ARAŞTIRMA MAKALESİ / RESEARCH ARTICLE

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Bakırlı Rahim İçi Araç ve Deri Altı İmplantın Yerleştirildikten Bir Yıl Sonraki Menstrüel Değişikliklerinin Karşılaştırılması

Comparison of Menstrual Cycle Changes with The Copper Intrauterine Device and Subdermal Implant One Year After Insertion

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ÖZ

Giriş: Bu çalışmada, bakırlı rahim içi araç (Cu-RİA) ile etonogestrel içeren subdermal implantın yerleştirildikten bir yıl sonraki menstrüel siklus değişikliklerini karşılaştırmayı amaçladık.

Yöntem: Araştırma, Ocak 2020 ile Aralık 2021 tarihleri arasında Türkiye'de üçüncü basamak bir kadın hastanesinde doğum kontrolü arayan 18-45 yaş arası kadınları içermektedir. Gruplar adet süresi, sıklığı, adetin ikinci gününde kullanılan ped sayısı ile tanımlanan kişi tarafından bildirilen ortalama adet kan kaybı, dismenore ve disparoni açısından incelendi. Anlamlılık düzeyi olarak p<0,05 kabul edildi.

Bulgular: Gebeliği önleyici yöntem kullanımı sonrası adet görme süresi (7,00 ± 3,52) ve siklusun 2. günü kullanılan ped sayısı (3,66 ± 1,53) 'Cu-RİA' grubundaki hastalarda 'İmplant' grubundaki hastalara göre anlamlı olarak daha yüksekti (sırasıyla 4.36 ± 3.26, 2.33 ± 1.55) (sırasıyla p<.001 ve p<.001).

Sonuç: İmplant grubunda Cu-RİA'ya göre intermenstrüel süre daha uzun ve adet kanaması daha azdı. Etonogestrel içeren subdermal kontraseptif implant, daha hafif ve daha seyrek adet görmeyi tercih eden kadınlarda uygun bir seçim olabilir.

Anahtar Kelimeler: etonogestrel, implant, bakırlı rahim içi araç, menstrüel siklus

ABSTRACT

Objective: In this study, we aimed to compare the menstrual cycle changes with a copper intrauterine device (Cu-IUD) to that of an etonogestrel subdermal implant one year after insertion.

Method: The research included women aged 18 to 45 who sought contraception at a tertiary women's hospital in Turkey between January 2020 and December 2021. The groups were examined in terms of mean menstrual blood loss, dysmenorrhea, and dyspareunia, defined by the duration and frequency of menstruation, and the number of pads used on the second day of menstruation. p<0.05 was accepted as the level of significance.

Results: After the contraceptive method use the duration of menstruation (7.00 ± 3.52) and the number of pads used on the 2nd day of the cycle (3.66 ± 1.53) were significantly higher in the patients in the 'Cu-IUD' group compared to the patients in the 'Implant' group (4.36 ± 3.26, 2.33 ± 1.55, respectively) (p<.001 and p<.001, respectively).

Conclusion: Intermenstrual period was longer, and menstrual bleeding was lower in the implant group when compared with the Cu-IUD. Etonogestrel-bearing subdermal contraceptive implant can be favorable choice in women who prefer to have lighter and less frequent menstruation.

Keywords: etonogestrel, implant, copper intrauterine device, menstrual cycle

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INTRODUCTION

Modern contraceptive methods consist of reversible methods that include combined or progestin-only hormonal contraceptives, intrauterine devices, and permanent methods of female and male sterilization. There are different modes of delivery for the hormonal methods, such as oral tablets, vaginal rings, subdermal implants, transdermal patches, and hormone-bearing intrauterine systems (1). Among all contraceptive methods, long-acting reversible contraceptive (LARC) methods are safe and cost-effective as their efficacy in preventing or reducing unintended pregnancy is comparable to permanent contraception (2). Intrauterine devices and subdermal implants are the most effective types of LARC contraceptives (3). Intrauterine devices and implants are commonly recommended as first-line contraceptive options in many settings due to their high efficacy (3, 4).

