

The Levonorgestrel Intrauterine Device: An Effective and Acceptable Alternative for the Management of Menorrhagia

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Abstract

Objective: The objective of this study was to evaluate the efficacy, performance and acceptability, for up to 2 year, of an intrauterine device releasing 20 µg/day of levonorgestrel (LNG-IUD) in the treatment of women with menorrhagia.

Materials and Methods: It was a descriptive, prospective, non-comparative study. A 20 µg/day LNG-releasing-IUD was inserted following menstrual period to 44 women (between 31 and 49 years of age) who presented with menorrhagia after medical therapies had failed. Menstrual patterns were assessed, hemoglobin concentrations were measured and transvaginal sonography was done before LNG-IUD was inserted and at 45 days, 3 months and then at 6 month interval for 2 years.

Results: The most common bleeding pattern at 3 months after insertion was spotting, and after 1 year and thereafter 41 women (93%) presented with amenorrhea or oligomenorrhea. Three women (6.8%) requested removal of the LNG-IUD because of continuous spotting, and two women (4.5%) expelled it spontaneously. Hemoglobin levels were improved from 10.0 mg/L to 11.4 and 12.8 mg/L at 1 and 2 year respectively, after insertion of the LNG-IUD. At end of 2 year 88.6% of participants continued the use of LNG-IUD and found it acceptable.

Discussion: LNG-IUD was an effective treatment for women with menorrhagia and could be an alternative treatment for women with menorrhagia who are either contraindicated for or refuse hysterectomy or endometrial ablation. Its acceptability is high.

Keywords: levonorgestrel, LNG-IUD, menorrhagia

Özet

Levonorgestrelli Rahim İçi Araç (RİA): Menorajinin Yönetiminde Etkili ve Kabul Edilebilir Bir Alternatif

Amaç: Bu çalışmanın amacı, menorajili kadınların tedavisinde 20 µg/gün levonorgestrel salımlı (LNG) RİA'nın, >2 yıl kullanım şartıyla, etkinliği, performansı ve kabul edilebilirliğinin değerlendirilmesidir.

Materyal ve Metot: Bu, karşılaştırmalı olmayan, tanımlayıcı ve prospektif olan bir çalışmadır. Medikal tedavi sonrası menoraji şikâyeti olan 44 kadına (31-49 yaş aralığında) menstrüel periyodu takiben 20 µg/gün levonorgestrelli RİA takıldı. Levonorgestrelli RİA takılmadan önce hemoglobin değerleri ve transvajinal USG (ultrasonografi) ölçümleri ile menstrüel patenler değerlendirildi ve değerlendirme 2 yıl içinde 45 gün, 3 ay ve 6 ay aralığında tekrarlandı.

Bulgular: LNG-RİA uygulanmasından sonra en yaygın kanama paterni hafif lekelenme tarzında vajinal kanama idi ve 1 yıl sonrasında 41 kadında (%93) amenore ya da oligomenore şikâyetleri izlendi. Üç hasta (%6.8) sürekli vajinal kanamadan dolayı LNG-RİA'nın çıkartılmasını istedi ve 2 hasta (%4.5) kendiliğinden LNG-RİA'yı çıkarttırmıştı. LNG-RİA takıldıktan 1 yıl sonra hemoglobin seviyesi 10.0 mg/L'den 11.4 mg/L'ye, 2 yıl sonra 12.8 mg/L seviyesine yükseldi. İki yıl sonunda katılımcıların %88.6'sı LNG-RİA kullanımına devam etmekte idi ve LNG-RİA'yı kabul edilebilir bir seçenek olarak görmekte idi.

Tartışma: LNG-RİA, menorajili kadınlar için etkili bir tedavidir ve hem histerektomi veya endometriyal ablasyon tedavisini kabul etmeyen hem de bu tedavilerin kontrendike olduğu menorajili kadınlarda alternatif- kabul edilebilirliği yüksek bir tedavi yöntemidir.

Anahtar sözcükler: levonorgestrel, LNG-RİA, menoraji

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Introduction

Menorrhagia is an important cause of ill health in women and it accounts for 9-14% of all gynecology referrals in India. Menorrhagia is clinically defined as greater than or equal to, 80 ml blood loss per menstrual cycle but women may complain of excessive bleeding when their blood loss is less than 80 ml. Hysterectomy is often used to treat women with this complaint. Previous research has shown that hysterectomy is a highly effective treatment for menorrhagia with high satisfaction rate. Since hysterectomy is a major surgical procedure alternatives methods must be assessed against the recognized high satisfaction rates following hysterectomy (1). Because menorrhagia is often a reason for seeking medical attention, it is important to consider outcomes and costs associated with alternative treatment modalities. Additional issues that would also need to be addressed include tolerance, acceptability, complication rates and side-effects.

