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The effects of levonorgestrel-releasıng ıntrauterıne devıce on urınary ıncontınence and female sexual lıfe

Levonorgestrel salınımlı rahim içi araçların üriner inkontinans ve kadın cinsel yaşamı üzerine etkileri

Pelin Kundakçı Özdemir İnci Sema Taş Cenk Yaşa Özlem Dural

Funda Güngör Uğurlucan Halil Saygılı

Istanbul Faculty of Medicine, Gynecology and Obstetrics Department, Istanbul,Türkiye

ABSTRACT

Aim: Levonorgestrel-releasing intrauterine devices (LNG-IUDs) are widely used for long-acting reversible contraception due to their high efficacy, safety and cost-effectiveness. Beyond contraception, LNG-IUDs are widely used in gynecological practice for various medical treatments. Progesterone influences the lower urinary tract by affecting bladder and urethral tone, potentially contributing to urinary symptoms. However, the impact of LNG-IUDs on urinary incontinence and sexual function remains unclear. This study aims to evaluate these effects in women undergoing LNG-IUD insertion.

Materials and Methods: This prospective cohort study included women aged 20-55 who underwent LNG-IUD insertion at Istanbul University Istanbul Faculty of Medicine Gynecology and Menopause clinic between December 2021 and May 2022. Baseline assessments included gynecological examination, ultrasonography, stress test, 24-hour pad test, and validated questionnaires (FSFI, IIQ-7, UDI-6). Follow-ups occurred at 1, 3, and 6 months, with repeated assessments at 6 months.

Results: The study which started with 89 patients, was completed with 80 patients. The mean age was 39 ± 8 years, and mean BMI was 28.1 ± 4.9 kg/m2 . Indications for LNG-IUD insertion included abnormal uterine bleeding (43.7%), contraception (27.5%), pelvic pain (7.5%), and hormone therapy (7.5%). Stress test results remained unchanged, with positiveness in 6 patients at both baseline and 6 months. The 24-hour pad test was positive in 13 patients initially and 12 patients at 6 months (p>0.999). While the total UDI-6 score decreased, urge and stress incontinence scores showed no significant change. Frequence and pelvic pain scores were lower in 6 months. FSFI scores improved significantly, with increases in arousal, lubrication, and pain domains, while no significant changes were observed in desire, orgasm, or satisfaction.

Conclusion: LNG-IUD insertion improved sexual function but had no significant effect on urinary incontinence.

Keywords: Levonorgestrel, LNG-IUD, sexual function, urinary incontinence

ÖZ

Amaç: *Levonorgestrel salınımlı rahim içi araç (LNG-RİA) yüksek etkinlik ve güvenliği nedeni ile uzun etkili geri dönüşümlü kontrasepsiyon yöntemleri arasında yaygın olarak kullanılmaktadır. Kontrasepsiyonun yanı sıra LNG-RİA jinekoloji pratiğinde bir çok endikasyon ile medikal tedavi için kullanılmaktadır. Ancak , LNG-RİA 'nın üriner inkontinans ve cinsel fonksiyon üzerine etkileri net değildir. Bu çalışmanın amacı LNG-RİA uygulanan kadınlarda bu etkileri değerlendirmektedir.*

Corresponding author: İnci Sema Taş
Istanbul Faculty of Medicine, Department of Obstetrics and Gynecology, Istanbul,Türkiye
E-mail: *incisematas@gmail.com*
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Gereç ve Yöntem: *Bu prospektif kohort çalışmasına Aralık 2021 Mayıs 2022 tarihleri arasında İstanbul Üniversitesi İstanbul Tıp Fakültesi Jinekoloji ve Menapoz kliniğine başvuran 20-55 yaş arasında olan ve LNG-RİA takılan hastalar dahil edildi. Jinekolojik muayene , ultrasonografi, stres test, 24 saatlik ped testi ve anketler (IIQ-7, UDI-6, FSFI) hastalara uygulandı. 1,3, ve 6.aylarda takipler yapıldı.*

