IS HISTORY OF PREVIOUS MULTILOAD 375 IUD EXPULSION A RISK FACTOR FOR LEVONORGESTREL-RELEASING INTRAUTERINE DEVICE USERS?

ÖNCEKİ MULTİLOAD 375 RAHİM İÇİ ARAÇ ATILIMI LEVONORGESTREL SALGILAYAN RAHİM İÇİ ARAÇ İÇİN RİSK FAKTÖRÜ MÜDÜR?

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Abstract

Objective: Although intrauterine devices (IUDs) is one of the most frequently used contraceptive methods, the pregnancy rate is estimated between 1 and 3 per 100 woman-years. Third generation copper IUDs and the levonorgestrel-releasing device (LNG-IUD) are both safer than conventional IUDs with a low failure rate. The contraceptive efficacy of an IUD is thought to be related to its position in the uterine cavity. In previous reports expulsion was associated with a significantly higher risk for a re-expulsion in IUD patients. Although several trials examined the rate of multiload 375 IUD and LNG-IUD expulsions, none have evaluated the partial and complete expulsion rates of the LNG-IUD in previously dislocated multiload 375 IUD users.
Materials and method: This prospective study involved a total of 127 LNG-IUD inserted patients. In 57 patients Multiload 375 IUD have previously dislocated (n=57, study group) and in 70 patients IUD have never been applicated (control group). Transvaginal ultrasound was used to monitor the LNG-IUD position immediately after insertion, 10 days after and later on at 6 months intervals for a 2 years follow-up.
Results: Demographic characteristics of groups were similar. Hypermenorrhea was not found to be associated with an increased dislocation rate in LNG-IUD users. We detected only one dislocation in study group and two dislocations in control group (1,8% vs 2.8%, p>0.05).
Conclusion: History of previous Multiload 375 IUD expulsion was not found to be a risk factor for LNG-IUD failure. With a very low dislocation rate LNG-IUD might provide a higher contraceptive efficacy than other IUDs.
Keyword: Intrauterine devices, levonorgestrel-releasing device, contraception, dislocation, expulsion

Özet

Amaç: Rahim içi araç (RİA), en sık kullanılan doğum kontrol yöntemleri biri olarak kullanılmasına karşın gebelik oranı yıl başına 1-3/100 kadın olarak tahmin edilmektedir.. Üçüncü nesil bakır RİA ve levonorgestrel salan cihaz (LNG-RİA) gebelik oranlarının düşüklüğü ile geleneksel RİA'dan daha güvenlidir. RİA'nın gebelik önleyici etkinliği rahim boşluğu içindeki konumu ile ilgilidir. Önceki yayınlarda multiload 375 RİA ve LNG-RİA yerinden çıkmaları değerlendirilmişse de, daha önce multiload 375 RİA çıkmış olanlarda, LNG-RİA'nın tam çıkma ya da kısmi yer değiştirmeleri incelenmemiştir
Gereçler ve Yöntem: Bu prospektif çalışma toplam 127 LNG-IUD takılmış hastayı içermektedir. 127 hastanın çalışma grubunu oluşturan 57'sinde daha önce Multiload 375 RİA atılımı öyküsü mevcutken(çalışma grubu), 70 hastada daha önceden RİA atılımı öyküsü yoktur (kontrol grubu). LNG-RİA konumunu izlemek için transvajinal ultrasound RİA takılmasından sonraki 10. gün, 6 aylık aralıklarla ve toplamda 2 yıllık izlemler olacak şekilde değerlendirilmiştir.
Bulgular: Grupların demografik özellikleri benzerdir. Hipermenore, LNG-RİA kullananlarda artmış yer değiştirme ile ilişkili bulunmadı. Çalışma grubunda bir LNG RİA atılımı ve kontrol grubunda iki atılım((% 1,8'e karşılık % 2.8, p> 0.05) tespit edildi.
Sonuç: Önceki Multiload 375 RİA atılımı LNG-RİA başarısızlığı için bir risk faktörü olarak bulunmamıştır. Yerinden oynama riskinin çok düşük olduğu LNG-RİA, diğer RİA'lardan daha yüksek kontraseptif etkinlik sağlayabilir.
Anahtar Kelimeler: rahim içi araç, levonorgestrel-salgılayıcı ilaç, kontrasepsiyon, yer değiştirme, atılma

