Original Article

Assessment of Effectiveness and Side Effects of Subdermal Implant among User Women

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Abstract

Background: Implanon is a progestin-only implantable contraceptive; it offers promise, long-term, with a high-efficacy contraceptive. It is one of the most effective reversible contraceptives and is of the same effectiveness to sterilization. **Objective:** To assess the adverse effect profile and effectiveness of subdermal implants. **Materials and Methods:** A prospective study involved 48 women attending for insertion of the subdermal implant on days 2–5 of their cycle. The implant was inserted subdermally under the effect of local xylocaine of the nondominant arm. **Results:** The commonest side effect was weight gain constituted 62.5%. At the same time, amenorrhea was reported in 31.3%. Pain at the site of insertion constitutes 14.6%. While bleeding occurred in one case, which responded to local pressure. The commonest cause of discontinuation was weight gain constituted 12.5%. Followed by disturbances in the menstrual cycle. Discontinuation rate 41.7% (20 out of 48 cases). **Conclusion:** Implanon is an effective long-term contraception with few adverse effects.

Keywords: Contraceptive, implanon, side effect

Introduction

A subdermal implant is the most effective long-acting contraceptive method, which lasts for 3 years.[1] It is of higher efficacy compared to short-term contraceptives. It is of similar efficacy to sterilization. Pregnancy rarely got in women utilizing the implant, the pregnancy rate was 0.1%, and if the implant could not be localized, it can be investigated by ultrasound of the arm or by checking the level of etonogestrel in serum.[2,3]

The Implanon is composed of 68 mg of etonogestrel and a (40%) essential part of ethylene vinyl acetate and surrounded by 100% ethylene vinyle acetate about 60 mm in diameter. The implant is composed of a single rod measuring 2 mm in diameter and 4 cm in length. It releases initially at a rate of 60–70 µg/day, which decreases gradually to about 25–30 µg/day by the end of 3 years.

However, a lack of good insertion techniques can lead to deep insertion with difficulty in removal in the future. Nexplanon® composed of a few amount of barium, which allows it to be detected by X-ray. Also, using low-frequency ultrasound probes can localize it, which may help to remove implants that are not easily palpable.[4]

The implant suppresses ovulation in all users for at least 30 months and in virtually all women (97%) for at least its full 36 months of approved life. The progestin also thickens cervical mucus, which protects against ascending of sperms into the upper genital tract, which would prevent fertilization in any case where ovulation may occur.[5]

Amenorrhea occurs in up to 20% of implant users. The others have irregular or regular light and unpredictable bleeding. Excessive bleeding is uncommon.[6]

Pain is one of the commonest complications at the site of insertion, which happens in less than 3% of women, according to one study.[7] This discomfort is usually

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temporary and subsides with time. Other rare complications include retention of the implant in the needle applicator, redness or bleeding at the site of insertion, and hematoma formation. Bruising at the site of insertion may occur and mostly resolve within a few days.[8]

An implant has been reported to be effective in the treatment of dysmenorrhea. Although primary dysmenorrhea is not a life-threatening case, it can pose a fundamental burden on the QoL of women or female adolescents.[9]

Implantable contraceptive devices are likely to cause a flare-up of acne, which is one of the communal dermatological complaints.[10]

The aim of this study was to assess the effectiveness and side effects of a subdermal implant (Implanon) among women seeking long-term effective contraceptive methods.

Materials and Methods

A prospective cohort study was conducted at a private clinic from February 2021 to January 2022. The study enrolled 48 healthy women of reproductive age group with regular menstrual cycles, their mean age between 33.44 ± 5.69 years attended the private clinics for an effective contraceptive method of long duration after obtaining written consent from all participants and counseling them about the anticipated adverse effects of an implant such as irregular unpredictable vaginal bleeding, acne or gaining increasing weight and disturbances of mood.

The study was approved by the gynecologic department at Medical College, University of Babylon.

Exclusive criteria: (1) Women with suspicion of pregnancy, (2) active liver disease and liver tumors, (3) unexplained irregular vaginal bleeding, (4) current or past history of carcinoma of the breast, and (5) women with chronic use of liver enzyme inducers such as rifampicin and antiepileptic drugs.

Women attend the clinic on days 2–5 of the menstrual cycle, and in women without a menstrual cycle, insertion of the implant was performed after the exclusion of pregnancy by beta human chorionic gonadotropin.

A contraceptive implant is an implantable medical device used for the purpose of birth control. The implant may depend on the timed release of hormones to hinder ovulation.

The implant was inserted subdermally under the effect of 1% xylocaine in the inner part of nondominant arm with the aid of a specific applicator, which is inserted at first at a 30-degree angle from skin and then changed to a horizontal plane once the needle penetrates the dermis. The implant is inserted superficially to avoid injury to large vessels and nerves. Following insertion, the implant will be palpated by the gynecologist, and the women are also asked to palpate it, with a dressing of the site for 24–48 h.

Follow-up of women after the next menstrual period and then every 3 months for 3 years. The women were asked to report side effects such as irregular vaginal bleeding or weight gain.

Pregnancy should be excluded in women with prolonged amenorrhea of more than 6 weeks by beta human chorionic gonadotropin.

Statistical analysis

Statistical analysis was conducted by IBM SPSS statistic for windows, version 22.0. The qualitative data, such as irregular vaginal bleeding and acne, were expressed as frequency and percentage. The quantitative data, such as age and BMI, were expressed as mean ± standard deviation. A *P*-value of less than 0.05% is regarded as statically significant.