Bulgular: *Toplam 89 hastadan 80 tanesi çalışmayı tamamladı. Ortalama yaş 39 ±8 yıl , ortalama BMI 28.1±4.9 kg/m2 idi. LNG-RİA endikasyonları arasında anormal uterin kanama (%43.7) , kontrasepsiyon (%27.5), pelvik ağrı (%7.5) ve HRT (%7.5) bulunuyordu. Stres testi sonuçları değişmezken, başlangıçta 13 hastada pozitif olan 24 saatlik ped testi 6.ayda 12 hastada pozitifti (p>0.999) UDI-6 toplam puanı azalırken , urge ve stres inkontinans skorlarında anlamlı değiişiklik olmadı. Frequency ve pelvik ağrı skorları 6.ayda daha düşük bulundu. IIQ-7 skorlarında anlamlı değişiklik olmadı. FSFI skorları anlamlı şekilde artarken özellikle uyarılma, lubrikasyon ve pelvik ağrı skorlarında iyileşme gözlendi. Cinsel istek, orgazm ve tatmin skorlarında değişiklik saptanmadı.*

Sonuç: *LNG-RİA, cinsel fonksiyonları iyileştirirken, üriner inkontinans üzerinde anlamlı bir etki göstermedi.*

Anahtar Sözcükler: *Levonorgestrel, LNG-RİA, cinsel fonksiyon, üriner inkontinans*

INTRODUCTION

The levonorgestrel-releasing intrauterine device (LNG-IUD) is a T-shaped device that continuously releases levonorgestrel (LNG) into the uterine cavity. Levonorgestrel exerts localized effects on the uterus and cervix and diffuses through the endometrium into the bloodstream. The primary action of the LNG-IUD is local, achieved by suppressing the endometrium. This suppression reduces the responsiveness of endometrial estrogen receptors, leading to thinning of the endometrium. Additionally, it increases the expression of glycodelin A in the endometrium, a protein that prevents sperm from binding to the zona pellucida of the ovum, thus inhibiting fertilization. Furthermore, the thickening of cervical mucus impedes sperm entry into the uterus (1). Estrogen and progesterone significantly impact the lower urinary tract, influencing both anatomical and functional aspects. Estrogen plays a crucial role in maintaining the health of the urothelium and connective tissues in the bladder and urethra. During estrogen deficiency, such as in menopause, tissue elasticity can decrease, leading to symptoms like increased urinary frequency and urgency (2). Hormone Replacement Therapy (HRT) with estrogen can alleviate these symptoms by restoring tissue elasticity (3). On the other hand, progesterone affects the lower urinary tract by modulating smooth muscle tone and receptor sensitivity. Elevated progesterone levels during the luteal phase can exacerbate symptoms like urgency and frequency (4). The effects of progesterone are mediated through beta-adrenergic receptors, which influence bladder contractility and tone (5). The balance between estrogen and progesterone affects urinary tract function; estrogen therapy may be effective for certain urinary symptoms, while progesterone's effects can vary depending on individual factors and hormonal regimens (6). Understanding these interactions is essential for optimizing treatment strategies for hormone-induced urinary symptoms. Levonorgestrel-releasing IUDs are among the most commonly used methods for long acting reversible contraception due to their effectiveness, safety comparable to surgical sterilization, ease of use, and cost-effectiveness. Studies have demonstrated that, beyond contraception, these devices are useful for managing abnormal uterine bleeding, treating endometrial hyperplasia, and providing endometrial protection in hormone replacement therapy (7). LNG-IUDs are considered a first-line treatment for abnormal uterine bleeding. Research has shown that they can improve quality of life compared to other treatments for abnormal uterine bleeding (8). Urinary incontinence, characterized by involuntary leakage of urine, can significantly affect quality of life. Approximately 10-20% of women and 77% of women in nursing homes experience urinary incontinence, yet only about 25% seek treatment. Unfortunately, incontinence can have a profound impact on quality of life (9). Female sexual dysfunction (FSD) is defined as the lack of at least one component in the sexual response cycle (i.e., desire, arousal, ability to reach orgasm, and pain during sexual intercourse). At least 40% of women worldwide have one or more sexual problems (10). Studies have revealed that female sexual

