USE OF MIRENA – LEVONORGESTREL INTRA – UTERINE SYSTEM (LNG IUS) IN DYSFUCTION UTERINE BLEEDING IN THE REPRODUCTIVE AGE GROUP

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ABSTRACT

Objective: To assess the efficacy of Mirena in patients with dysfunctional uterine bleeding of reproductive age group.

Study Design: Quasi-experimental study.

Place and Duration of Study: the Department of Obstetrics and Gynecology Lady Lady Willingdon Hospital Lahore, from Jan 2012 to July 2012.

Material and Methods: Patients with dysfunctional uterine bleeding diagnosed on histopathology, not requiring conception, Unfit / unwilling for surgery were included in the study after ruling out all other causes of abnormal uterine bleeding. In thirty three patients of dysfunctional uterine bleeding, mirena was inserted. Sampling strategy was non-probability purposive sampling.

Results: Among thirty three subjects inserted with Mirena LNG system follow up at 3 months, 36.4% had no bleeding, 15.2% had spotting and 48.5% had heavy menstrual bleeding. At 6 month follow-up 90.9% had no bleeding and 9.1% had heavy menstrual bleeding (p=.000). Efficacy at three month follow up was in 36.4% of the subjects and at 6 months follow-up was in 75.8% of the patient (p=.000).

Conclusion: Mirena is an effective non-surgical treatment for dysfunctional uterine bleeding, in women of reproductive age group with fewer incidences of side effects.

Keywords: Dysfunctional uterine bleeding, Mirena, Levonorgestrel-releasing intrauterine system.

INTRODUCTION

Abnormal uterine bleeding in the absence of an identifiable organic cause is called dysfunctional uterine bleeding[1]. Mirena is the, non-invasive, nonsurgical, option for many cases of 'Abnormal uterine bleeding' i-e Fibroid, Adenomyosis, Endometrial hyperplasia, and Dysfunctional uterine bleeding[2].

In 1996, it was concluded that the levonorgestrel intra-uterine system (levonorgestrel IUS; Mirena–Schering Health Care) was an effective contraceptive. The product is now also licensed as a treatment for "idiopathic menorrhagia", with the claim that it " may be particularly useful in woman with idiopathic menorrhagia requiring reversible contraception"[3]. Mirena consists of a plastic T-shaped frame with a steroid reserviour around the vertical stem of polymethylisilicone. The stem contains 52mg of Levonorgestrel, the levo-isomer of norgestrel, derived from the 19 nor-testosterone progestogens, released at a rate of 20µg per day[4].

The effect of all progestogens on the endometrium is mediated via a decrease in oestrogen receptors and an increase in the 17α oxoreductase activity that converts oestradiol to oestrone[5]. The normal treatment options for menorrhagia are oral medications, injections, diagnostic curettage (D & C), Endometrial ablation and hysterectomy etc.

Hysterectomy leads to a lot of personal trauma to both the patient and her family. The pre-post-operative medications along with loss of working days and disturbance from the normal

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routine add to the cost of therapy. Surgery is irreversible leading to loss of fertility and loss of organ. It is difficult to perform in cardiac, diabetic and obese patients.

Mirena offers an ideal option to every woman who could like to conserve her organ, avoid surgery and anemia, save time and money with least interference with her day-to-day life[6].

The LNG-IUS reduces menstrual bleeding and dysmenorrhea, and is an effective nonsurgical treatment for idiopathic menorrhagia in premenopausal women. Women using the device experience significant reductions in menstrual flow and increases in haemoglobin[7]. The LNG-IUS has been used in the prevention and treatment of iron deficiency anemia. Correct insertion is essential, and complications and side effects are rare; fertility is preserved[8].

