Original Article

Rise of Discontinuation of the Subdermal Contraceptive: A Randomized Cross Sectional Study in Korangi

Haniyah Qamar[1], Rozina Mustafa[2]

[1]Assistant professor of Obstetrics and Gynaecology United Medical and Dental College, Karachi.
[2]Professor of Obstetrics and Gynaecology United Medical and Dental College, Karachi

Correspondence: *Dr. Haniyah Qamar,*
Assistant Professor Obstetrics & Gynaecology UMDC, Karachi.
Email: haniyahqamar@gmail.com

Abstract

Objective: To assess and determine discontinuation reason for the subdermal contraceptive implants before the completion of the duration of implant in the females.

Methodology: This is a randomized cross sectional study conducted from June 2016 to June 2018 conducted in Creek General Hospital and population welfare center. 300 subjects were randomly interviewed arriving in the outpatient department; out of which 170 subjects were enrolled for the study as per the informed consent they signed. All women age (18 to 45 years), wishing to discontinue the embedded subdermal contraceptive implant in their body before completion of its period were taken into account in this study. The reasons for their discontinuation was assessed through Performa's with a relevant question related to the withdrawal of the implant.

Results: Abnormal uterine bleeding's relative frequency (34 %) was highest among the other causes to discontinue the usage of the contraceptive implant. However, the result showed significant evidence that after a year 85 % of young aged females, mostly aged 25 to 30 years (42%) started to develop side effects that with time became intolerable.

Conclusion: The discontinuation of subdermal contraceptive implants due to known side effects is already evident from the other studies but this study clearly indicates that there was lack of awareness among the people in dealing with some minor side effects because as per other studies these side effects temporarily reside and vanishes after its removal.

Keywords: Contraceptive implant, abnormal uterine bleeding, weight gain, family planning.

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Introduction

Subdermal contraceptive implants are new contraceptive techniques used in the current era, aiming to prevent pregnancy. Therefore, reduces the need for taking protection during sexual activities. This birth control implant embedded subdermally is equal to a size of matchstick that stimulates the body to releases hormones that will prevent conception.[1]

The subdermal implant is a non-biodegradable implant containing 68 mg of etonogestrel (progestogen) in ethylene vinylacetate (EVA) copolymer core, covered by EVA membrane. Most women, especially during the middle age take precautions to avoid further parity. In order to avoid surgical or medical intervention used in family planning, women often opt for this technique for safe and secure long-acting

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reversible contraception techniques.

However, this device had certain eligibility criteria for women desiring to use it that is contraindicated in blood disorder, liver diseases, hypertension, diabetes, allergy and pregnancy.[2] These safety precautions are necessary to avoid future risk of health outcomes.

Unlike intrauterine devices that are embedded into the patient uterus; this implant is inserted into the arm; hence, protecting the patient from conceiving for approximate 3 - 5 years. Currently two versions of this rod is most commonly used, implanon and nexplanon. Implanon (etonogestrel) is the first generation single rod while Nexplanon is second generation. Both of these versions induce the human body to releases hormone progestin.[3,4] With new improvements and modifications made a double rod implant Jadelle (levonorgestrel is also available in the market for use.

The device is successful in reducing pregnancy rate to 0.05% in two ways, by thickening of cervix mucous membrane lining and inhibition of ovulation. However, in 11 major international clinic trials, 942 subjects underwent this clinical trial.[5] A few common side effects reported were breast tenderness, gain in weight, headache and irregular periods. [6]

The present study was conducted in a creek hospital and population welfare clinic korangi Karachi to determine the reason for the discontinuation of the contraceptive before the completion of its life span.

Methodology

This randomized cross sectional study was conducted in the female patient visiting the gynaecologist in the outpatient department (OPD) of creek hospital and population welfare center in Korangi from June 2016 to June 2018. Women ages ranging from 18 to 45 years were included in the study. Among these women, few of them got these implants inserted from the gynaecologist of these hospitals while others were referred from other clinics to get the implants removed.

The sample size was taken out using the WHO sample size calculator of a minimum of 170 subjects. The researcher interviewed 300 subjects randomly from the OPD. Using the purposive sampling technique, 170 eligible subjects were included in the study as per specified inclusion criteria while taking into 95% confidence level and 5 % error margin into account. The women who could not read or write were provided assistance.

The data collected was through a standardized designed Performa with informed consent. The questionnaire consisted of questions that aided analyses of the reasons for their discontinuation. The variables such as age, socioeconomic status, duration of insertion and parity that influences the pregnancy decision were critically analyzed.

After data collection, the results were analyzed using SPSS version 21.0. The quantitative and categorical data was calculated using frequency and relative frequency. The final results were displayed in form of bar chart and pie chart that displayed the difference between the variables evidently. The variables that were the main focus of the study included reasons listed for discontinuation, age group, parity, and duration of insertion.

