regarding duration of bleeding, frequency of bleeding, regularity of menses, volume of menstrual blood. All women underwent a general physical examination and systemic examination including per abdominal examination, per speculum, per vaginal, and bimanual pelvic examination was done to rule out organic pelvic lesion. Routine blood investigation were done like complete blood count, urine pregnancy test, bleeding time, clotting time, prothrombin time and INR to rule out and coagulopathy.

A basic ultrasonography of lower abdomen and pelvis is done to rule out organic pathology and congenital and acquired uterine anomaly as a cause heavy menstrual bleeding. Chest X-ray and ECG get done before pre-anaesthetic check-up. All eligible women underwent a screening phase lasting two to three menstrual cycles to assess baseline menstrual blood loss. During this phase, Menstrual blood loss of 80 mL or more per cycle was confirmed in at least two screening menstrual cycles before the participants were randomized for women, two methods were suggested to the women who refused any kind of surgery, the evaluation of heavy menstrual bleeding done by Higham VBS (VISUAL BLOOD SCORE) (9). The technique developed by Higham and his friends has been used to find out the difference of blood loss between normal menstrual period and HMB. The evaluation for the menstrual blood loss, the degree of the dirtiness was done by using the form with picture drawings as seen in Fig.1.

The numbers 1, 5, 20 have been given for sanitary pads and tampons considering the degree of dirtiness as minimum, middle and heavy. The cut of value in VBS is 185. The predictive value has been found as 85%.

80 women with heavy menstrual bleeding were selected, LNG-IUD was inserted in women, who want IUD and can afford IUD (MIRENA), 40 women were treated with IUD and 40 women were treated with oral medroxyprogesterone acetate. Women with LNG-IUD had the system placed within 7 days of the onset of menstruation, under short general anesthesia, The day on which the levonorgestrel-releasing intrauterine system was placed was considered the first day of cycle 1, and each cycle was considered to last for 30 days.

Women on oral medroxyprogesterone acetate received 10 mg of the drug once daily for 10 consecutive days in each cycle (the highest dose and regimen indicated in the current label for the treatment of abnormal uterine bleeding attributable to hormonal imbalance in the absence of organic pathology), starting on day 16 of their

menstrual cycle and used the diary cards to record tablet intake (along with the return of unused treatment packs) so that treatment adherence could be monitored, each menstrual cycle was considered to start on the first day of menstrual bleeding and last until the last non-bleeding day before the onset of the next bleeding episode.

All the participant were asked to write down the menstrual period, the women with medroxyprogesterone will be asked to write diary for tablet intake period, patient will be asked to use same brand sanitary pad and change them when they get same amount of dirty.

The menstrual pictogram that is currently in use is a modification of the previous PBAC technique was used to quantify menstrual blood loss at the end of 6 months in both group. The menstrual pictogram is shown in Figure 2.

All information and reports will be recorded on a predesigned proforma and will be entered in Microsoft Excel sheet to prepare master chart. Appropriate parametric test will be used for linear variables and non-parametric tests will be used for categorical variables as per nature and yield of data. P-value <0.05 was be considered as significant.