Mirena is inserted during the menses or within seven days from the beginning of Menstrual cycle. It is checked after four to six weeks. Yearly checks are advised after this appointment. Mirena lasts for 5 years, if required; a new one can be inserted at the same time the old is removed[9]. The most common problem associated with Mirena is that it takes about 3 months for the endometrium to atrophy. During the time bleeding can be heavy and erratic but almost always settles after 3-6 months usage[10]. Temporary side effects may include headache, nausea, mood changes, breast and acne[11]. By providing improvement in Health-related quality of life (HRQL) at relatively low cost, the LNG-IUS may offer a wider availability of choices for the patients and may decrease costs due to interventions involving surgery[12].

The rationale of this study was to assess the efficacy of mirena for safety, effectiveness, non invasiveness, cost effectiveness and the patient morbidity and mortality associated with surgery.

MATERIAL AND METHODS

A Quasi-experimental Study was carried out at department of Obstetrics and Gynecology, Unit-III, Lady Willingdon Hospital, Lahore, during a period of one year and 7 months. A total of thirty three patients of dysfunctional uterine bleeding not requiring contraception and unfit or unwell for surgery were included in the study through non probability purposive sampling after ruling out all other causes of abnormal uterine bleeding among these patients. After an informed consent age, parity, obstetrical history, gynecological history, past medical and surgical drug and menstrual history and changes in the bleeding pattern were evaluated. Detailed systemic examination was carried out. Laboratory investigations specified for the study were mandatory for all patients and included following tests: Ultrasonography, hepatitis screening, histopathology of endometrial curetting and high vaginal swab. The efficacy of Mirena and the side effects experienced were evaluated 3 months and up to 6 months follow-up. Efficacy was measured by amount of blood loss assessed by pictorial blood loss assessment chart (PBAC) at 3 & 6 months follow up, by patient's subjective assessment of amount of blood loss in terms of number of sanitary napkins soaked and passage of clots and was categorized as spotting, heavy menstrual bleeding and no bleeding.

Data had been analyzed in SPSS version 17.0. Frequency and percentage were calculated for menstrual pattern, complications of Mirena and effectiveness at 3 and 6 month follow up. Marginal homogentiy test was used to assess the statistical significance for pattern of menstrual bleeding, effectiveness and complications at 3 month and 6 month follow up with $p<0.05$ as statistical significant.

RESULTS

Thirty three subjects those fulfilling the inclusion criteria were included in the study. Pattern of cycle showed 81.8% had polymenorrhagia while 18.2% had menorrhagia. (Graph no-1). At 3 months follow up 36.4 % had no bleeding, 15.2 % had spotting and 48.5 % had heavy menstrual bleeding. At 6 month follow-up 90.9 % had no bleeding and 9.1 % had heavy

menstrual bleeding. (p<.000) (table-1). Regarding side effects at 3 months, 18.2% of subjects had pain, 21.2% had pain and infection, 45.5% experience no side effect. At 6 months follow up 18.2% had pain, 6.1% had pain and infection while 60.6 % had no side effect. Mirena was expelled or misplaced in 15.2 % of patients (p<.002). At three month follow up Mirena was effective in 36.4 % of subjects, 63.3% it was ineffective. After 6 months follow-up Mirena was effective in 75.8% of the patient and was ineffective in 24.2% of the patients. (p<.000) (table-2).

DISCUSSION

A sample of thirty three patients was collected from Gynecology and Obstetrics unit-III, lady Willington Hospital Lahore. These patients were diagnosed and labeled as cases of dysfunctional uterine bleeding after excluding other organic causes of abnormal uterine bleeding by detailed history, thorough examination and relevant investigations. At 3 months of follow up 48.5% had heavy menstrual bleeding 36.4% had no bleeding and 15.2% had spotting but at 6 month follow-up 90.9% had no bleeding and only 9.1% had heavy menstrual bleeding. Mirena was effective in 75.8% of the patient at end of six month follow up. A similar study was conducted by Monterio I et al. The objective of this study was to evaluate the efficacy and performance, of Mirena up to 1 year, in the treatment of women with menorrhagia. The most common bleeding pattern at 3 months after insertion was spotting, and after 6, 9 and 12 months the majority women presented with

Table–1: Menstrual pattern after 3 & 6 months follow up (n=33).