response is influenced by a range of biopsychosocial factors. Both physiological, psychological, and sociocultural factors, as well as interpersonal relationships, play a role in sexual function and/or dysfunction in both genders (11). Despite its increasing use and significance in gynecological practice, the impact of LNG-IUDs on women's daily lives remains uncertain. The literature includes a few studies evaluating the effects of LNG-IUDs on urinary and sexual functions in patients with abnormal uterine bleeding. These studies have produced varying results regarding the effects of LNG-IUDs on urinary incontinence and female sexual life, and no consensus has been reached (12). This study aims to investigate the effects of the levonorgestrel-releasing intrauterine device on urinary incontinence and female sexual function by comparing assessments of urinary incontinence, incontinence questionnaires, and sexual function using the FSFI questionnaire, before and after LNG-IUD insertion, in patients at the Istanbul University Istanbul Faculty of Medicine Gynecology and Menopause Clinic. Our hypothesis was that LNG-RIA would have no impact on urinary incontinence but would have a positive effect on sexual function.

MATERIALS AND METHODS

This prospective study included patients who were scheduled to receive a levonorgestrel-releasing intrauterine device (LNG-IUD) for any reason at the Gynecology and Menopause Clinic of Istanbul University, Istanbul Faculty of Medicine. Patient evaluations commenced in December 2021. Informed consent forms were obtained after informing patients about the procedure. Those who agreed to participate were included in the study. Written informed consent was obtained from the patient for the publication of their medical data. Ethical approval for the study was granted by the Istanbul University Istanbul Faculty of Medicine Ethics Committee (19.11.2021 – Approval Number:2021/1984). Women aged 20-55 in their reproductive years were eligible for the study. Exclusion criteria included postmenopausal women, adolescents, individuals with known neurological disorders, and those receiving medical or planning surgical treatment for urinary incontinence. Of the patients receiving the LNG-IUD, three were excluded due to ongoing medical treatment for urinary incontinence, and one was excluded due to a planned surgical intervention for stress urinary incontinence. Ultimately, 89 patients were included, and follow-ups began. Four patients underwent surgery before completing the 6-month follow-up due to persistent abnormal uterine bleeding, two had device expulsion, and three withdrew from the study voluntarily. Thus, 80 patients were assessed at both the 0-month and 6-month time points during the 6-month follow-up period. Prior to LNG-IUD insertion, patients underwent a detailed medical history review, routine gynecological examinations, and transvaginal ultrasound. Data collected included age, demographic information, medical history, obstetric and gynecological history, height, weight, body mass index, gynecological examination findings, and ultrasound results. Menstrual bleeding volume was assessed using the Pictorial Blood Loss Assessment Chart (PBAC), based on the amount of bleeding and symptoms reported. Additionally, a stress test was performed, and a 24-hour pad test was planned and explained to the patients. The Female Sexual Function Index (FSFI), Incontinence Impact Questionnaire (IIQ-7), and Urogenital Distress Inventory (UDI-6) questionnaires were completed. Patients received counseling about the procedure, and verbal consent was obtained. Following the placement of a sterile speculum, the vagina and cervix were cleaned with an iodine solution. For anteverted uteri, the cervix was held with a tenaculum at the upper lip, while for retroverted uteri, it was held at the lower lip, and the uterus was positioned accordingly. The LNG-IUD was then inserted using a hysterometer to measure uterine size. After the procedure, the position of the device was confirmed with transvaginal ultrasound. Patients were scheduled for follow-up visits at 1, 3, and 6 months. At 1 and 3 months, routine gynecological examinations were performed, and data were recorded. At the 6-month visit, in addition to gynecological examination and ultrasound, the stress test, 24-hour pad test, and FSFI, UDI-6, and IIQ-7 questionnaires were repeated. Menstrual bleeding volume was reassessed using the PBAC visual form. The Pictorial Blood Loss Assessment Chart (PBAC) is a semi-quantitative tool for assessing menstrual blood loss. It evaluates the number of sanitary products used, the degree of blood soiling on these products, the number and size of blood clots, and any leakage incidents (13). The Female Sexual Function Index (FSFI) was developed in 2000 to assess female sexual function based on the model described in DSM-IV and ICD-10. The FSFI is a 19-item questionnaire covering six domains of female sexual function:

