RESEARCH ARTICLE

Potential determinants of early discontinuation of Etonogestrel implant: a cohort prospective study

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Abstract

Objective: To assess the frequency of early discontinuation of Implanon as a method of contraception.

Method: The cohort prospective study was conducted at the Obstetrics and Gynaecology Department, Al-Yarmouk Teaching Hospital, Baghdad, Iraq from January 2017 to January 2021, after approval from the ethics review committee of the College of Medicine, Al-Mustansiriyha University, Bghadad, Iraq, and comprised women of child-bearing age seeking long-acting contraception. The participants received Implanon, an etonorgestril implant, under local anaesthesia, and were followed up for 12 months for possible side effects. Data was analysed using SPSS 26.

Results: There were 115 women with mean age 29.8±6 years (range: 15-44 years) and mean body mass index 27±4.9 kg/m^2. Early discontinuation of the plant was done by 32(27.8%) subjects, and the overall incidence of early Implanon removal per 1,000 women per month was 14.47 (95% confidence interval: 10.24-20.47). Lower body mass index, dizziness and insertion-site side effects were the potential determinants of early discontinuation ($p<0.05$).

Conclusions: More than a quarter of the sample opted for early Implanon discontinuation. Low body mass index, dizziness and insertion-site side effects were potential determinants of early removal.

Key Words: Etonogestrel, Anaesthesia, Dizziness, Gynaecology, Incidence, Contraception

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Introduction

According to the World Health Organisation (WHO), implants represent an excellent choice to achieve any reproductive intention[1]. It is a favourable contraceptive method for women in developing countries owing to its cost-effectiveness, long duration of action, being convenient, safe for use while breastfeeding, and high probability of maintaining fertility after discontinuation[2-5]. Besides, once the implant is inserted, no attention is required from the user until the time of removal, the woman does not need to keep supplies at home, nor does she need continued resupply or clinical follow-up for contraception[6]. In Iraq, the modern contraceptive prevalence rate in 2018 was 36%[7] and about 0.6% of which was by way of implants[8]. Contraceptive discontinuation is a worldwide problem[9]. it is common in developing countries (18-63%)[10] and it often leads to an unintended pregnancy with potentially unsafe induced abortions and unplanned births that expose a woman to great risk[11]. Every year, about one-third of the 182 million pregnancies occurring worldwide are unplanned[9]. A significant number of women who choose Implanon, an etonorgestril implant, as a contraceptive method request early removal despite the absence of an intention to have a pregnancy[12]. The factors that may be associated with early implant discontinuation are experience of side effects, absence of counselling services, and living in rural areas[5].

The current study was planned to assess the frequency of early discontinuation of Implanon as a method of contraception.

Subjects and Methods

The cohort prospective study was conducted at the Obstetrics and Gynaecology Department, Al-Yarmouk Teaching Hospital, Baghdad, Iraq from January 2017 to January 2021 after approval from the ethics review committee of the College of medicine, Al-Mustansiriyha University, Bghadad, Iraq. The sample was raised using convenience sampling technique from among women visiting the outpatient department (OPD). Those included were healthy, non-pregnant women aged 15-44 years seeking long-acting contraception without previous exposure to impants. Although the legal age of marriage in Iraq is 18 years, special authorisation can be issued by the relevant judge for those who are underage.[13] Those with a prior history of chronic disease, abnormal cervical cytology, abnormal vaginal and post-coital bleeding, history of breast malignancies, and chronic liver diseases were excluded.

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After taking written informed consent from the participants, basic data regarding age, occupation and previous medical and obstetrical history was collected. General physical, pelvic and cervical examinations of the women were also carried out before the procedure.

Local anaesthesia was used consisting of 2% lidocaine, and about 3ml was injected at the site of insertion. The implants were inserted in the subdermal part of the non-dominant arm of each participant about 10cm above the medial epicondyle, during the menstrual cycle to avoid unexpected pregnancy.

All women were followed up for a period of 12 months, over the phone and, when necessary, in the clinics, for possible side effects. Data noted was the date of insertion and removal, if applicable, of implants, systemic side effects of the implanted rods, including headaches, dizziness, acne, mood swings, breast tenderness, weight-gain, pain or itching, willingness to use again, hirsutism and loss of libido. Complains at the insertion site, like pain, annoying itching, numbness, bruising, scar, and/or infection, were also noted.