		Follow-up	
		At 3 month Follow-up	**At 6 month Follow-up**
Menstrual pattern	No bleeding	12 (36.4%)	30 (90.9%)
	Spotting	5 (15.2%)	0 (0.0%)
	Heavy menstrual bleeding	16 (48.5%)	3 (9.1%)
Total		**33**	**33**

Table-2: Effectiveness of LNG-IUS at 3 & 6 months (n=33).

			Follow-up	
			At 3 month Follow-up	**At 6 month Follow-up**
Effectiveness	Yes	Count	12	28*
		% within Follow-up	36.4%	75.8%
	No	Count	21	5
		% within Follow-up	63.6%	9.1%
Total		Count	33	33
		% within Follow-up		

amenorrhea or oligomenorrhea. Three women requested removal of the LNG-IUS because of spotting, and six women expelled it spontaneously. At 12 months 79.5% of participants continued the use of LNG-IUS[13]. Nagrani R et al conducted a similar study. The four to five year long term follow up study showed 50% of women continued to use the device and 67.4% avoided surgery[14]. Xiao B at al conducted a similar study. The objectives of the study was to investigate the effect of the levonorgestrel-releasing intrauterine system (LNG-IUS) in the treatment of idiopathic menorrhagia. In my study At 3 months follow up 36.4% had no bleeding, 15.2% had spotting and 48.5% had heavy menstrual bleeding but at 6 month follow-up 90.9% had no bleeding and 9.1% had heavy menstrual bleeding and after 6 months follow-up of Mirena was effective in 75.8% of the patients.

In another study Thirty-four patients were selected with menstrual blood loss over 80ml. Mirena was inserted on cycle days 5-7 and follow up was done at 3 months interval for 3 years. A significant reduction of menstrual blood loss to 2.7ml (97.7% decrease), and 13.7ml (85.0% decrease), at 6, 12, 24, and 36 months respectively. After 6 months one-third of the patents experienced amenorrhea, and one-fourth spotting[15].

In our study complications at 3 months, 18.2% of subjects had pain, 21.21% had pain and infection while at 6 months follow up 18.2% had pain, 6.1% had pain and infection. Mirena was expelled or misplaced in 15.2% of patients.

Stewart A et al conducted a study to determine whether the levonorgestrel-releasing device (LNG-IUS) licensed at present for contraceptive use, may reduce menstrual blood loss with few side effects. If effective, surgery could be avoided with consequent resources savings. Five controlled trials and five case series were found which measured menstrual blood loss. Nine studies recorded statistically significant average menstrual blood loss reductions with LGN-IUS (range 74%-97%). Another showed reduction in menstrual disturbance score. The LGN-IUS was more effective than tranexamic acid, but slightly less effective than endometrial resection at reducing menstrual blood loss. In one study, 64% of women cancelled surgery at six months, compared with 14% of control group women. In another 82% were taken off surgical waiting lists at one year[16].

CONCLUSION

Mirena reduces menstrual bleeding and is an effective non-surgical treatment for dysfunctional uterine bleeding, in pre-menopausal women with less complications among patients.

CONFLICT OF INTEREST

Authors have no competing financial, professional or personal interests that might have influenced the performance or presentation of this work described in this manuscript.