desire (items 1-2), arousal (items 3-6), lubrication (items 7-10), orgasm (items 11-13), satisfaction (items 14-16), and pain (items 17-19). A Turkish version of the FSFI is available (14). The Urogenital Distress Inventory (UDI-6) is a condensed version of the UDI questionnaire designed for ease of use. It includes questions related to urinary frequency, urge urinary incontinence, stress urinary incontinence, dribbling, difficulty in voiding, and pelvic pain, scored from 0 (none) to 3 (very much) (15). The Incontinence Impact Questionnaire (IIQ-7) is a seven-item form assessing the impact of urinary incontinence on daily life. It includes questions about the effects on physical activity (questions 1 and 2), travel (questions 3 and 4), social activities (question 5), and emotional well-being (questions 6 and 7). Turkish versions of the UDI6 and IIQ-7 questionnaires are used (16).

Data was collected using Excel and analyzed with R software (version 4.1.2) for statistical analysis (R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria, Available online: http://www.rproject.org/). The summary v1.5.2 package was used for the analysis. The normality of continuous data was assessed using the Kolmogorov-Smirnov and Shapiro-Wilk tests, Q-Q plots, and histograms. Continuous data are presented as median with 25th and 75th percentiles or as mean ± standard deviation, while categorical data are presented as frequencies and percentages. Mann-Whitney U tests were used for comparing nonnormally distributed continuous data between independent groups, and Wilcoxon tests were used for dependent continuous groups. Fisher's exact test was used for comparing categorical data between independent groups, and McNemar's test was used for dependent categorical data. All tests were two-tailed, and statistical significance was set at $p < 0.05$.

RESULTS

The mean age of the patients was 39 ± 8 years. The mean gravida and BMI were 3 (range 2-4) and 28.1 ± 4.9 kg/m², respectively. An examination of the patients' complaints revealed that 35 (44%) presented with abnormal uterine bleeding (AUB), 8 (10%) had AUB combined with pelvic pain, and 6 (7.5%) reported pelvic pain alone. Additionally, 6 (7.5%) patients had postmenopausal bleeding, and 3 (3.8%) patients experienced spotting at the end of their menstrual periods. Of the patients, 22 (28%) sought treatment primarily for contraception.

An analysis of FSFI scores at 0 and 6 months indicated a significant change, with scores at 6 months being higher than at baseline (p=0.004). Subscale analysis revealed no significant differences between the desire, orgasm, and satisfaction scores at 0 and 6 months (p>0.05). However, scores for arousal, lubrication, and pain were significantly higher at 6 months compared to baseline (p values: 0.049, 0.014, 0.002, respectively).

There was no significant difference in IIQ-7 scores between 0 and 6 months (p=0.93). However, the total UDI-6 score was lower at 6 months (p=0.004). Analysis of UDI-6 subscales showed no significant differences in scores for urge urinary incontinence, stress urinary incontinence, dribbling, and difficulty in voiding between 0 and 6 months (p-values: 0.773, 0.424, 0.346, >0.99, respectively). The average scores for frequency and pelvic pain were significantly lower at 6 months compared to baseline (p-values: 0.005, <0.001, respectively).

