INTRODUCTION

Heavy menstrual bleeding is clinically defined as blood loss greater than or equal to 80 ml per menstrual cycle. Hysterectomy is often used to treat women with this complaint but medical therapy may be a successful alternative.¹

For women in their reproductive years, the LNG-IUS (Levonorgestrel-releasing intrauterine device) has become one of the most acceptable medical treatments for menorrhagia, reducing referrals to specialists and decreasing the need for operative gynaecological surgery.² The local release of levonorgestrel into the uterine cavity results in a strong uniform suppression of the endometrial epithelium as the epithelium becomes insensitive to estradiol released from the ovaries. This accounts for the reduction in menstrual blood loss.³

LNG-IUS is a long-acting, fully reversible method of contraception which gives the users many non-contraceptive benefits. The amount of menstrual bleeding and the number of days of menstrual bleeding are reduced, which makes it suitable for the treatment of menorrhagia.

LNG-IUS has proved to be more effective than cyclical norethisterone (for 21 days) as a treatment for heavy menstrual bleeding and it costs less than hysterectomy.⁴ Dysfunctional uterine bleeding (DUB) occurs frequently in women at the reproductive age and is unrelated to structural uterine abnormalities. It significantly impairs the quality of life for many otherwise healthy women.⁵ LNG-IUS device has also been found to be cost-effective with less side effects and to increase the quality of life (QOL).⁶ The QOL of women treated with the LNG-IUS is markedly improved, causing high levels of patient satisfaction.⁷ Moreover, it has been reported to be useful in patients with dysmenorrhea, fibroids, endometriosis, adenomyosis and endometrial hyperplasia.⁸ The health risks in association with the use of the LNG-IUS appear to be minimal, while the benefits are similar to those obtained with other methods of contraception, with the exception of sterilisation.⁹ Compliance can sometimes

ABSTRACT

Objective: To find out clinical response, side effects and patients’ acceptability of levonorgestrel-releasing intrauterine system (LNG-IUS).

Study Design: Observational study.

Place and Duration of Study: Gynaecology Department of Shifa International Hospital, Islamabad, from June 2005 to May 2008.

Methodology: Adult women were enrolled in the study. In group-A, 57 married women were enrolled presented with abnormal uterine bleeding while in group-B, 16 married women attended for contraception. All women in group-A had thyroid stimulating hormone, pelvic ultrasound and outpatient endometrial biopsy. Detailed counselling was done before insertion. Outcome variables were improvement in bleeding pattern, safety profile, spontaneous expulsion rate and continuation at the end of one year.

Results: In group-A (abnormal bleeding) menstrual cycle became normal in 40.4% women in the first 3 months. At the end of one year, 50.9% women experienced normal cycle, 8.8% were oligomenorrhoeic and 12.3% were amenorrhoeic. In group-B (contraceptive group) all women started with normal cycles. At the end of 3 months 42% complained of vaginal spotting which reduced to 10% at the end of one year. Menstrual pattern at the end of one year showed normal cycles in 52%, oligomenorrhoea in 19% and amenorrhoea in 10% women. Vaginal spotting was experienced by 42% women at 3 months as main complaint which reduced to 10% at the end of one year, however, 7% women requested for removal of device at one year.

Conclusion: LNG-IUS is an effective and acceptable treatment for abnormal uterine bleeding as well as for contraception. Vaginal spotting was the most frequent side effect experienced by both groups.

Key words: Contraception. Abnormal bleeding. Levonorgestrol releasing intrauterine system (LNG-IUS).
be hampered by troublesome side effects (principally breakthrough bleeding) but appropriate counselling can reduce unnecessary discontinuation.9

There was no literature on its use in Pakistani population so the aim of this study was to assess the response of LNG-IUS in cases of abnormal uterine bleeding as well as in contraception and its acceptability in local population.

**METHODOLOGY**

It was an observational study conducted over a period of 3 years from June 2005 to May 2008 in Gynaecology Department of Shifa International Hospital, Islamabad. Sample size was calculated with software Epi info 6; with expected frequency of 6%, sample size for 95% confidence interval and 90% power came to 87.

Response, side effects and acceptability of LNG-IUS was seen for two different indications for which patients were divided into two different groups. In group-A, 57 married women were enrolled who presented with abnormal uterine bleeding while in group-B, 16 married women who attended for contraception were enrolled.

For women with group-A (abnormal bleeding) complete blood picture, thyroid stimulating hormone, ultrasound pelvis and out patient endometrial biopsy were performed. Women presenting with abnormal uterine bleeding with normal or simple endometrial hyperplasia on biopsy were included in the study. Women found to have vaginal bleeding due to malignancy, intermenstrual or postcoital vaginal bleeding, coagulopathy, medical disorders like thyroid disturbance, women on anti-coagulation therapy and multiple fibroids, the largest more than 3 cm were excluded from the study. In group-B (contraceptive group), 16 women attending for contraception were enrolled. In both the groups after selection detailed counselling was done. The outcome variables in group-A included continuation of device at the end of one year, bleeding pattern, safety profile and spontaneous expulsion rate. Outcome variables for group-B were efficacy in contraception, change in menstrual cycle, continuation rate and side effects were noted. All data entered on SPSS 10 and analyzed.

**RESULTS**

Seventy three women were enrolled in the study with mean age of 39.6 ± 7.85 years. All women tolerated the device well.