Alternative method for treatment of menorrhagia includes endometrial ablation and progesterone releasing intrauterine device. Hysteroscopic procedures that ablate and resect the endometrium without hysterectomy have been widely adopted as most patients prefer surgery to the available medical treatments.

The levonorgestrel intrauterine system (LNG-IUS), a steroid-releasing intrauterine system, is a T-shaped device that releases levonorgestrel directly into the uterine cavity at an initial rate of 20 µg/day. The contraceptive and therapeutic benefits of the LNG-IUS stem primarily from its local effects. The local hormone delivery causes high levonorgestrel levels in the endometrial tissue but low levels in the systemic circulation. This leads to strong endometrial suppression and, in many cases, a dramatic reduction in menstrual blood loss (2,3). The levonorgestrel intrauterine system can treat a variety of gynecological disorders, including menorrhagia and anemia. The high contraceptive efficacy is well documented through extensive international clinical research (4). Like oral contraceptives, intrauterine contraceptives confer important noncontraceptive health benefits (4).

However, future research will have to determine the attractiveness of this treatment to patients waiting for a minimally invasive surgical treatment.

Materials and Methods

The present study was done to determine the effectiveness and acceptability of LNG-IUD in achieving a reduction in heavy menstrual bleeding. Study was approved by institutional review board.

Forty four women of age group 31-49 years were offered LNG-IUD insertion after complete assessment and adequate counseling. Counseling was done regarding advantages and side affects of the use of LNG-IUD.

Women with postmenopausal bleeding, inter-menstrual or irregular bleeding, or pathological causes of heavy menstrual bleeding was excluded. Required criteria for all women in the study were recurrent menorrhagia of at least 6 months duration with failed medical therapy. All of them underwent abdominal and transvaginal ultrasonography, hysteroscopy, and endometrial biopsy before study entry.

An IUD releasing 20 µg/day of levonorgestrel was inserted within 7 days of the onset of menses and insertion of device was done under short general anesthesia and there was no perforation recorded. A menstrual diary was completed pre-insertion and again at each follow-up. Follow-up examinations were conducted at 45 days, 3 month and at every 6 month till 2 year. Participants were monitored for symptoms, side effects and menstrual blood loss pattern using a diary and a visual analog scale. On each follow up hemoglobin concentration was measured and transvaginal sonography done.

Long term acceptability of a levonorgestrel releasing intrauterine system was also evaluated by asking all participants to fill a preset proforma. The primary outcome to be evaluated were reduction in menstrual blood loss, decrease in dysmenorrhoea, incidence of side effects, improvement in hemoglobin level, changes in quality of life. Satisfaction and acceptability with use of LNG-IUD was also assessed. All the women had completed their families and eight had history of cesarean section. These women had used estrogen+progesterone or progestogens with or without tranexamic acid in the past but were dissatisfied and finally had opted for hysterectomy. After screening them for both their clinically suitability for intra uterine contraceptive device insertion and in accordance with WHO criteria, mirena was offered as an alternative to hysterectomy.

Results

In all the patients the procedure was successfully performed without any intraoperative and immediate postoperative complications. Patients were discharged on the same day and were able to perform their routine duties from the very next day. Out of 44 women in which LNG-IUD was inserted 2 woman (4.5%) experienced LNG-IUD expulsion 1.8 months after insertion and three women (6.8%) requested removal at 4.2 months because of persistent irregular blood loss. Six months after LNG-IUD insertion, amenorrhea was observed in 2 women, oligomenorrhea in 1 woman, and occasional spotting in 7 women; the remaining 29 women had scanty but regular periods.

At 12 months, 2 women reported amenorrhea, 3 had oligomenorrhea, 2 had spotting, and 22 had regular periods. All menstrual anomalies were well tolerated except for three participants who requested removal. IUD-related side effects included headache (24%), breast tenderness (10%), acne (21%), and weight gain (30%). Significant increases ($p<0.05$) in hemoglobin level i.e. from 10.4 mg/dl before

insertion to 11.4 and 12.8 mg/L at 1 year and 2 year, respectively.

Amenorrhea and oligomenorrhea was considered by most of them as positive change. The proportion of women with menstrual pain was reduced from 60% before use to 29% after 24 month of use with LNG-IUS ($p < 0.05$). Degree of dysmenorrhoea decreased throughout follow-up. Fear of unwanted pregnancy became less wide spread with duration of use and the device has no disturbing effects on the women or there partners during sexual intercourse.