Results

The mean age group of the study subjects in medroxyprogesterone group was 37.15 years with standard deviation 2.283 years(table1) and in LNG-IUD group Mean age of the study subjects was 37.65 years with standard deviation 2.91 years. (Table-2). Maximum proportion of study subjects' medroxyprogesterone group were residents of urban area (72.5%) while only (27.5%) were living in rural area. Maximum proportion of study subjects with LNG IUD group were residents of urban area (60%) while minimum (40%) were living in rural area. Maximum proportion of the study subjects in medroxyprogesterone group were from Class III (52.5%) followed by Class II (47.5%) of BG Prasad classification of socio-economic status. None of the study subjects were in Class I, IV and V. Maximum proportion of the study subjects with LNG IUD were from Class III (55%) followed by Class II (45%) of BG Prasad classification of socioeconomic status. None of the study subjects were in Class I, IV and V. Maximum (52.5%) of the study subjects of medroxyprogesterone group were having 2 parity followed by 25% as 3 parity, 15% having 4 parity and minimum 7.5% having 1 parity. Maximum (50%) of the study subjects with LNG IUD were having 2 parity followed by 22.5% having 3 parity, 12.5% having 4 parity and minimum 7.5% having 1 parity and 5. In medroxyprogesterone group 37.5% of the study subjects reported 6-10 month of heavy menstrual flow, followed by 27.5% reported heavy menstrual flow for 11-15 month , 15% reported heavy menstrual flow for 16-20 month,10% for 1-5 month, 7.5% for 21-25 month and only 2.5% reported heavy menstrual flow for 26-30 month.(table-3) In LNG-IUD group 35% of the study subjects reported 11-15 days of heavy menstrual flow, followed by 32.5% reported heavy menstrual flow for 6-10 days, 10% reported heavy menstrual flow for 16-20 days and for 21-25 7.5% for 26-30 days and only 5% reported heavy menstrual flow for 1-5 days.(table-4)

Baseline blood loss in Medroxyprogesterone group was 106.23±17.58 ml while blood loss at 6 months is 53±15.35. This difference in blood loss at baseline & 6 months after using Medroxyprogesterone was statistically significant (t=16.499, Df= 39, P value<0.001). In study subjects with LNG IUD, baseline blood loss was 106.13±19.95 ml while blood loss at 6 months was 33.88±15.25 ml. This difference in blood loss at baseline & 6 months after using LNG IUD was statistically

significant (t=19.811, Df= 39, P value<0.001). The mean improvement in blood loss in study subjects taking Medroxyprogesterone was 53.23±20.40 ml while in LNG IUD group, the mean improvement in blood loss was 72.25±23.06 ml. This difference in mean improvement in blood loss among both groups was statistically significant (p value<0.001).

Baseline blood loss in Medroxyprogesterone group was 106.23±17.58 ml while blood loss at 6 months is 53±15.35. This difference in blood loss at baseline & 6 months after using Medroxyprogesterone was statistically significant (t=16.499, Df= 39, P value<0.001). In study subjects with LNG IUD, baseline blood loss was 106.13±19.95 ml while blood loss at 6 months was 33.88±15.25 ml. This difference in blood loss at baseline & 6 months after using LNG IUD was statistically significant (t=19.811, Df= 39, P value<0.001). (Table-5)

The mean improvement in blood loss in study subjects taking Medroxyprogesterone was 53.23±20.40 ml while in LNG IUD group, the mean improvement in blood loss was 72.25±23.06 ml.

This difference in mean improvement in blood loss among both groups was statistically significant (p value<0.001). (table-6) (fig-3)

Discussion

The result from this study demonstrate that, Compared with medroxyprogesterone acetate, treatment with the levonorgestrel-releasing intrauterine system resulted in greater absolute and percentage reductions in menstrual blood loss. our data suggest that lng-iud can be used as better and effective mean of prevention of heavy menstrual bleeding in females with idiopathic heavy menstrual bleeding.

Although losses of 80 ml or more are traditionally considered the criterion for menorrhagia [1], which was used in trials included in this review and many other treatment trials, only about half of women seeking treatment meet this criterion (10), the mean blood loss in our study was 106.23±17.58 ml. All the women using both type of treatment achieved a final of blood loss below 80ml significantly reducing there menorrhagia ,but The mean improvement in blood loss in study subjects in LNG IUD group was 72.25±23.06 ml, which is significantly higher from the study subjects taking Medroxyprogesterone was 53.23±20.40 ml. Similar result were found in Kauntz m et al (55) all where the absolute reduction in median menstrual blood loss was significantly greater in the levonorgestrel-releasing intrauterine system group (—128.8 mL, range —393.6 to +1242.2 mL) than in the medroxyprogesterone acetate arm (—17.8 mL, range—271.5 to +78.6 mL, P < .001), and the proportion of women with successful treatment was significantly higher for the levonorgestrel-releasing intrauterine system (84.8%) than for medroxyprogesterone acetate (22.2%,P < .001).