Figure 1 shows details of patients in group-A (abnormal bleeding), menstrual cycle became normal in 40.4% women in first 3 months. At the end of one year, 50.9% women experienced normal cycle, 8.8% were oligomenorrheic and 12.3% were amenorrheic. In first 3 months vaginal spotting was the most frequent complaint of women (38.6%), which persisted in 3.5% at the end of one year. At the end of one year, only 1.8% women complained of persistent vaginal bleeding and 14% were lost to follow-up. In group-A (abnormal bleeding) spontaneous expulsion was noticed in 8.8% women within 3 months which did not increase at the end of one year.

Figure 2 describes the follow-up of group-B (contraceptive group). At 3 months, 42% complained vaginal spotting which reduced to 10% at the end of one year. Menstrual pattern at the end of one year showed normal cycles in 52%, oligomenorrhoea in 19% and amenorrhoea in 10% women.

**DISCUSSION**

Although menorrhagia is frequent even in young women, the percentage of women with menorrhagia is higher above 40 years of age. This is mainly explained by the higher frequency of uterine pathology, such as fibroids and polyps, which are more common during the pre-menopausal years.

This is a well recognized and established fact that the LNG-IUS offers potential therapeutic benefits in other clinical contexts, including menorrhagia and symptomatic
fibroids etc. However, it frequently produces menstrual disturbances initially that can limit its use by clinicians. In the present study the aim was to document the response of this device in cases of abnormal uterine bleeding and side effects experienced in both groups who used LNG-IUS for abnormal uterine bleeding as well as for contraception.

It was found that 40.4% women noticed normal cycles at 3 months follow-up, by the end of one year only 1.8% women reported persistent vaginal bleeding. Kriplani in a study also concluded that using the LNG-IUS is an effective and well-accepted option for the overall medical management of menorrhagia.

The amount of blood loss is gradually decreased with the use of LNG-IUS. After 6 months many women have no bleeding: in Finnish study one-third of women had no bleeding. In a Brazilian study, 44% of women reported amenorrhea at the 6th month of the study. In a study from Austria, 56% subjects experienced an absence of menstruation, either completely from the time of insertion (47%) or temporarily (9%).

Orbo et al. reported that progestin concentrations in the uterine mucosa provided by the LNG-IUS exceeded that from traditional systemic treatment by several-fold. This ensures superior compliance compared to oral treatment and constitutes a valuable alternative to hysterectomy especially in younger women who still want to preserve fertility and in older women who either refuse operation or their health status is not permitting surgery.

Successful treatment may be obtained even if the uterus is enlarged (e.g. adenomyosis) or in case of small intramural and subserosal fibroids. Despite the introduction of attractive alternative therapies, the total hysterectomy rate in the management of DUB is still high.

In this study, LNG-IUS was generally well tolerated by the women attending for contraception. Removal of device was requested by only 1.8% women at in abnormal bleeding group and 05% in the contraceptive group.

This has also been found in other studies that levonorgestrel-containing intrauterine system is an effective and safe form of long-term yet reversible birth control. It combines the advantages of both hormonal and intrauterine contraception.

Contraceptive efficacy was found to be 100% and no complications (e.g. infection, ectopic pregnancy, expulsion or perforation) or pregnancies were noticed in this study like most of the other studies. Clinical experience with pregnancies in women using a LNG-IUS is virtually non-existent. Comparative studies report that LNG-IUS provides superior effectiveness to copper IUDs. Similarly continuation of LNG-20 IUS use was similar to continuation of the non-hormonal IUDs and Norplant. Thus, the benefits of the LNG-IUS make it a very suitable method of contraception for most women and change in weight of users was of the same magnitude as that of copper IUD users.

Many studies have reported that first few months of use are often characterized by irregular, scanty bleeding, which in most cases resolves spontaneously. In group-A 38% women experienced vaginal spotting at the end of 3 months, however, at the end of one year it reduced to 3.5%. Similarly in group-B (contraceptive) at 3 months follow-up, vaginal spotting was the most troublesome complaint by 40% women and it went down to 10% at the end of one year.

These statistics can help in counselling our patients as abnormal bleeding pattern in first few months can limit its use by patients as well as by clinicians. Studies have mentioned all possible patterns of bleeding observed among users of the levonorgestrel-releasing IUS. In a 3 years follow-up study it was found that 76% of the women were amenorrheic at the 20 months, and 79% at 38 months after insertion. At the end of one year 21% of the presently reported patients who initially presented with abnormal bleeding were amenorrheic or oligomenorrhea. In group-B, amenorrhea was observed in 10% cases at the end of one year which was a significant number in young females. In another study, amenorrhea was noticed in up to 25% of women wearing LNG-IUS for contraception. Although it can be looked upon as beneficial to health, amenorrhea also leads to discontinuation of the method in a significant number of women, as a result of anxiety and cultural non-acceptance. However, most of the women who experience total amenorrhea continue to ovulate. This therapeutic effect of LNG-IUS is highly desirable, particularly in women with heavy bleeding or anemia in developing countries. This treatment modality in addition to providing long-term contraception will protect them from future menorrhagia becoming more cost-effective, non-invasive and convenient in the long-run. Women should be informed of this prior to insertion. The risk of premature removal can be markedly diminished with good pre-insertion counselling, which also markedly increases user satisfaction.

In group-A (abnormal bleeding) spontaneous expulsion was noticed in 8.8% women within 3 months and none in contraception group. It has been noticed that adding oral progestosterone or combined oral contraceptives in first 3 months (i.e. till LNG-IUS has its full effect on endometrium) can reduce the risk of spontaneous expulsion by reducing blood flow. It has also been suggested insertion by the end of menstrual phase can reduce expulsion rate.
CONCLUSION
LNG-IUS is an effective and acceptable treatment for abnormal uterine bleeding as well as for contraception with minimal side effects. Vaginal spotting was the most frequent side effect experienced by both groups.

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