The subjects were also asked about any change in their menstrual cycles, such as inter-menstrual spotting and amenorrhea defined as the absence of menstruation for 3 months[14]. Regular bleeding was defined as recurring bleeding that occurred at intervals of 28±7 days. There was also irregular bleeding considered in amenorrhea cases, including irregular frequent, infrequent or prolonged bleeding[15]. Frequent bleeding meant >5 bleedings within 3 months. Bleeding for <3 days in 3 months was considered infrequent. Prolonged bleeding was defined as one or more than one bleeding lasting 14 days.

The dependent variable explored was the early removal of the implant, defined as removal in <30 months[16].

Data was analysed using SPSS 26[17]. Categorical data were represented as frequencies and percentages, while continuous data was represented as mean ± standard deviation. Hazard ratios (HRs) were calculated using the number of events per 1,000 person-time per month. The test for covariance was done before fitting the significant variables in the regression model. Only the significant variables in the bivariate crude HR analysis were included in the multivariate adjusted model. The cumulative HRs were compared using the Cox-regression model and Hazard curve. P<0.05 was taken as significant.

Results

There were 115 women with mean age 29.8±6 years (range: 15-44 years) and mean body mass index (BMI) 27±4.9 kg/m^2. Side effects of Implanon were reported by 92(80%) women. The decision of Implanon as contraception was advised by physicians in 44(38.3%) cases.

Table-1: General characteristics of the study cohort.

Variables		Count	%
Age groups(years)	<30	54	47.0%
	>=30	61	53.0%
Body mass index	<25 kg/m^2	41	35.7%
	>=25 kg/m^2	73	63.5%
Occupation	Housewife	79	68.7%
	Employed	36	31.3%
Parity	<2	18	15.7%
	>=2	97	84.3%
Abortion	Yes	15	13.0%
	No	100	87.0%
Previous caesarean section	Yes	29	25.2%
	No	86	74.8%
Other method of contraception	Yes	70	60.9%
	No	45	39.1%
Systemic side effects of	Yes	92	80.0%
	No	23	20.0%
Frequency of menstrual cycle	Yes	36	31.3%
	No	79	68.7%
Inter menstrual spotting	Yes	35	30.4%
	No	80	69.6%
Amenorrhea	Yes	46	40.0%
	No	69	60.0%
Dysmenorrhea	Yes	24	20.9%
	No	91	79.1%
Prolonged bleeding	Yes	37	32.2%
	No	78	67.8%
Mood swings	Yes	21	18.3%
	No	94	81.7%
Headache	Yes	20	17.4%
	No	95	82.6%
Dizziness	Yes	8	7.0%
	No	107	93.0%
Acne	Yes	18	15.7%
	No	97	84.3%
Hirsutism	Yes	15	13.0%
	No	100	87.0%
Breast tenderness	Yes	24	20.9%
	No	91	79.1%
Weight gain of 5-10 kg	Yes	28	24.3%
	No	87	75.7%
Loss of libido	Yes	20	17.4%
	No	95	82.6%
Insertion site side effect	Yes	16	13.9%
	No	99	86.1%
Who choose the method	Patients side	71	61.7%
	Doctor	44	38.3%

Early discontinuation of the plant was done by 32(27.8%) subjects, and the overall incidence of early Implanon

Table 2: Cox-regression analysis for early Implanon removal.

