ORIGINAL ARTICLE

SAFETY AND EFFICACY OF A SINGLE-ROD SUB DERMAL CONTRACEPTIVE ETONOGESTREL IMPLANT: SIX MONTH FOLLOW-UP EXPERIENCE IN WOMEN OF REPRODUCTIVE AGE

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Background: Etonogestrel implant is an effective and healthier contraceptive method for women in developing countries because of its convenience, price, long duration, and safety of use while breastfeeding. It has high possibility of return to fertility after removal. The objective of the study was to determine the efficacy in term of frequency of compliance of etonogestrel implant and side-effects in women receiving it as reversible contraception. **Methods:** A descriptive case series was designed and was conducted in Family Planning Centre, Federal Government Polyclinic, Islamabad. The study was carried out in 265 women of age 15–45 years with regular menstrual cycle, normal pelvic and systemic examination, and willing for long term reversible contraception. Non-probability consecutive sampling was used for collection of subjects. After informed consent etonogestrel implant was inserted and followed for its efficacy and side effects. Data were analysed using SPSS-16. Qualitative variables like side effects, efficacy and compliance were measured as frequency and percentage. Quantitative variables like age of patient were measured as Mean±SD. **Results:** Mean age of the patients was 27.86±6.67 years. Compliance to, acceptance, and efficacy of etonogestrel implant as reversible contraception was found in 249 (93.96%) patients while rest of the patients had removed the etonogestrel implant due to any side-effects. **Conclusion:** Etonogestrel implant demonstrated excellent contraceptive efficacy and was well tolerated. The vaginal bleeding pattern was variable and was characterized by relatively few bleeding events, but proved acceptable to most subjects.

Keywords: Etonogestrel implant, efficacy, polymenorrhagia, frequency, acne, amenorrhea

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INTRODUCTION

Regardless of significant advances in contraceptive methods unplanned pregnancies remain a health problem worldwide. Globally, approximately 208 million pregnancies occur each year of which 41% are unplanned and about 21% results in elective, induced abortion.[1,2] The rate of abortion of unplanned pregnancies can be significantly reduced by proper accessibility and utilization of contraceptives. The United States has one of the highest unplanned pregnancy rate among developed countries. In Pakistan out of estimated nine million conceptions, unplanned and unintended pregnancy rate is 46%, and out of them 54% ends up in intended abortions.[3] Healthier pregnancies and infants can result if the women are properly helped and counselled in planning whether they should have more children and when to have them. This can be achieved by increasing their access to contraceptives. The women are mostly motivated immediately after birth or an abortion, so it's the important time to start contraceptive.[4]

Contraception is an important public health device.[5] It is responsible for playing a major role in decreasing maternal and neonatal morbidity and mortality which often occur as a result of unplanned pregnancy along with the socio-economic burden usually related to it.[6]

Availability of different family planning methods also provides useful substitutes for those having bad experiences with their existing methods in addition to helping those who need and want proper contraception.[7] Currently among the family planning programs the use of hormonal implants has gained considerable attention. Long-acting reversible contraceptives (LARCs) including intrauterine devices (IUDs) and subdermal contraceptive implants are methods that offer successful long-term contraception without any action by the user. Usage of hormonal implants as family planning method has different advantages in terms of long-term effectiveness, availability and improved compliance of user.[8]

Nowadays sub-dermal contraceptive implants are popular contraceptive methods due to reduced need to take protection during sexual activities. The sub-dermal contraceptive implants are of a matchstick size and stimulate release of hormones which prevent pregnancy.[9] The etonogestrel-releasing implant contains 68 mg etonogestrel which is surrounded by ethylene-vinyl-acetate rod which is marketed as Implanon® and Nexplanon® in the United States. Etonogestrel is the biologically active metabolite of desogestrel which is

used in some progestogen-only and combined contraceptive pills. The etonogestrel-releasing implant is presently designed for 3 years of use. Contraceptive implants perform their action by binding to their specific receptors present in various target cells which are dispersed along the hypothalamic-pituitary-gonadal-genital tract axis. The implant interferes with several important processes necessary for gamete union and fertilization. Progestins inhibit ovulation and cause thickening of the cervical mucus.[10] This implant is inserted into the arm, unlike intrauterine devices, and provide contraception for a period of approximately 3–5 years.[11,12]