DISCUSSION

Levonorgestrel-releasing intrauterine devices (LNG-IUDs) have gained substantial prominence in gynecological practice due to their expanding range of applications. Numerous studies have demonstrated that, beyond their use for contraception, LNGIUDs can also address abnormal uterine bleeding, serve as a medical treatment for endometrial hyperplasia, and provide endometrial protection against estrogen in hormone replacement therapy (7, 17). The female lower urinary tract is considered a target organ for the effects of sex steroid hormones such as estrogen and progesterone (18). Progesterone receptors are found in conjunction with estrogen receptors in the subepithelial vaginal stroma and throughout the lower urinary tract (19). Progesterone reduces ureteral, bladder, and urethral tone by increasing beta-adrenergic stimulation (20). During the luteal phase of the menstrual cycle, when progesterone is predominant, urinary symptoms often worsen. While the precise mechanism is not fully understood, it is considered that progesterone may contribute to the urinary urgency symptoms observed during pregnancy (21). Several studies have linked oral progestins to adverse effects on urinary incontinence and overactive bladder

symptoms (22). Bennes et al. found that, clinically, while progesterone are associated with increased irritative bladder symptoms and leakage in incontinent women receiving hormone replacement therapy, they do not appear to alter the urethral pressure profile in women without urinary incontinence (23). In a study by Iliadou et al., a reduction in stress urinary incontinence symptoms, urge urinary incontinence, and mixed urinary incontinence risk were observed in users of oral contraceptives (24). However, no significant reduction in urinary incontinence symptoms was noted in patients with LNG-IUDs compared to those not using any form of contraception (25).

Heliövaara-Peippo et al. conducted a prospective randomized study comparing the long-term outcomes of LNG-IUDs and hysterectomy on lower urinary symptoms. They found that stress urinary incontinence and a sensation of incomplete bladder emptying were significantly more common in the hysterectomy group, while the LNG-IUD group showed a statistically non-significant increase in these symptoms (26). Sexual dysfunction is associated with a range of interpersonal, psychological, physiological, medical, social, and cultural factors (27). Epidemiological studies estimate that approximately 40% of women experience at least one sexual dysfunction (28). In a randomized controlled trial comparing patients using LNG-IUDs and hysterectomy, Halmesmäki et al. observed no changes in sexual satisfaction or sexual dysfunction in the LNG-IUD group. However, partner satisfaction decreased in 12 months (P = 0.05) and remained lower in 5 years (29).

A detailed analysis of sexual function in women using different types of intrauterine devices compared to those not using any contraceptive method revealed statistically significant differences. Women using LNG-IUDs demonstrated significantly better results in sexual desire, arousal, orgasm, satisfaction, and dyspareunia (30). When comparing pain scores among LNG-IUD users, copper IUD users, and controls, LNGIUD users had significantly higher pain scores, while no differences in pain scores were observed between copper IUD users and controls (31). Bastianelli et al. found that while sexual dysfunction was not observed in LNG-IUD users, there was an increase in sexual satisfaction and a reduction in dyspareunia (32). There is limited research on the impact of this frequently used treatment on lower urinary tract symptoms and women's sexual health, and existing studies do not reach a consensus. Our findings can be explained through several mechanisms. Notably, the improvement in FSFI scores, particularly in sexual arousal and lubrication, can be attributed to the local hormonal effects of the LNG-IUD. We believe that these local hormonal effects may enhance vaginal lubrication and reduce abnormal uterine bleeding, potentially leading to less discomfort during sexual activity. The effects on urinary incontinence and lower urinary tract symptoms are more complex. UDI-6 results suggest that the LNG-IUD is effective in reducing overall urinary incontinence symptoms but does not significantly impact specific types of incontinence, such as urge or stress incontinence. IIQ-7 scores did not show any significant changes. Taken together, these results suggest that while the LNG-IUD may contribute to the improvement of urinary symptoms, it does not appear to have a significant effect on urinary incontinence.

CONCLUSION

Our study has demonstrated that LNG- IUD has a positive effect on women's sexual health but has no impact on urinary incontinence. There's an opinion that LNG- IUD may have potential in enhancing urinary symptoms, suggesting the need for additional detailed study into its effects on specific types of incontinence and daily life. During the course of our study, noticeable and statistically significant differences observed between the study groups. Additional study is needed with larger case populations and randomized controlled prospective studies that include objective criteria in the study design to investigate the differences between groups.

Conflict of Interest: The authors declare no conflict of interest related to this review.

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