The two available types of intrauterine devices (IUDs) are copper-IUDs and hormonal IUDs, which are defined as hormone-bearing intrauterine systems (5). On the other hand, the subdermal progestin implant is an alternative for women who choose to use a hormonal method of contraception but have difficulty remembering to take a pill every day, or replace a patch or ring as needed, or utilize a barrier method of contraception during intercourse or prefer to use a progestin-only method with no estrogen-related side-effects (6). The Etonogestrel subdermal implant is a radiopaque rod that contains 68 mg of etonogestrel and is effective for 3 years (7). The copper IUD (Cu-IUD) is allowed for up to ten years of contraception, where as the subdermal implant is approved for up to three years (5, 7). The contraceptive effect of the implant is based on its atrophic effect on the endometrium besides this, it alters the cervical mucus by making it hostile to sperms. Moreover, etonogestrel suppresses follicular development and midcycle LH peak and thus inhibits ovulation (8).

Irregular bleeding, spotting, and amenorrhea are common side-effects of progestin-only contraceptive methods, and patients should be counselled about these menstrual changes prior to the insertion of the implant in order to increase compliance with the method. Changes in menstrual bleeding caused by the contraceptive method should be viewed as a significant issue in contraceptive counseling as a remarkable portion of the discontinuations are related to menstrual irregularities (9). Changes in bleeding patterns, such as heavy and/or prolonged bleeding with Cu-IUD, are also a reason for discontinuation (10).

This study aims to compare the mentrual changes in women with Cu-IUD to women who use etanogestrel subdermal implants at least one year of continuation.

MATERIALS AND METHODS

Women who applied for contraception to the Family Planning Clinic of a tertiary women's health training and research hospital in Turkey between January 2020 and December 2021 between the ages of 18 and 45 and met the inclusion criteria were recruited for the study. The inclusion criteria were being between the ages of 18 to 45, preferring Cu-IUD or subdermal implant for contraception, having a year's continuation of the chosen contraceptive method, attending to the scheduled follow-up exam at the 12th month after initiation of the method, and having all the electronic medical files completed. Patients aged <18, >45, who were menopausal, who discontinued the method earlier than 12 months, women having an endocrine disease or known hematologic pathologies or on psychotic drugs were excluded from the study.

As a part of the clinical protocol, comprehensive counselling is given to all patients who attend to the Family Planning Clinic by a trained service provider followed by method specific counselling after the patients' decision. The study protocol was approved by the institutional review board of a tertiary women's health research and training hospital affiliated with a university (Date:19.03.2022, Decide No:11). As a hospital policy, a written informed consent was obtained from each patient before each procedure that gave permission to use the medical data anonymously for future studies.

Electronic medical records covered demographic and medical history of the patients and gynecological complaints (dysmenorrhea, dyspareunia) previously used contraceptive method, menstrual pattern (menstrual duration, frequency, self-reported avarage menstrual blood loss defined by the number of pads used on the second day of menstruation), examination findings including intermenstrual bleeding. During the follow-up visits, the same findings were recorded.

The data about menstrual pattern were processed in line with the International Federation of Gynecology and Obstetrics' (FIGO) 2018 modification of the terminology for normal and abnormal uterine bleeding symptoms (AUB). Accordingly, those whose menstrual durations lasted more than 8 days were classified as 'prolonged', while those whose periods lasted 8 days or fewer were classified as 'normal'. Frequency was recorded as frequent (<24 days), normal (≥24 to 38≤ days), and infrequent (>38 days). Intermenstrual bleeding was grouped as early, mid, or late, depending on when it occurred during the cycle (11).

For the patients who preferred to have an IUD, Cu-IUD (SMB copper t 380A, Kadıköy, İstanbul) was inserted during the first 5 days of the menstruation and women who preferred a subdermal progestin implant a 69 mg etonogestrel bearing single-rod implant was inserted (Nexplanon® Merck & Co, Whitehouse station, NJ).

Statistical analysis: In the definition of continuous variables, mean, standard deviation, median, minimum, and maximum values are specified; for categorical variables, frequency (n) and percentage (percent) values are specified. The Kolmogorov-Smirnov test was used to determine the variables' normality assumptions. To compare continuous variables between patients in the 'Implant' and 'Cu-IUD' groups, the Mann–Whitney U test was performed. Chi-square / Fisher exact analysis was used to explore the relationships between categorical variables. The IBM SPSS.25 (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.) program was used in all analyses, and $p<0.05$ was accepted as the level of significance.