The women who visit the gynaecologist with the purpose of removal of the implant were included in the study while the women who had successfully completed their 5 years period of the implant insertion and were visiting the hospital for the removal were excluded from the study.

A proper approval was taken from the ethics committee of creek hospital and population welfare center to perform this study in the outpatient department of gynaecology and obstetrics. Each individual women was explained the study and they were provided with informed consent to be signed based on their own willingness. 170 subjects recruited were assured confidentially related to their personal information.

Results

From 300 interviewed subjects, 170 eligible subjects were determined to get the implant

removed. Among these 170 females, most of them expressed the need to get removal of the implant due to the implants side effects. The pie chart below highlights the reasons for the discontinuation of the implant. Out of 170 subjects,34% (n=34)subjects were withdrawing the implant device due to the abnormal uterine bleeding, 35%(n=35) subjects encountered side effects such as weight gaining, abnormal hair growth, and body aches, 16%(n=16) subjects developed diseases such primary hypertension and ovarian cyst while other 15%(n=15) subjects were discontinuing due to the will of getting pregnant and peer pressure.

The pie chart provides a distinct understanding of the three major categories that are further represented in the bar chart

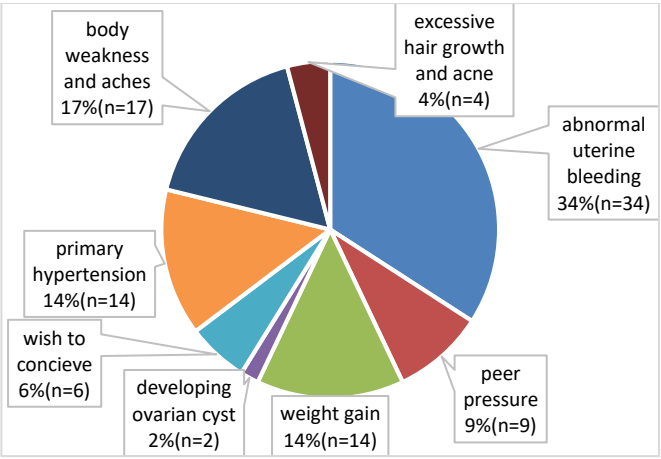

Figure 1. Reasons for discontinuation

Further evaluation was performed by measuring the duration of period of the implant insertion. It was significant that the majority of subjects had implants for around 2.5 years. However, only 4 subjects managed to continue it for more than 3 years. However, 10 – 20% subjects managed to continue with the device for around one to two years. This histogram when critically analysed gave a profound knowledge related to the timing of the side effects. A linear trend line was drawn according to the mean of the variables. This clearly shows that the maximum number of the subjects were able to ignore the minor side effects and continued the procedure. This timeline provides a definite assurance that the implant was successful in providing maximum benefit.

As shown in Table I, the majority of the women who randomly were selected for the study had age ranging from 25 to 30 years. Out of 170 subjects, 43 % women belonged from age group 25 to 30 years, 26% from 35 to 30 years age and 9% from 20 to 25 years age group while rest were below 20 years and above 35 years. This clearly indicated that middle-aged group women are most popular group using contraceptives. In the current era, the women are managing too many responsibilities at a time; hence, they need to stay comfortable rather than stressing over the side effects experiencing from the device *(4, 7,8). This raises concerns related to adverse reactions due to spreading misconceptions among these women. Therefore, they opt to get it discontinued.

Table I: Age distribution in contraceptive implant user

Age in years	N=170(%)
<20	3(2%)
20-25	49(29%)
25-30	72(42%)
30-35	43(25%)
>35	3(2%)

Table II shows another set of variables, parity divided the women subjects into 5 groups based on the number of the times they were pregnant. Among them 39 %, females were twice pregnant, 26 % were thrice pregnant, 23% were four times pregnant, and 9% subjects got pregnant once. Nevertheless, only 2% subject managed to have five children. This result clearly indicates the concerns of the educated middle class group.

Table II: Parity index among contraceptive users

Parity	N=170(%)
P1	16(9%)
P2	66(39%)
P3	46(26%)
P4	39(23%)
P5	3(2%)

The socioeconomic variable was also critically analysed, to assess and determine the influence on the intention of the subjects. Majority of the subjects belong to the middle class group (92%) while the poor and upper class group accounted

for 6% and 2% respectively. The location of the hospital specifies the reason for inconsistency in the data collection of the three groups. Nevertheless, the upper class was also not a major part of the study, due to the location of the hospital. Many of the upper-class visit city-centrally located and well-reputed hospitals. Therefore, the study lacks the perception of upper class people who are major user of the sub dermal implant.