Introduction

From a public health viewpoint, the intrauterine device (IUD) is the most widely used contraceptive method in the world. Prevalence rates range among countries from 2 to 80% of contraceptive users. During 5 years of IUD use, pregnancy occurs in less than 3 per 100 insertions. In 1997 a new type of IUD, the levonorgestrel-releasing device (LNG-IUD) was introduced in Switzerland. The LNG-IUD directly targets the endometrium by releasing levonorgestrel into the uterine cavity. The cylinder containing 52 mg of LNG is covered by a rate-controlling membrane which regulates the daily release rate of the hormone. The initial release rate is 20 µg/day, declining to 11 µg/day at the end of 5 years. The mean release rate over 5 years is 14 µg/day (1,2).

Third generation copper IUDs and LNG-IUD are very safe contraceptive methods with a low failure rate (3). The prevalence of IUDs use differs greatly between regions and countries. In European countries the prevalence is higher (3–20%) in comparison to North America, where the prevalence is less than 1% (4). One of the reasons for the low rate of IUD insertions is the concern that IUD users are at higher risk of pelvic inflammatory disease (PID). Exclusion of nulliparous women and women with multiple sexual partners from this contraceptive method contributes to the current low rate of genital infections in IUD users. Many women in their 30s and 40s have risk factors or contraindications for the use of combined hormonal pills. For this age group the IUD is an important contraceptive choice. A special advantage of the LNG-IUD is the positive effect on menorrhagia and hypermenorrhea, both common menstrual problems in perimenopause and dysmenorrhea.

The risk of pregnancies in IUD users can be increased by incorrect insertions and partial or complete expulsions. Several studies show that the rate of complete expulsions varies from 2 to 8 per 100 women in the first year after insertion (5-7). Partial expulsions may cause symptoms including menorrhagia or pain. Because of symptoms partial expulsions can be diagnosed in some women. However, asymptomatic IUD displacements are only detected, if regular sonographic controls of the IUD position are performed. Previous expulsion of an IUD, young age, hypermenorrhea, nulliparity and uterus sounding > 9.0 cm are associated with a higher rate of IUD dislocations (4,8,9). Most downward migrations of IUD are thought to occur within 6 weeks after insertion (10).

Our aim was to evaluate the partial and complete expulsion rate of the levonorgestrel-releasing device (LNG-IUD) in previous expulsion of the multiload 375 IUD patients.

Materials and Method

In Fatih University Hospital, we inserted 127 LNG-IUD from 2006 to 2008, in 57 patients Multiload 375 IUD (ML 375) had previously dislocated (study group) and in 70 patients IUD have never been applicated (control group).

We gave these patients detailed information about LNG-IUD, especially about bleeding patterns. Before the IUD insertion, informed consent was given and signed by each volunteer.

Only women with documented ultrasound assessment of the IUD position were included. We monitored the position of each intrauterine device immediately after insertion using transvaginal ultrasound. Every IUD insertion was documented with the name of the patient, the date of insertion. The devices were inserted during days 1–5 of the menstrual cycle by two doctors. The LNG-IUD users have had day regular follow-up visits 10 days after insertions and later on 6 months.

Before insertions, the length of the uterus from endometrium to the external cervical ostium was determined using a uterine sound. Women whose uterus sounded >9.0 cm were not included. Gynecological examinations including Pap smear and chlamydia screening were performed before every IUD insertions. The observation period ranged from 10 days after insertion to 24 months. Age, parity, hysterometry, delivery route and uterine sounding, as possible factors influencing the expulsion rate were documented for all women.

A 6.5 MHz multifrequency vaginal probe was used for the transvaginal ultrasound. The distance between the top of the vertical arm of the IUD and the junction between the endometrium and the uterine cavity (IUD-ED) was measured in the mid-longitudinal plane. Women with partial or total expulsions were recommended to removal of the IUD.

The analyses were performed by using the SPSS 17.0 version statistics program.

Results

Over the entire study period from insertion to 24 months, all patients returned to the hospital for follow-up visits after the insertion. Therefore, the sonographic control of the IUD position 10 days after insertion included 127 LNG-IUD users.

All of dislocations were seen in 12 months after the insertion. Table I demonstrates the influence of age, parity, hysterometry and delivery route on the rate of IUD dislocations. Expulsion of devices occured without clinical symptoms such as pain and menorrhagia.