RESULTS

A total of 83 patients who met the inclusion criteria were included in the study, of which 33 (39.8%) were in the 'Implant' and 50 (60.2%) in the 'Cu-IUD' arm. Sociodemographic and medical characteristics of all patients are shown in Table 1. The mean age of the women were 34.83 ± 7.48 (Range: 22-45) and the mean number of gravida, parity and abortions were 2.65 ± 1.41, 2.12 ± 1.10 and 0.28 ± 0.55, respectively. Overall 80 patients were married (%96) while the remaining 3 were single (Table 1).

Table 1. Sociodemographic characteristics of 83 women recruited to the study		
	N	**Mean ± SD.**
Age (years)	83	34.83 ± 7.48
Gravida	83	2.65 ± 1.41
Parity	83	2.12 ± 1.10
Number Of Abortions	83	.28 ± .55
Marital Status	83	**%**
Not married	3	4.0
Married / partner	80	96.0
SD: standard deviation		

Before contraceptive method use, there was no significant difference between the two groups in terms of age, gravida, parity, abortion, number of living children, menstrual frequency, and the number of pads used on the 2nd day of menstruation (p>.05) (Table 2).

One year after Cu-IUD and subdermal implant use, 72.7% of the patients in the 'Implant' group and 94% of the women in the 'Cu-IUD' group had normal menstrual frequency. On the other hand, 24,2% of the women in the 'Implant' group and 28% of the patients in the 'Cu-IUD' group described intermenstrual bleeding (p>.05) (Table 2).

When previous contraception method choice was compared, women who did not use any contraceptive method were similar in two groups (42.4% in the implant group and 44.0% in the 'Cu-IUD' group). 39.4% of patients in the implant group and 28% of patients in the Cu-IUD group had prior experience with these techniques. Before initiation of the contraceptive method, patients in the “Implant” group had a higher incidence of dyspareunia (21.2%) when compared to the 'Cu-IUD' group (4.0%) (p=.026). However, this significance was not valid after one year of the contraceptive method use (p=.185). In addition, there was no significant difference in the incidence of dysmnorrhea between the groups prior to contraceptive method use (p=.707) (Table 2).

The duration of the menstrual period was significantly longer in the Cu-IUD group (7.00 ± 3.52 days) when compared with the women in the 'Implant' group (4.36 ± 3.26 days) (p<.001) (Table 3). The number of pads used on the 2nd day of menstruation in the 'Cu-IUD' group (3.66 ± 1.53) was significantly higher than the patients in the 'Implant' group (2.33 ± 1.55) (p<.001) (Table 3). The range of intermenstrual period was wider (0-90) and longer in the implant group when compared with the Cu-IUD group however the difference was not statistically significant (p>.05) (Table 3).

Table 2. Comparison of Previous Contraceptive Method and Menstrual Patterns Before and After The Current Ontraceptive Method Use in The 'Implant' and 'Cu-IUD' Groups

	Implant (n=33)		Cu-IUD (n=50)	
Parameters	**N**	**%**	**N**	**%**
Previous Method of Contraception[a]				
No	14	42.4	22	44.0
Withdrawal	1	3.0	11	22.0
Cu-IUD	3	9.1	14	28.0
LNG IUD	0	0.0	1	2.0
COC	1	3.0	2	4.0
Implant	13	39.4	0	0.0
Depot injection	1	3.0	0	0.0
Menstrual Pattern Prior to The Method Use				
Menstrual Frequency * (days)				
Frequent	2	6.1	2	4.0
Normal	31	93.9	48	96.0
Duration of Menstruation*(days)				
Normal	28	84.8	44	88.0
Prolonged	5	15.2	6	12.0
Dysmenorrhea*				
No	29	87.9	46	92.0
Yes	4	12.1	4	8.0
Dyspareunia*				
No	26	78.8	48	96.0
Yes	7	21.2	2	4.0
Menstrual pattern after one year of method use Menstrual frequency[a] (days)				
Frequent	3	9.1	3	6.0
Normal	24	72.7	47	94.0
Infrequent	6	18.2	0	0.0
Duration of menstruation (days)				
Normal	29	87.9	43	86.0
Prolonged	4	12.1	7	14.0
Dysmenorrhea *				
No	27	81.8	44	88.0
Yes	6	18.2	6	12.0
Dyspareunia*				
No	27	81.8	46	92.0
Yes	6	18.2	4	8.0
Intermenstrual bleeding**				
No	25	75.8	36	72.0
Yes	8	24.2	14	28.0
Timing of intermenstrual bleeding[a]				
Early cycle	6	75.0	9	64.3
Mid cycle	2	25.0	4	28.6
Late cycle	0	0.0	1	7.1

LNG IUD; intrauterine device with levonorgestrel, COC; combined oral contraseptive.
[a]p value is not given because the assumption of Chi-square analysis was not met. *Fisher's Exact Test, ** Chi-square test.

