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Levonorgestrel containing intrauterine device (Mirena®) in the treatment of dyfunctional uterine bleeding; patients' view and our experience

Disfonksiyonel uterin kanamada levonorgestrel içeren rahim içi araç (Mirena®) kullanımı, hastaların memnuniyeti ve deneyimimiz

Burçin KARAMUSTAFAOĞLU BALCI, Meryem HOCAOĞLU, Gökhan GÖYNÜMER, Ahmet GÖÇMEN

ABSTRACT

Abnormal uterine bleeding is a common cause for visits to gynecology polyclinics and one of the treatment options is levonorgestrel containing intrauterine device (LNG IUD; Mirena®). The aim of this study is to evaluate patient satisfaction following insertion of Mirena® in women with the indication of abnormal uterine bleeding and to share our data concerning the use of Mirena. The study population of this retrospective study consisted of women with the diagnosis of dysfuntional abnormal uterine bleeding with Mirena® inserted between 1 January 2015-31 December 2015. Information about age, obstetric and gynecologic history of the patients, histologic diagnosis of endometrial sampling, pelvic ultrasound reports were retrieved from medical records of the patients. Afterwards, interviews on phone were conducted. Patient satisfaction, complications, rate of amenorrhea, rate of expulsion or displacement, need for removal and if removed the treatment modality preferred were noted. Patient satisfaction was assessed by a scale of four as not satisfied, satisfied, very satisfied and extremely satisfied. A total of 61 Mirena® were inserted during study period and 50 patients were included in the study. We could interview with 31 patients on phone. No complication occurred related to vaginal insertion of Mirena® Twelve patients were amenorrheic, 4 patients oligomenorrheic, 4 patients were complaining of metrorrhagia (spotting). Displacement of Mirena® did not occur, however in 6.45%. of the patients Mirena® came out accidentally. Four patients wanted their Mirena® to be removed. Eight patients were "not satisfied" at all, the other patients were satisfied from the treatment. As a result, Mirena® was overall a well-tolerated treatment modality and around three-quarter of the patients with Mirena® inserted for the treatment of abnormal uterine bleeding are satisfied from the treatment.

Keywords: *Levonorgestrel- releasing intrauterine device, Mirena®, satisfaction, expulsion*

ÖZ

Anormal uterin kanama jinekoloji polikliniklerine yapılan başvuruların önemli bir nedenidir. Tedavi yöntemlerinden biri de levonorgestrel içeren rahim içi araçtır (Mirena®). Bu çalışmanın amacı, anormal uterin kanama endikasyonu ile Mirena® uygulanan hastaların memnuniyetini değerlendirmek ve Mirena® tedavisi ile ilgili deneyimimizi paylaşmaktır. Bu retrospektif çalışmaya disfonksiyonel uterin kanama tanısı ile 1 Ocak 2015 - 31 Aralık 2015 tarihleri arasında Mirena® uygulanan hastalar alınmıştır. Hastaların yaşları, obstetrik ve jinekolojik anamnezleri, endometrial örnekleme sonuçları, pelvik ultrason raporları kayıtlardan elde edilmiştir. Sonrasında hastalara telefon ile ulaşıldı. Hastaların memnuniyetleri, komplikasyonlar, amenore oranı, Mirena®'nın düşme veya kayma oranı, Mirena® çıkartma gerekliliği ve eğer çıkartıldı ise sonra tercih edilen tedavi kaydedildi. Hasta memnuniyeti "hiç memnun değil", "memnun", "çok memnun", "kesinlikle çok memnun" olarak dört tercihli soru ile değerlendirildi. Çalışma sürecinde toplam 61 Mirena® uygulandı. Çalışmaya alınma kriterlerini 50 hasta karşıladı, telefon ile 31 hastaya ulaşıldı. Mirena® uygulaması ile alakalı komplikasyon gelişmedi. On iki hasta amenoreik, 4 hasta oligomenoreik olmuştu, 4 hasta lekelenmeden yakınıyordu. Mirena® kayması hiç olmadı fakat Mirena® düşme oranı %6,45 olarak saptandı. Dört hasta Mirena®'nın çıkartılmasını istedi. Sekiz hasta hiç memnun olmadığını belirtti, diğer hastalar Mirena® tedavisinden memnundu. Sonuç olarak, Mirena® iyi tolere edilen bir tedavi yöntemidir ve disfonksiyonel kanama nedeni ile Mirena® uygulanan hastaların ¾'ü bu tedaviden memnun kalmaktadır.