Table I: Clinical characteristics of the patients

Characteristics	Study Group (n=57)	Control Group (n=70)
Age*	33.61 ± 5.8	36 ± 7.1
Parity	3	3
Delivery Vaginal Delivery (%) Cesarean Delivery (%)	 30 (52.6) 27 (47.3)	 37 (52.8) 33 (47.4)
Uterine Sounding (cm)*	7.9 ± 0.4	7.8 ± 0.5
No of expulsion (%)	1 (1.8)	2 (2.8)

*mean ± Standart deviation

Prior to the sonographic control after 6 months, five women wished removal of the device because of menorrhagia or pain but we gave these patients medical therapy and continued the follow-up. No serious adverse reactions requiring treatment discontinuation were observed.

Demographic characteristics of groups were similar. We detected only one dislocation in study group and two dislocations in control group (1,8% vs 2.8%, p>0.05). No statistically significant difference was noted for the expulsion rate for both groups.

Discussion

IUD is the most frequently used reversible family planning method in the world. In two studies that compared copper devices and LNG-IUD pregnancy rates were lower with the LNG-IUD than with copper devices (1,2).

Side effects and device-related complications such as expulsions and perforations are comparable between copper IUDs and the LNG-IUD. Proper insertion is the key to preventing complications including perforations, expulsions and pain. Expulsion of an IUD occurs in 1 in 20 women, and is most common in the first 3 months after insertion, often during menstruation (11).

LNG-IUD is associated with reduced menstruel flow and less painful menstruation (12). The irregular bleeding or spotting that does occur with the LNG-IUD is usually limited to the initial months of use. Once the endometrial effects are established, the bleeding pattern with the LNG-IUD turns gradually to oligomenorrhea or amenorrhea.

The expulsion rate of the LNG-IUD has been reported to be higher in comparison with third generation copper-IUD in studies not monitoring the correct device position with ultrasound (10,13). Both studies were not primarily designed to evaluate the number of partial or complete expulsions. The authors reported the number of complete expulsions in the follow-up of their clinical trial. The 3-year expulsion rates were 10% (LNG-IUD) and 7% (ML 375) in 909 women (13). No difference in the expulsion rate for both IUD types was reported by Anderson et al. (14). We detected only one dislocation in study group and two dislocations in control group (1,8% vs 2.8%, $p>0.05$).

There are many explanations for the different rates of expulsion rates. By using transvaginal ultrasound we did not only identify complete expulsions, but also partial expulsions; in our study, the rate of dislocation was lower for both groups.

Difficult insertions were noted more frequently for the LNG-IUD in the study of Sivin et al. (15). Because it was not evaluated whether those IUDs were in the correct position, we hold the view that at least some of the expulsions have been due to insertion failures. In our trial, women with documented failed insertions were excluded and all insertions were performed by experienced doctors. Different study designs and the method of follow-up to determine the IUD position may explain the different results.

There is little evidence concerning risk factors for the expulsion of the LNG-IUD. Diaz et al. (16) found an increased risk for dislocations in parous adolescents. The expulsion rate for the LNG-IUD has been reported to be slightly increased in women younger than 25 years (15). Age did not have an influence on the dislocation rate in our study, probably because we usually do not insert IUDs to adolescents in our clinic.

Nulliparity, but not higher parity, has been reported to be a risk factor for IUD expulsions (16). Higher parity and delivery rate was not associated IUD dislocations in our study.

This study was designed to detect expulsion rates of the LNG- IUD in two groups. However, it is known that the IUD frame produces foreign body reactions and contractions of the uterus. Furthermore, progesterone suppresses myometrial contractions (17). In this trial we used LNG-IUD. We hypothesize that the addition of the progestagen in the LNG-IUD diminishes the amount of myometrial contractions after insertion resulting in a lower number of downward migrations.

This is the first study demonstrating that previous expulsion has not been detected to be a risk factor for re-expulsion in LNG-IUD users. Using vaginal sonographic monitoring, we demonstrated a significantly lower rate of partial or complete expulsions in LNG-IUD users. Considering that the LNG group included more women with risk factors for partial expulsion like previous dislocation and hypermenorrhea, we conclude that, after insertion, the expulsion rate of the LNG-IUD is lower than that for the ML 375 IUD.

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