Table 3. Comparison of Continuous Variables in The Implant and Cu-IUD Groups					
	Implant (n=33)		Cu-IUD (n=50)		
	Mean ± SD.	Median (Min. - Max.)	Mean ± SD.	Median (Min. - Max.)	U Test
Age***	36.24 ± 7.39	36 (22 - 50)	34.72 ± 8.54	34 (23 - 52)	715.50
Gravida***	2.61 ± 1.64	2 (0 - 7)	2.68 ± 1.25	3 (1 - 7)	753.50
Parity***	2.15 ± 1.23	2 (0 - 6)	2.10 ± 1.02	2 (0 - 5)	823.00
Abortion (N)***	.33 ± .65	0 (0 - 2)	.24 ± .48	0 (0 - 2)	794.00
Living Children (N)***	2.18 ± 1.26	2 (0 - 6)	2.06 ± .98	2 (0 - 5)	804.00
Menstrual frequency prior to the contraceptive method use***(N)	28.27 ± 3.68	30 (15 - 30)	29.12 ± 3.11	30 (15 - 35)	732.00
The number of pads used on the 2nd day of the menstruation prior to the contraceptive method use *** (N)	2.52 ± 1.46	3 (0 - 5)	3.06 ± 1.32	3 (2 - 5)	670.00
Menstrual frequency after contraceptive method use *** (days)	32.85 ± 18.09	30 (0 - 90)	28.72 ± 3.59	30 (15 - 35)	764.50
Duration of menstruation after contraceptive method use ***(days)	4.36 ± 3.26	4 (0 - 15)	7.00 ± 3.52	6 (2 - 20)	359.00
The number of pads used on the 2nd day of menstruation after contraceptive method use ***	2.33 ± 1.55	2 (0 - 5)	3.66 ± 1.53	3 (2 - 10)	450.50
***Mann Whitney U Test					

DISCUSSION

Safety, efficacy, side-effects, non-contraceptive benefits; accessibility; cost-effectiveness are factors that play an important role in contraceptive choice besides individual's preferences (12). In addition, the satisfaction with the method and method compliance are well affected by menstrual symptoms. As a result, menstrual changes play an important role in method satisfaction and thus compliance (13). Hormonal contraceptives are often discontinued by women who experience mentrual irregularities related to the method. To ensure patient compliance, a thorough explanation of bleeding patterns should be given during counselling (14, 15). While methods that lead to less frequent and lighter periods are favorable for patients with anemia, method induced amenorrhea might be worrisome by some women if they have not been informed about this effect of the contraceptive method. It is very important to inform the women about the possible menstrual changes related to the preferred method.

Various studies have reported menstrual disorders using different terminologies (infrequent bleeding, amenorrhea, protracted bleeding, metromenorrhagia, frequent bleeding, oligomenorrhea, menorrhagia, and unpleasant bleeding) (8). In our study, we expressed menstrual disorders as defined by FIGO in 2018 (11), and the results of our study intermenstrual period was longer and menstrual bleeding was lower in the implant group when compared with the Cu-IUD. We focused on patient follow-up in the first year of contraception because menstrual changes are common in the first 3-6 months after starting a contraceptive method.

Menstrual abnormalities are the most common reason for terminating the use of subdermal implants. However, weight gain, acne, headaches, and mood disorders are also encountered side effects (16, 17). Despite that, in this study, we did not include any symptoms other than menstrual disorders, dysmenorrhea, and dyspareunia, as this was not our focus.