Amongst 44 women, 4 had laparoscopically diagnosed endometriosis and had dysmenorrhoea for which they needed medication. After 3 months of LNG-IUS insertion all the 4 had significant pain relief. Four women had fibroid largest being 4x6 cm. All fibroids were away from endometrium and not distorting the cavity. In one women with fibroid LNG-IUS got displaced and she continued to have heavy flow. She underwent hysterectomy within 6 months of LNG-IUS insertion. Histopathology of endometrium showed cystic glandular hyperplastic endometrium in six cases and rest were normal proliferative endometrium.

Discussion

In the present study we found that LNG-IUS was an effective and simple alternative method for the treatment of menorrhagia. Our finding was in accordance with many previous studies (1,3,5,6).

In this study women with fibroid, adenomyosis, endometriosis or dysfunctional uterine bleeding having menorrhagia were included. In fibroid group there was decreased blood loss, improved hemoglobin status and decreased endometrial thickness in 75% women. Rest 25% continued to have heavy flow due to displaced LNG-IUS and underwent hysterectomy.

In endometriotic and adenomyosis group, apart from decreased flow, pain relief was also experienced. Studies suggest that adenomyosis-associated menorrhagia is improved with use of a levonorgestrel-releasing intrauterine device alone (7). In the present study dysmenorrhoea was significantly improved following LNG-IUS insertion.

Also LNG-IUS was found effective with minimum side-effects in women with symptomatic endometriosis (8).

With LNG-IUS local endometrial concentration of levonorgestrel is high and uniform as compared to blood concentration and this account for lesser side effects. Four women achieved amenorrhea after 12 months and many complained of intermittent spotting at 3 months which further decreased at 6 and 12 months postinsertion.

Alternative medical and surgical options are defined for managing menorrhagia. Patient education regarding these options is essential for patient compliance and satisfaction. The choice of treatment should be tailored to the women's need and preferences (9).

Various studies suggest the superiority of LNG-IUS over other mode of treatment (5,6). The proportion of women who were satisfied with their treatment was higher in the LNG-IUS group than in the control group but this difference did not reach statistical difference (10). The LNG-IUS produced greater reductions in menstrual blood loss than mefenamic acid (11). Endometrial ablation reduces menstrual blood flow, but its benefits relative to hysterectomy lessen over time (1).

The combination of endometrial resection and the insertion of the LNG-IUS is described. Especially in patients with adenomyosis, the combination of LNG-IUS with endometrial resection augments the success rate (12).

The treatment with LNG-IUS seemed to be an appropriate alternative to hysterectomy for all women who perceived their MBL heavy (5,6).

Hysterectomy is expensive and many complications can occur, although treatment effect is permanent. This operation implies a hospital stay of about one week and subsequent sick leave of 4-6 weeks (12). The overall mortality rate is 16.1/10 000 operations and complication rates are 43% and 25% after abdominal and vaginal hysterectomy respectively (13).

Other uses of LNG-IUS are in the treatment of Stage I Grade I endometrial cancers that are at high risk for surgery (14,15).

LNG-IUS acceptance and awareness are poor in our society. Although we offered LNG-IUS to many menorrhagic women, only the educated one accepted it. For most of the women in this study obtained information about LNG-IUS from our clinic; i.e. they were unaware of it before they visited our clinic. Amenorrhea in Indian women can cause psychological and social problems but these can be managed satisfactorily by prior counseling. A better understanding of these effects, both beneficial and deleterious, should lead to more effective patient counseling, which in turn should improve user quality of life, minimize unnecessary removal and maximize continuation of use (12).

LNG-IUS has significant impact on quality of life. In all anemic patients mean hemoglobin level improved after 6 months of LNG-IUS use. Satisfaction level was high except in 2 women and who underwent hysterectomy. Banu et al. reported that satisfaction, health-related quality of life and psychosocial well-being are reportedly similar between hysterectomy and the LNG-IUS, but the latter has the advantage of reduced cost (1,3). LNG-IUS use proves to be cost effective. Cost savings were in terms of decreased clinic

visits, decreased need for hormone therapy as well as analgesics and no need of contraceptive measures. In present study follow up was only for two year. The LNG-IUS is economical in short term but may produce unexpected costs during longer follow up. Further need for hysterectomy, continuing requirement for cervical smear, risk of uterine cancer and uncertainty about further vaginal bleeding during use of LNG-IUS will be more thoroughly assessed after 5 years of follow up (16).

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