Insertion of implants is generally even easier than insertion of IUDs, but removal can be more challenging than insertion. Problems with removal tend to occur in rare cases when the implant breaks or is difficult to locate. Self-removal is not a feasible option for implants. After implant removal, women can expect a rapid return to fertility. Within three weeks of removal, ovulation resumes in more than 90% of women.[13]

Mostly women, during the middle age go for subdermal implant for safe and secure long-term reversible contraception in order to avoid surgical or medical intervention used for family planning.[14] However, the women who desire to use this device, must be eligible for it to avoid future hazard of health outcomes. It is contraindicated in liver diseases, blood disorders, allergy, diabetes, hypertension, and pregnancy.[15]

The objective of this study was to determine the efficacy in term of frequency of compliance of etonogestrel implant and side-effects in women receiving it as a method of reversible contraception.

PATIENTS AND METHODS

This descriptive case series study was conducted in Family Planning Centre, Federal Government Polyclinic, Islamabad (FGPC). The duration of study was 6 months from 23 Feb to 22 Aug, 2018. World Health Organization (WHO) software for sample size determination in health studies was used to calculate the sample size. Sample size was calculated with 95% confidence level, 4.5% Population Proportion of amenorrhea, 2.5% Precision, and 5% level of significance.[11,16] Sample size thus calculated was 265.

Non-probability consecutive sampling was used after approval from the Ethical Committee of FGPC Islamabad. Patients were selected from influx of women visiting Out-patient Department in antenatal clinic and Family Planning Centre fulfilling eligibility criteria. After informed written consent, healthy female volunteer of reproductive age (15–45 years) with regular menstrual cycle, normal pelvic and systemic examination, and willing for long term reversible contraception were selected. Women who were pregnant, diabetic, hypertensive, had liver disease, ovarian or breast cancer, or history of thromboembolism, sexually transmitted disease, and congenital uterine anomalies were excluded. Details about past medical and surgical history were recorded, necessary systemic, and specifically pelvic examination was done. Visiting cards were issued on which date of insertion and date of removal of etonogestrel implant were mentioned for the convenience of patient and doctor. Efficacy was measured by variables like compliance of patient and side-effects in 6 months follow-up.

Data was analysed using SPSS-16. Results were presented in table form. Qualitative variables, i.e., side effects, efficacy, and compliance were measured as frequency and percentage. Quantitative variables like age of patient were measured as Mean±SD.

RESULTS

Mean age of the patients was 27.86±6.67 (15–45) years. The patients were categorised into 3 age groups. Most of the patients receiving etonogestrel implant were in age group 35–45 years. (Table-1).

Acceptability of etonogestrel implant as reversible contraception was 93.96%, while the rest of patients had removed the etonogestrel implant due to side-effects. The side-effects were found only in 16 (6%) of patients. Frequency and percentage of compliance and side-effects in different age groups is shown in (Table-2).

Amenorrhea and polymenorrhagea were the leading side-effects. Parity had no role over efficacy and common side-effects. In primipara women, the efficacy was 94.4%, while in multipara women it was 93.9%. (Table-3).