Variables		Early removed		Total	Time (days)	Person-time incidence rate	Hazard ratio	
		Count	%	Count			Bivariate Crude (95%CI)	Multivariate Adjusted (95%CI)
Age groups (years)	<30	9	16.7%	54	954.53	9.43	1	1
	>=30	23	37.7%	61	1256.33	18.31	2.36 (1.09 - 5.1)*	2.15 (0.97 - 4.76)
Body mass index	<25 kg/m^2	16	39.0%	41	675.97	23.67	2.48 (1.24 - 4.97)*	2.81 (1.35 - 5.85)*
	>=25 kg/m^2	16	21.6%	74	1531.4	10.45	1	1
Occupation	Housewife	18	22.8%	79	1523.37	11.82	1	
	Employed	14	38.9%	36	687.5	20.36	1.71 (0.96-3.04)	
Parity	<2	4	22.2%	18	239.47	16.7	1	
	>=2	28	28.9%	97	1971.4	14.2	1.3 (0.52-3.26)	
Abortion	Yes	4	26.7%	15	206.47	19.37	1	
	No	28	28.0%	100	2004.4	13.97	1.05 (0.43-2.57)	
Previous caesarean section	Yes	14	48.3%	29	570.77	24.53	2.31 (1.32-4.03) *	1.81 (0.86 - 3.81)
	No	18	20.9%	86	1640.1	10.97	1	1
Other method of contraception	Yes	24	34.3%	70	1376.93	17.43	1.93 (0.95-3.91)	
	No	8	17.8%	45	833.93	9.59	1	
Frequency of menstrual cycle	Yes	11	30.6%	36	710.93	15.47	1.15 (0.62-2.12)	
	No	21	26.6%	79	1499.93	14	1	
Inter menstrual spotting	Yes	9	25.7%	35	692.7	12.99	1	
	No	23	28.8%	80	1518.17	15.15	1.12 (0.58-2.16)	
Amenorrhea	Yes	13	28.3%	46	822.77	15.8	1.03 (0.56-1.87)	
	No	19	27.5%	69	1388.1	13.69	1	
Dysmenorrhea	Yes	5	20.8%	24	508.5	9.83	1	
	No	27	29.7%	91	1702.37	15.86	1.42 (0.61-3.30)	
Prolonged bleeding	Yes	10	27.0%	37	714.9	13.99	1	
	No	22	28.2%	78	1495.97	14.71	1.04 (0.55-1.97)	
Mood swings	Yes	10	47.6%	21	340.87	29.34	2.04 (1.14-3.63) *	1.62 (0.59 - 4.44)
	No	22	23.4%	94	1870	11.76	1	1
Headache	Yes	11	55.0%	20	343.57	32.02	2.49 (1.44-4.30) *	1.31 (0.46 - 3.74)
	No	21	22.1%	95	1867.3	11.25	1	1
Dizziness	Yes	5	62.5%	8	117.23	42.65	4.72 (1.80 - 12.39)*	4.00 (1.28 - 12.46)*
	No	27	25.2%	107	2093.63	12.9	1	1
Acne	Yes	5	27.8%	18	367.03	13.62	1	
	No	27	27.8%	97	1843.83	14.64	1.00 (0.45-2.25)	
Hirsutism	Yes	4	26.7%	15	268.43	14.9	1	
	No	28	28.0%	100	1942.43	14.41	1.05 (0.43-2.57)	
Breast tenderness	Yes	9	37.5%	24	530.9	16.95	1.48 (0.79-2.78)	
	No	23	25.3%	91	1679.97	13.69	1	
Weight gain of 5-10 kg	Yes	12	42.9%	28	514.1	23.34	1.86 (1.05-3.31) *	1.44 (0.61 - 3.41)

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	No	20	23.0%	87	1696.77	11.79	1	1
Loss of libido	Yes	5	25.0%	20	390.5	12.8	1	
	No	27	28.4%	95	1820.37	14.83	1.14 (0.50-2.59)	
Insertion site side effects	Yes	8	50.0%	16	299.77	26.69	2.06 (1.13-3.76) *	2.66 (1.07 - 6.58)*
	No	24	24.2%	99	1911.1	12.56	1	1
Who chose the method	Patients side	16	22.5%	71	1327.57	12.05	1	
	Doctor	16	36.4%	44	883.3	18.11	1.61 (0.90-2.89)	

* Significant at 0.05 alpha level.

removal per 1,000 women per month was 14.47 (95% confidence interval (CI): 10.24-20.47).

Bivariate analysis showed that the chance of early Implanon removal was significantly higher in older women (HR: 2.36; 95%CI: 1.09-5.1), those with BMI <25kg/m^2 (HR: 2.48; 95%CI: 1.24-4.97), women with a history of caesarean section (CS) deliveries (HR: 2.31; 95%CI: 1.32-4.03), women having post-implant side effects such as dizziness (HR: 4.72; 95%CI: 1.80-12.39), mood swings (HR: 2.04; 95%CI: 1.14-3.63), headache (HR: 2.49; 95%CI: 1.44-4.30) and insertion-site side effects (HR: 2.06; 95%CI: 1.13-3.76). Among the 28(24.3%) women who gained weight, early Implanon discontinuation was recorded in 12(42.9%) of the women. Among the 87(75.6%) women who did not report weight-gain, Implanon discontinuation was done by 20(23%) (HR: 1.86; 95%CI: 1.05-3.31).