References

1. National Collaborating Centre for Women's and Children's Health; National Institute for Health and Care Excellence. NICE guideline CG44: heavy menstrual bleeding. London: Royal College of Obstetricians and Gynecologists, 2007.

2. Bang RA, Bang AT, Baitule M, Choudhary Y, Sarmu kaddam S, Tale O. High prevalence of gynecological diseases in rural Indian women. Lancet, 1989; 1:85-88.

3. Jeyaseelan L, Rao PS. Effect of occupation on menstrual cycle length: causal model. Hum Biol, 1995; 67:283– 290.

4. van Eijkeren MA, Schotten PC, Christiaens GCML, Alsbach GPJ, Haspels AA. The alkaline haematin

method for measuring menstrual blood loss: a modification and its clinical use in menorrhagia. Eur J Obstet Gynecol ReprodBiol 1986; 22:345–51.

5. Rybo G. Menstrual blood loss in relation to parity and menstrual pattern. Acta Obst Gynecol Scand 1966;45 Suppl 7:25–45.

6. Nieboer TE, Johnson N, Barlow D, Letha by A, Tavender E, Curr E, et al. Surgical approach to hysterectomy for benign gynecological disease. Cochrane Database of Systematic Reviews 2006, Issue 2. Art. No.: CD003677.

7. National Health Committee New Zealand Working Party. Guidelines for the management of heavy menstrual bleeding. Wellington: National Health Committee New Zealand; 1998

8. McCausland AM, McCausland VM. Long-term complications of endometrial ablation: cause, diagnosis, treatment, and pre- vention. J Minim Invasive Gynecol 2007; 14:399 – 406

9. Higham JM, O'Brien PMS, Shaw RW. Assessment of menstrual blood loss using a pictorial chart. Br J Obstet Gynaecol 1990; 97:734–9.

10. Committee on Practice Bulletins – Gynecology. Practice bulletin no. 128: di- URL: http://www.nice. org.uk/guidance/CG44

Legend Figures and Tables

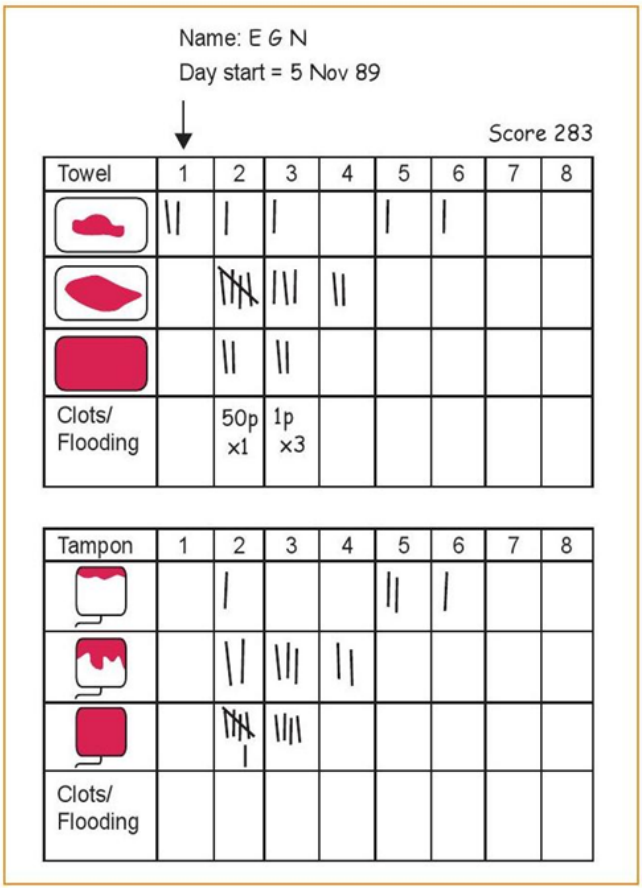

Figure 1: Pictorial blood loss assessment charts (adapted from Higham et al., 1990).