REFERENCES

1. Chohan A. Abnormal Uterine Bleeding. In: Chohan A. Fundamentals of gyaecology. 1st ed. Lahore: MAR Publications; 2000: 31-42.
2. Comeron IT. Menstrual disorders. In: Edmonds DK Dewhursts. Text book of abstetrics and gynaecology for Postgraduates. 6th ed. London: Blackwell Science, 1999: 410 – 19.
3. Levonorgestrel intra-uterine system for menorrhagia. [online] [cited 2001 Nov]. Available from: URL: http: //wwwoncbi. nlm.nih.gov /enterz /query. fcgi? cmd= Retrieve & db =pubmed & dopt = Abstract.
4. Lumsden MN, McGaviganJ.Menstruation and menstrual disorder. In: Shaw RW, Soutter WP, Stanton SL. Gynwecolody 3rd ed. London: Elsevier Science, 2003: 459 -76.
5. Panny N, Studd J. Non-contraceptive uses of the hormone releasing intra uterine system. In: Studd J Progress in obetetrics and gynaecology. Vol. 13th Edinburgh: Churchill Livingstone, 1998: 379-95.
6. Mirena Nonsurgical treatment for heavy menstrual bleeding [online] [cited 2003] Avaiable from URL: http: //www. indianinfoline. com/bize/mirc/html.
7. Jensen JT. Noncontraceptive applications of the levonogestrel intrauterine system [online] [cited 2002 Dec 2] Available from URL: http: // wwwoncbi. nlm. nih. gov/enterz /query. fcgi? cmd= Retrieve & db = pubmed & dopt =Abstract.
8. Luukkainen T. The levonorgestrel intrauterine system: therapeutic aspects. [onlie] [cited 2000 Oct-Nov] Available from URL: http: //wwwoncbi .nlm. nih. gov/enterz /query. fcgi? cmd=Retrieve & db=pubmed & dopt=Abstract.
9. Tucker D E. Mirena intrauterine system (IUS) [online] [cited 2001 July] Available from URL: http://www. women- health. com. uk/mirena.html.

10. Steinmann R. An intrauterine device: the Mirena, Women's Life [online][cited 2001] Available from URL: http: / / www. womenslife. com.za / Default. asp? Action = article and content. ID = / 175.
11. Mitchel J. New Approval – Contraceptive IUD, Newsletter from Target Health Inc. [online] [citied 2003 Dec. 10] Available from URL: http: / / www. targethealth.com / publicmenu.html.
12. Hurskainen R, Teperi J, Ressanen P, Aattl AM. Grenam S, KivelaA et al. Clinical outcomes and costs with the levonorgestrel-releasing intrauterine system or hysterectomy for treatment of menorrhagia: randomized trail 5-year follow-up. [online] [citied Mar 24] Available from URL: http: / / www. ncbi. nim. nih. Gov / enterz / query. fcgi? cmd= Retrieve & db= pubmed & dopt=Abstract.
13. Monteiro I, Bahamondes L, Diaz J, Perrotti M, Petta C. Therapeutic use of levonorgestrel-releasing intrauterine system in women with menorrhagia: a pilot study(1). [online] [Cited 2002 May] Available from URL: http: / / www. ncbi. nlm. nih. gov / enterz / query. fcgi PMID: 12057782 [PubMed - Indexed for MEDLINE].
14. Nagrani R, Bowen-Simkins P, Barrington JW Can the levonorgestrel intrauterine system replace surgical treatment for the management of menorrhagia? [Online] [Citied: 2002 Mar] Available from URL: http: / / www. ncbi. nlm. nih. gov / enterz / query. fcgi PMID: 11950191 [PubMed - indexed for MEDLINE].
15. Xiao B, Wu SC, chong J, Zeng T, Han LH, Luukkainen T Therapeutic effects of the levonorgestrel-releasing intrauterine system in the treatment of idiopathic menorrhagia [online] [cited] 2003 April] Available from URL: http: / / www. ncbi. nlm. nih. gov / enterz / query.fcgiPMID: 12749438 [PubMed - Indexed for MEDLINE]
16. Stewart A, Cummins C, Gold L, Jordan R, Phillips W The effectiveness of the levonorgestrel-releasing intrauterine system in menorrhagia: a systematic review. [online] [cited 2001 Jan] Available from URl: http: / / www. ncbi. nlm. nih. gov / enterz / query. fcgi PMID: 11213008 [PubMed - Indexed for MEDLINE].