In the literature, Cu-IUD has been shown to increase the amount and length of menstrual bleeding in females (18-20). We also concluded that the duration and frequency of menstrual bleeding were prolonged in patients using Cu-IUD. Furthermore, to determine the amount of bleeding, we looked at the number of pads used by the patients on the second day of the cycle, as this was expected to be the day when menstrual bleeding usually reachs to its maximum flow. In the presented study, the number of pads on the second day were significantly lower in the subdermal implant

group when compared to the Cu-IUD group, thus menstrual blood loss was less with the implant use when compared with the Cu-IUD. Due to the difference in the perception of the women and the range of the pads used this evaluation method might be critisized for its accuracy in, assessing the volume of blood loss. Some studies evaluated the menstrual blood loss by using a menstrual pictogram (21).

According to Weisberg et al., patients who used an intrauterine device were more likely to experience intermenstrual spotting in the first year than those who used subdermal implants (22). They stated that intermenstrual spotting in the subdermal implant group, became less common over time, while it became more common in the intrauterine device group (22). In or study groups, approximately ¼ of the patients in both groups experienced intermenstrual bleeding, and this symptom was more predominant in the Cu-IUD group. Intermenstrual bleeding was mostly in the early phase of the cycle both in the implant group and the Cu-IUD group (75% and 64,3%, respectively) (Table 2). As a result, as the cycle proceeds and contraception is continued, the subdermal implant has a gradually decreasing influence on the symptoms of intermenstrual bleeding.

Previous contraceptive method use was evaluated in both groups as a sign for method satisfaction. Overall, 39.4% of the subdermal implant users and 28% of Cu-IUD users have used the same method before, which shows that they were satisfied with the contraception method and wanted to continue with the same method. Apter et al. investigated the satisfaction rates of women using etonogestrel implant and discovered that the rate of those who were 'satisfied' was 26.3%. (23).

In a study on evaluating the incidence of dysmenorrhea, Piva et al. found that dysmneorrhea was encountered in 16.7% of the Cu-IUD users' (24). This rate increased from 8% to 12% in our study group; but the number of patients recruited to the Cu-IUD group is higher that the nmber of patients recruited to Piva et al.'s study (n=6). However, there was no significant difference in the incidence of dysmenorrhea between the groups after one year of use when compared to individuals who used subdermal implants, as in our study (24). They didn't follow up on the dyspareunia. Within one year, we discovered that symptoms of dyspareunia rose in the Cu-IUD group and decreased in the subdermal implant group. Nevertheless, more research is needed to declare this conclusion significant.

Studies have demonstrated that the side effects related to the contraceptive method is the most frequent reason for the discontinuation of the contraceptive method (25-29). In our study, discontinuation rate is not analyzed as continuing the method of contraception during the first year was our inclusion criterion. However, we compared groups using Cu-IUDs and subdermal implants to assess menstrual abnormalities, which are known to be the most common reason for method discontinuation (30, 31). Our goal was to detect the most common menstrual irregularities in our study group and use this knwoledge in contraceptive method counseling.

As a result, given that abnormal uterine bleeding is the most prevalent reason for subdermal contraceptive implant and Cu-IUD discontinuation, counseling before implant or Cu-IUD insertion and throughout the method's usage is the most effective strategy for assisting users in understanding and accepting these minor side effects (32). The small sample size, lack of body mass index in the data, not analyzing the dropout rates of the method and other side effects are the limitations of this study.

Use of etonogestrel subdermal contraceptive implant has more favorable effect on menstrual blood loss and menstrual frequency when compared with the copper IUD and there was no substantial difference in other menstrual parameters.

Ethics Committee Approval: The research was conducted in compliance with the ethical principles specified in the 1964 Declaration of Helsinki and its later amendments, as approved by the Etlik Zubeyde Hanim Training and Reserch Hospital's committee (approval number: 16.03.2022/04).

Author' s Contributions: Consept: Ç.A., B.D., Ş.A.M.; Design: Ç.A., Ş.A.M; Supervision: B.D.; Resources: Ç.A., B.D., Ş.A.M, İ.Ö.U.M.; Materials: Ç.A., Ş.A.M, İ.Ö.U.M; Data Collection: Ç.A., Ş.A.M, İ.Ö.U.M; Analysis and İnterpretation: Ç.A., B.D., Ş.A.M; Literature Search: Ç.A., İ.Ö.U.M; Writing Manuscript: Ç.A., B.D.; Critical Review: B.D.

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