Discussion

The Subdermal implant contraceptives were developed far back in the 1900's; however, with ever-changing trends and patterns, it has become worldwide famous with time. Pakistan is among the developing countries with increasing population. However, with time, inspite of measures taken to provide effective contraception in our population, failure have been observed in achieving desired results. We have done this study to observe reasons for discontinuation of this contraceptive implant.

In our study 34% withdraw due to abnormal uterine bleeding being the most common reason for removal, which is same as observed by Sznajder KK et al[7] but they found a low discontinuation rate as compared to our study, also it was associated with sexually transmitted infection which was not observed in our study. This finding is most probably due to cultural and religious difference in the both study settings.

In study by Patel PR [8], the percentage of women who used long term contraception increased for all age groups, with the greatest increase for women 20-24 years old (<1% to 9%) as compared to our study, women aged 20 – 35 and majority having more than 2 kids, occupied most of the study population sample.

It was observed by Crockett AH [9], a total of 4% of women had documented implant removal within 6 months post-insertion, with no difference between postpartum, inpatient and outpatient (delayed postpartum or interval). A total of 12% had documented implant removal within 12 months. This can be appreciated from the time duration statistics indicating in our study that an average woman continued with the device for more than one year to two and half year.

Lopez Del Cerro E [10] found that effectiveness was 100% and good tolerability was recorded for 86.5%. Infrequent bleeding was the most common bleeding pattern, followed by amenorrhea. Of the 221 implants inserted, 47.5% were removed. The main reasons were expiration (54.3%) and discomfort due to bleeding alterations and other adverse effects (25.7%) as compared to our study in which we observed amenorrhea as being not a significant reason of removal, also side effects made the subjects to remove it before the expiration. This shows our subjects had less tolerability of side effects as compared to observed by L'opez Del Cerro E et al.

Dickerson LM [11] found that early removal was done in 24.2% of women, Younger and nulliparous women were more likely to have an subdermal implant placed, whereas older and multiparous women chose the Intrauterine contraceptive device. Increased frequency in bleeding were associated with early removal rates and only one in four opt for early removal which is comparable to our study and supports our observation which showed that majority of the subjects managed to continue its use for up to 2.5 years.

Nevertheless, analyzing the data, the peer pressure group mostly likely seems to be the lower class group. These people ought to be rural area residents who do not have profound knowledge regarding these contraceptives. These women face a lot of peer pressure from the family and friends to discontinue the using implant. In a peer project conducted in Pakistan Brown E et al [12]observed that men overall supported a 'smaller' family size and use of contraceptive methods. Men wanted to have better access to information through a range of channels. Understanding, the sociocultural contexts in which masculinities are constructed, is essential before involving men in family planning programs, so that gender inequalities are not reinforced, due to traditional

and cultural reasons. This observation supports the involvement of peers in contraceptive decisions which will improve the outcome in our women.

Ovarian cysts were detected in 5.2%, 13.0% and 1.9% of users of Implanon, Jadelle by Hidalgo MM et al.[13] 2% in our study developed ovarian cyst. They presented with pain, removal of implant in these cases resulted in degeneration of the cyst. Hidalgo has suggested no use of medical intervention as these cysts are not pathological.

Balogun OR et al [14] observed a progressive increase in the weight as well as in the level of systolic blood pressure. As compared to the baseline values, statistically significant difference in the mean values of systolic blood pressure ($p<0.01$), weight gain ($p=0.001$) were recorded at the first year. Weight gain ($p=0.001$), significant at the third year. In our study 14% had removal due to weight gain within 2.5 year of use and 14% established new onset blood pressure within 6 months use. Removal of implant returned the weight and blood pressure to pre implantation levels in all of these subjects. The same study concluded that hematological and biochemical parameters change with Implanon use but they were not significant to cause clinical sequelae. Implanon remains a safe long term contraceptive. There was no failure of contraception in our study, and this was corresponding with the results of pushpa et al [15] research.

Limitations: This study implies some limitations that can offers hindrance in confirmatory evidence. One of them is lack of proper information from the subjects regarding their pre counseling. Before the insertion of the implants it is important to counsel the patient regarding the device and its side effects and the patients should be advised to have regular follow up check-ups.

Medical records were one of the other limitations in the study. There were no proper medical records available of the patient before the insertion and after wards of the subjects who were referred from the other hospitals. Therefore, a lack of previous history causes hindrance in determining whether the disorder or side effects acquired by the subjects were due to the implant or any other cause. Hence, causality assessment is needed to determine a positive relation.

Conclusion

The study with the strength and imitation conclude that subdermal implants is safe, effective, well accepted method of contraception. Menstrual abnormalities were the major side effects. The reason indicated by the women surely highlight that the subjects should be given proper knowledge and guidance before using such devices in order to improve tolerance. Peers/husbands should always be involved in counselling to increase the acceptance. A proper health check-up is required before insertion.

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