Ethical approval

The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. It was carried out with patients' verbal and analytical approval before a sample was taken. The study protocol and subject information, and consent form were reviewed and approved by a local ethics committee according to document number 1497, including the number and the date on February 15, 2021, to get this approval.

Results

A cohort study involved 48 women who attended for implant insertion; their mean age was 33.44 ± 5.69 years. Table 1 shows the demographic characteristics of women.

Table 2 shows the side effects of the study group. The commonest side effect was weight gain constituted 62.5%, whereas amenorrhea was reported in 31.3%.

Table 3 shows complications that occurred during insertion. Pain at the site of insertion constituted 14.6%, whereas bleeding occurred in one case, which responded to local pressure.

Deep insertion occurred in one case, which necessitated removal under ultrasound control.

Table 4 shows the time of discontinuation of the implant, in which 58.3% continue to use the implant, whereas 22.9% discontinue the implant after less than 1 year.

Table 5 shows the etiology of discontinuation. The commonest cause was weight gain, which constituted 12.5%, followed by disturbances in the menstrual cycle.

Table 1: Demographic criteria of study group

Variable	Mean ± SD	
Age	33.44 ± 5.690	
BMI	25.3542 ± 3.50373	
Duration of implant	1.7500 ± .43759	
Parity	**Frequency**	**Percentage (%)**
1	2	4.2
2	12	25.0
3	12	25.0
4	13	27.1
5	5	10.4
6	4	8.3
Total	48	100%
Abortion	**Frequency**	**Percentage (%)**
0	26	54.2
1	8	16.7
2	6	12.5
3	6	12.5
4	2	4.2
Total	48	100%

Table 2: Side effects of implant

Variable	Frequency	Percentage
Amenorrhea		
Positive	15	31.3
Negative	33	68.8
Vaginal spotting		
Positive	14	29.2
Negative	34	70.8
Menorrhagia		
Positive	5	10.4
Negative	43	89.6
Weight gain		
Positive	30	62.5
Negative	18	37.5
Acne		
Positive	16	33.3
Negative	32	66.7
Total	48	100%

Discussion

Family planning could reduce maternal mortality by 33% and infant deaths by 10% when the spacing between pregnancies is more than 2 years. Short intervals among births were associated with increased infant and maternal morbidity and mortality.[11,12]

In the current study, the side effects of the implant were recorded in 33.34% of cases.

Irregular vaginal bleeding was reported in 14 women out of 48 (29.2%) in the present study. No case of pregnancy was reported.

Table 3: Complications of insertion

Variable	Frequency	Percentage
No complications	37	77.1
Pain	7	14.6
Bleeding	1	2.1
Infection	2	4.2
Deep insertion	1	2.1
Total	48	100%

Table 4: Discontinuation period

Variable	Frequency	Percentage
Not discontinued	28	58.3
≤1 year	11	22.9
>1 year	9	18.8
Total	48	100%

Table 5: Cause of discontinuation

Variable	Frequency	Percentage
Menorrhagia	4	8.3
Irregular bleeding	3	6.3
Pain	1	2.1
Acne	1	2.1
Headache	2	4.2
Weight gain	6	12.5
Pregnancy plan	3	6.3
Not discontinued	28	58.3
Total	48	100%

Discontinuation rate 41.7% (20 out of 48 cases)

While a study conducted by Sajid and Mehmood[13] reported side effects in 27.7% of women, with irregular vaginal bleeding constitute 14.6% and pregnancy occur in 13.1% of cases.

Croxatto[14] found side effects of an implant in 9.3%.

Blumenthal *et al.*[15] found side effects, about 13.9%.

A study performed by Darney *et al.*[8] found adverse reactions constitute 40.1%.

Yildizbas *et al.*[16] found irregular bleeding; 58.5% and 34.1% had amenorrhea, while no pregnancy was reported in this study, while mastalgia accounts for 12.2%.

While in the present study, amenorrhea was reported in 31.3% of cases. Menorrhagia constitutes 10.4%.

In the present study, the continuation rate after 1 year was 58.3%, whereas 41.7% discontinue the implant.

The commonest cause of discontinuation was weight gain constituted 12.5%, followed by disturbances of the menstrual cycle; menorrhagia accounted 8.3% and irregular bleeding constituted 6.3%, whereas planning for pregnancy constituted 6.3% of cases.

In the Netherlands, a cohort study conducted showed that the discontinuation rate of Implanon after 12 months and 24 months was 28% and 47%, respectively.[17]

As well as an Australia retrospective study showed that the removal rate of Implanon was 6% and 26% at 6 months and 1 year after insertion, respectively, and also showed that the discontinuation rate was 39% at 1.5 years, while 50% removed at 2 years. However, those women who were still using Implanon for more than 2.5 years were approximately about 40%.[18]

Another retrospective study on the other hand, which carried at Jordan, shows that within 1 year of initiating a method, many women discontinue contraceptive use. About 45% of users discontinue this contraception within 1 year.[19]

Jos, Nigeria showed in his retrospective cross-sectional study that about 33.3% of users had early Implanon removal due to menstrual disturbance, followed by 30% of women who had earlier removal because of their desire for another pregnancy closely.[20]

In Turkeian, a cohort study in Ankara, 39% had early Implanon discontinuation due to developing side effects in the form of menstrual disturbance in 18% of women and 5% due to weight gain.[21]

No case of exacerbating acne was reported in this study.

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Conflicts of interest
There are no conflicts of interest.

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