Table-1: Age-wise distribution of patients

Age (Years)	Frequency	Percentage
15–20	61	23.0
21–30	69	26.0
31–45	135	50.9
Total	265	100.0

Table-2: Compliance and side-effects in different age groups [n (%)]

	Age Groups (Years)		
	15–20	**21–30**	**31–45**
Compliance and Acceptability			
Yes	59 (96.7)	65 (94.2)	125 (92.6)
No	2 (3.3)	4 (5.8)	10 (7.4)
Side-effects			
Polymenorrhagia	0	1 (1.4)	4 (3.0)
Amenorrhea	2 (3.3)	2 (2.9)	2 (1.5)
Irregular vaginal spotting	0	0	3 (2.2)
Weight gain	0	0	1 (0.7)
Acne	0	1 (1.4)	0
None	59 (96.7)	65 (94.2)	125 (92.6)

Table-3: Efficacy and common side-effects based on parity of the subjects [n (%)]

	Parity	
	Primipara	Multipara
Compliance and Acceptability		
Yes	34 (94.4)	215 (93.9)
No	2 (5.6)	14 (6.1)
Side Effects		
Polymenorrhagia	0	5 (2.2)
Amenorrhea	1 (2.8)	5 (2.2)
Irregular vaginal spotting	1 (2.8)	2 (0.9)
Weight gain	0	1 (0.4)
Acne	0	1 (0.4)
None	34 (94.4)	215 (93.9)

DISCUSSION

In our study 94% participants continued etonorgestral implant at 6 months. This is in agreement with a community-based prospective cohort study by Akilimali PZ *et al*[17]. That study included 531 subdermal implant users who were 18–49 years old and were followed at 6, 9 and 12 months. Their reported rate of implant removal was 5.5% at 6 months, 8.4% at 12 months, 10.1% at 12 and 20% at 24 months from the date of insertion. Most of the women discontinue due to side-effects (72.3%), most common of which was heavy bleeding (30.0%).[17]

In contrast, lower continuation rates have been reported by Lakha and Glasier[18] which were 89% at 6 months, 75% at 1 year and 59% at 2 years. Commonest side-effect they observed was irregular vaginal bleeding in 27% cases. However, only 5% cases got subdermal implant removed due to this disorder. Prolonged spotting was reported in 23% cases but only 1% cases had implant removed due to this disorder. Amenorrhea was seen in 24% cases but only 4.5% cases got removal due to amenorrhea. Polymenorrhagia was observed in 22.5% and 16% cases got removal due to this.[18] In our study polymenorrhagia was found in 5 (1.9%), amenorrhea in 6 (2.3%), and 3 (1.1%) had irregular vaginal spotting.

Harrison-Woolrych and Hill have reported approximate failure rate of 1 per 1,000 insertions (218 out of 204,486).[19] Pregnancy due to subdermal implant failure has also been reported by Hamontri and Weerkul.[20] One case of ectopic pregnancy following implant failure has been reported by Mansour *et al*.[21] There was no failure of contraception observed in our study.

Mrwebi KP *et al* in their descriptive cross-sectional study reported 27.2% discontinuation rate of etonogestrel implant in the first 6 months of use. That study involved 188 women, 67.3% of whom removed the implant in the first year of use. Implant was discontinued by 71.3% of the participants because of side-effects out of which 75 (39.9%) participants had heavy bleeding.[22]

Parkpinyo N *et al*[23] in a retrospective cohort study involving 1,030 women having etonogestrel contraceptive implant, reported that 1.7% of the women had removal of their etonogestrel implant by 6 months. Most common reason (32%) for early removal was their wish to get pregnancy, and in 49 (22.5%) it was their menstrual disturbances.[23]

Dagnew *et al*[24] in a facility-based cross-sectional study observed that among 537 women about 37% of etonogestrel implant users had discontinued this method before the planned time. About 86% of them discontinued implant before two years of insertion, and about 13.6% discontinued at 6 months. The reasons for discontinuation in their subjects were the side-effects (mainly polymenorrhagia) followed by a desire for pregnancy.

CONCLUSION

Etonogestrel implant demonstrated excellent contraceptive efficacy and was well tolerated. Compliance to, acceptance, and efficacy of etonogestrel implant as reversible contraception was found in majority of users while only 6% users had removed the etonogestrel implant due to its side-effects. The discontinuation rates can be significantly lowered with sufficient counselling of the women about the expected bleeding pattern before insertion of subdermal implant.

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