Anahtar kelimeler: *Levonorgestrel içeren rahim içi araç, Mirena®, memnuniyet, atılma*

INTRODUCTION

Abnormal uterine bleeding is a common cause for clinic visits of women of reproductive age. Once menopause sets in, it resolves. Therefore, many women need treatment during premenopausal years. Dysfunctional abnormal uterine bleeding is treated with hormonal / non-hormonal medications and with surgery. Hormonal treatment modalities include oral contraceptive pills, oral gestagens, levonorgestrel-

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Istanbul Medeniyet University, Goztepe Training and Research Hospital, Department of Obstetrics and Gynecology
Yazışma adresi: Burçin Karamustafaoğlu Balcı, Istanbul Medeniyet University, Goztepe Training and Research Hospital, Department of Obstetrics and Gynecology, Istanbul
e-mail: burcinkaramustafaoglu@yahoo.com

containing intrauterine device (IUD). Non-steroidal anti-inflammatory drugs and tranexamic acid are non-hormonal treatment modalities. Surgical treatment options include endometrial ablation and hysterectomy. However, modern gynecology tends to apply conservative therapies and many women desire to preserve their uteruses. Also, hysterectomy is a major surgical procedure and is associated with social and economic costs. Levonorgestrel-containing IUD (LNG-IUD) is a good option for women who choose conservative treatment modalities and who do not desire to take pills or have trouble remembering to use them. It improves patients' quality of life and in addition, it has contraceptive properties.

LNG-IUD has been approved by the Food and Drug Administration of USA(FDA) for not only contraception but also for the treatment of abnormal uterine bleeding. The progestin that it contains decreases endometrial growth, induces atrophy and pseudodecidualization of the endometrium and as a result decreases the bleeding. Some patients may even be amenorrheic. Studies have shown that women who use LNG-IUD experience decrease in blood loss and increase in hemoglobin levels[1,2]. We often use LNG-IUD to treat abnormal uterine bleeding in our unit. In this study, we aimed to evaluate patient satisfaction following insertion of Mirena® in women with abnormal uterine bleeding and to collect our data for the use of Mirena® in our daily routine.

MATERIAL and METHODS

This retrospective study is carried out in Istanbul Medeniyet University, Goztepe Training and Research Hospital, Istanbul, Turkey. The study is approved by our Institutional Ethics Committee. Between 1 January 2015-31 December 2015, in total of 61 LNG-IUD were inserted in our gynecology out-patient clinic. Our study population consisted of women with the diagnosis of dysfuntional uterine bleeding using Mirena® IUD. Inclusion criteria consisted of women with the diagnosis of abnormal uterine bleeding, who had normal pelvic anatomy, normal endometrial sampling. These women had not used any hormonal therapy for at least 6 months before Mirena® insertion, and they volunteered to participate in the study. Exclusion criteria were the presence of pelvic pathology (e.g. myomas, polyps…), abnormal findings in endometrial samples (e.g. endometrial hyperplasia…), nondiagnosed vaginal bleeding, gynecological cancer story, desire for fertility, uterus size bigger than 10 weeks of gestational age. Also women in whom LNG-IUD was inserted for only contraceptive purposes were excluded from the study.

All patients were complaining from menorrhagia or menometrorrhagia. This diagnosis was made according to the patients personal statements, and menstrual blood loss was not measured objectively. The patients had not any pelvic pathology on ultrasound scan and every patient had normal endometrial sampling. Endometrial biopsy was performed with manual vacuum aspirator. Histological assssessment was done in our hospital's pathology laboratories. Mirena® was inserted near the end of or right after the menstrual period in our clinic. Information about age, obstetric and gynecologic history, histologic diagnosis of endometrial sampling, pelvic ultrasound reports were obtained from medical records of the patients. Following this, interviews were conducted with phone calls. During these phone calls, verbal informed consent were obtained from patients. Patient satisfaction, complications, rates of amenorrhea, expulsion or displacement, need of removal and the treatment modality used were noted. Patient satisfaction was assessed by a scale of four as not satisfied, satisfied, very satisfied and extremely satisfied. Statistical analysis was done using the software Statistical Package for the Social Sciences (SPSS) version 11.5 (SPSS Inc., Chicago, IL.). Descriptive statistical methods (mean and SD) were used to evaluate the study data. Qualitative data were expressed as percentages.

RESULTS

During the study period, a total of 61 LNG-IUDs were inserted in our gynecology outpatient clinic. In our clinic, we insert copper-containing IUDs for contraceptive purposes and Mirena® for the treatment

of gynecologic pathologies; so all of these 61 patients' IUDs were inserted for treatment. Endometrial biopsies of 6 patients revealed simple endometrial hyperplasia without atypia, so these patients were excluded from the study. Pelvic ultrasonographic scans of 5 patients showed uterine myomas, and these patients were also excluded. So, 50 patients met the inclusion criteria. Pelvic ultrasonographic scan and endometrial sampling results of all these 50 patients were within normal limits, as mentioned in inclusion criteria. Demographic data of the study group are presented in Table 1. Gynecologic surgical history of the population revealed three myomectomies (two abdominal, one hysteroscopic), one laparoscopy for ectopic pregnancy and one bilateral tubal ligation for contraception. Twenty-nine patients had their first IUDs inserted, whereas 21 had used IUD before Mean time interval after insertion of Mirena® was 10.5 months±4.1 (min: 3, max:16).