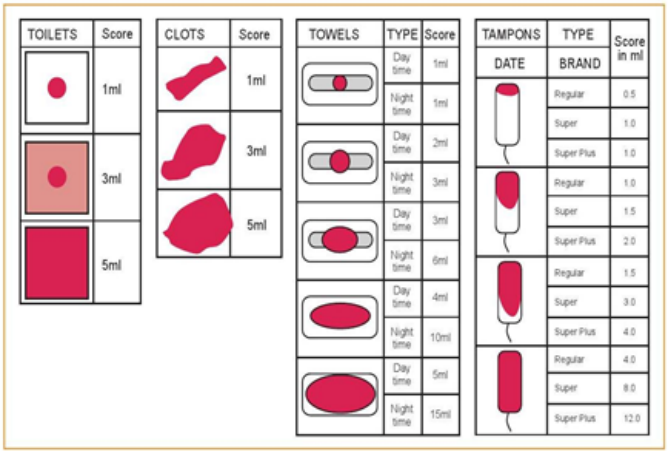

Figure 2: A representation of the menstrual pictogram with blood loss equivalents indicated.

Sn.	Age Groups (in years)	Number	Percentage
1	30-34	8	20
2	35-39	24	60
3	40-45	8	20
4	Total	40	100

Table 1: Age distribution of study subjects in medroxyprogesterone group.

Sn.	Age Groups (in years)	Number	Percentage
1	30-34	5	12.5
2	35-39	24	60
3	40-45	11	27.5
4	Total	40	100

Table 2: Age distribution of study subjects with LNG IUD

Sn.	Duration of heavy menstrual flow (In months)	Number	Percentage
1	1-5	4	10
2	6-10	15	37.5
3	11-15	11	27.5
4	16-20	6	15
5	21-25	3	7.5
6	26-30	1	2.5

Table 3: Duration of heavy menstrual flow in study subjects of medroxyprogesterone group.

Sn.	Duration of heavy menstrual flow (In months)	Number	Percentage
1	1-5	2	5
2	6-10	13	32.5
3	11-15	14	35
4	16-20	4	10
5	21-25	4	10
6	26-30	3	7.5
	Total	40	100

Table 4: Duration of heavy menstrual flow in study subjects with LNG IUD

Sn.	Blood loss (Baseline) in ml	Blood loss at 6 months	p value
Medroxyprogesterone	106.23±17.58	53±15.35	t=16.499, Df= 39, P value<0.001
LNG IUD	106.13±19.95	33.88±15.25	t=19.811, Df= 39, P value<0.001

Table-5: Improvement in Menstrual blood loss in both groups.

Sn.	Medroxyprogesterone	LNG IUD	p value
Improvement in Blood loss (in ML)	53.23±20.40	72.25±23.06	t=3.907, Df= 78, P value<0.001

Table 6: Comparison of Improvement in Menstrual blood loss among both groups

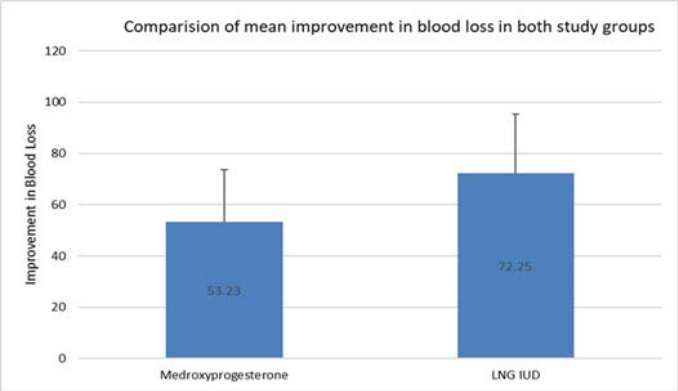

Figure 3