The cumulative hazard of early Implanon removal was significantly higher among women who suffered from side effects of the implant in general compared to those who had no complaints (p=0.012) (Figure).

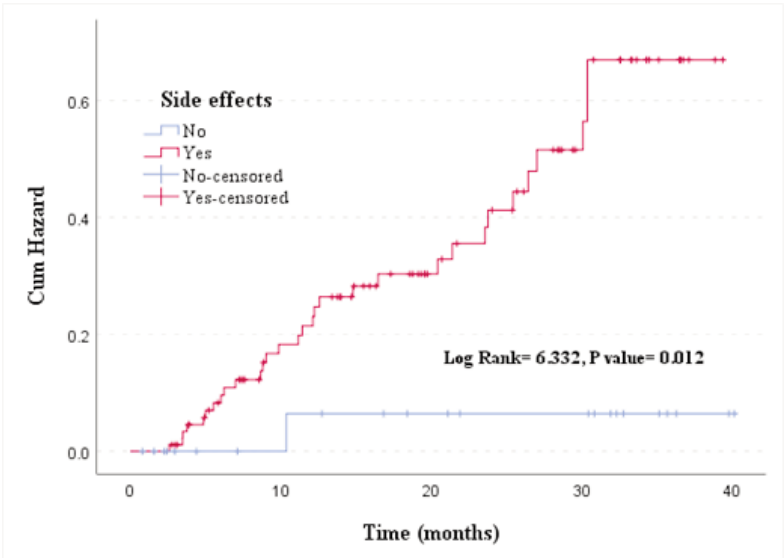

Figure: Early Implanon removal hazard ratio comparison with respect to side effects..

In the multivariate model, only lower BMI, dizziness and insertion-site side effects were the potential determinants of early implant discontinuation (p<0.05) (Table 2).

Discussion

The current study found that those who discontinued Implanon early (<30 months of insertion) were 14.47 per 1,000 women per month, with an overall discontinuation percentage of 27.8%, which was close to 26.1% reported in a Nigerian study[18], but higher than 16% found in a US study.[19] However, the discontinuation rate was much lower than 32.7% reported by an analysis of 11 international studies[20] and 46.4% reported by a Jordanian study[21]. Among the variables analysed, Cox Regression Model showed that the significant determinants of early Implanon discontinuation were lower BMI, dizziness and insertion-site side effects. Women who had normal or subnormal body weight (BMI <25) were more likely to discontinue the contraceptive implant early, and the finding was in line with earlier studies[19,22]. This could be owing to being more prone to side effects while using the implant[23]. Participants who had been experiencing attacks of dizziness during the contraceptive use in the current study also discontinued earlier than others, which was in agreement with other studies[24]. There is limited literature available in support of insertion-site side effects as a determinant of premature implant discontinuation, although they are common complications of contraceptive implants[25].

Contrary to other studies[19-21], there was no significant association in the current study between early implant discontinuation and bleeding irregularities. This might be attributed to

differences in the sample or the techniques employed in the two studies.

Limitations: The current study has limitations as some of the reported side effects of implant use were subjective, like feeling dizzy or suffering from insertion-site pain, so they might be prone to reporting bias. Furthermore, the study was conducted at a single heath facility in an urban setting, and the findings could be different in other hospitals located in other governorates. Also, the sample size was not calculated which could have influenced the power of the study. Lastly, despite using the Cox Regression Model to adjust for confounders, potential effects due to other variables, like participants' autonomy, regarding discontinuation cannot be excluded.

Conclusion

More than a quarter of the sample opted for early Implanon discontinuation. Low body mass index, dizziness and insertion-site side effects were potential determinants of early removal, suggesting the need for pre-insertion counselling, especially about side effects focussing on women with lower BMI, follow-up and early management of any side effects to bring the early discontinuation rate down, and to improve the satisfaction of the user.

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