Table 1. Demographic data of the study group. (std dev: standard deviation).

	Mean±std dev.	Minimum	Maximum
Age	41.65±5.48	30	52
Gravidity	2.65±1.74	1	7
Parity	2.16±1.39	1	5

We called these 50 patients for the interviews. We could reach to 31 patients. No complication occured during and/or after Mirena® insertion (no uterine perforation, infection and/or pelvic inflammatory disease). Twelve patients were amenorrheic, while 4 patients were oligomenorrheic, and 4 patients were experiencing metrorrhagia (spotting). The remaining 11 patients were having normal cycles with normal amount of bleeding. Any incident of Mirena® displacement were not reported but two Mirena® IUDs came out (expulsion rate: 2/31; 6.45%). One patient became pregnant and the other patient was under our surveillance, and she was not using any other treatment for her previous complaints . Four patients wanted their Mirena® IUD to be removed because it did not improve their symptoms (n=2), caused pelvic pain (n=1) and caused discomfort (n=1). One of them underwent hysteroscopic endometrial ablation. One patient was using oral gestagens, and two cases were not using any other treatment. Remaining 25 patients continued with Mirena®. Table 2 shows overall satisfaction rates of 31 patients'.

Table 2. Patient satisfaction. Patient satisfaction is assessed by a scale of four; not satisfied, satisfied, very satisfied and extremely satisfied.

	Patients	
Satisfaction status	**n**	**%**
Not satisfied	8	25.8
Satisfied	15	48.4
Very satisfied	7	22.6
Extremely satisfied	1	3.2
Total	31	100

Among 8 patients who were "not satisfied", and IUDs of 2 of them came out. Four patients out of 8 wanted their IUDs to be removed. The remaining 2 dissatisfied patients were having spotting and could not get used to their altered menstrual patterns. Nevertheless, these two dissatisfied patients are still retaining their Mirena®.

DISCUSSION

Heavy menstrual bleeding of unknown reason is a frequent problem and one of the first treatment alternatives is levonorgestrel-releasing intrauterine device. Hysterectomy is a major surgical, and definitive solution, but many physicians tend to preserve it for the patients who do not benefit from medical treatment and minimal invasive surgery (endometrial ablation). Also, as most of the women with dysfunctional abnormal uterine bleeding are in the reproductive age group, they may want to preserve their fertility. In fact, many of women experiencing dysfunctional abnormal uterine bleeding do not want to continue the first treatment option that they have chosen and often end up receiving another treatment modality.

Intrauterine devices are first introduced as contraceptives. The addition of progestagen to IUD (levonorgestrel-containing intrauterine device-Mirena®) in addition to

contraception, reduced menstrual bleeding effectively, LNG IUD-Mirena® contains 52 mg levonorgestrel and releases 20 µgr levonorgestrel daily. Levonogestrel inhibits endometrial growth, thereby shortens menstrual period and decreases the amount of bleeding. In our clinic, we mainly use copper-containing IUDs for contraceptive purposes and we generally keep Mirena® for patients having dysfunctional uterine bleeding.

Reports in English literature generally reveal high patient satisfaction among women using Mirena®. Generally, large-scale studies have reported very high overall satisfaction rates which range from 74 to 95%[3,4]. UK-based ECLIPSE trial (Effectiveness and Cost-effectiveness of LNG containing IUD in Primary care against Standard treatment for Menorrhagia) found that improvement gained from LNG-IUD was greater than the improvement gained from usual treatment options in the management of heavy menstrual bleeding[5]. Another research done in Asia-Pacific population revealed that LNG IUD improved quality of life of women more than conventional medical treatments in the management of heavy menstrual bleeding[6]. Over 80% of women using Mirena® for the treatment of heavy menstrual bleeding were "very satisfied" or "satisfied" with their Mirena®[6]. Our study found that 74.2% of the patients were satisfied ("satisfied", "very satisfied" and "extremely satisfied"). This rate is coherent with what is know from literature.

According to several studies, expulsion rate of copper-containing IUDs is between 2, and 8% during the first year after insertion[7-9]. In the literature, expulsion rate of Mirena® is found to be 7.5%[10], 8.5%[11] and 16%[12], and 37.5%[13]. Higher expulsion rates seem to be associated with large uterine volume[6]. In our study, in two patients Mirena® IUD expelled, therefore expulsion rate was 6.45%, coherent with the literature.

One of the limitations of this present study is that the follow-up period is short (maximum 16 months). When follow-up time increases complication rates may also increase. The other limitation is that our study group is small, we could not reach 38% of the patients who formed our study group.

In conclusion; Mirena® is overall a well-tolerated treatment modality and around three-quarter of the patients with Mirena® inserted for the treatment of abnormal uterine bleeding are satisfied from the treatment.

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