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The Safety And Efficacy of Implanon Implant in A Sample of Iraqi Women: A Cohort Study

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Abstract

Aim of the study: we planned and conducted the current cohort study to evaluate the safety and efficacy of this new contraceptive method in a sample of Iraqi women.

Patients and Method: This cohort study was carried out at some governmental health institutes such as Al-Diwaniyah Maternity and Child Teaching hospital and Al-Shamiyah teaching hospital and some private clinics. The beginning of the study is dated back to the 2nd of January 2016; the study continued till end of June 2019 and included 53 women. Inclusion criteria included any women with implanon implant that was recently impanted. The variables to be evaluated included age, residency, gravidity, parity and abortions in addition to principal outcomes, complications (amenorrhea, bleeding and development of ovarian cysts) and pregnancy six months following removal of the implant. All women participating in the current study were followed up till at least six months after implant removal.

Results: The outcome of implanon use was assessed following a period of follow up that ranged from 2 to 3 years with a mean of 2.89 years, as shown in table 2. Contraceptive failure was no seen in any case with a failure rate of 0.0 %. Amenorrhea was the most frequent side effect and it has been seen 18 (34.0 %). Ovarian cyst was seen in 6 cases accounting for (11.3 %) and bleeding was seen in 2 cases only accounting for (3.8 %). Complications, amenorrhea, ovarian cysts and bleeding were not significantly correlated to any of demographic or obstetric characteristics of the study group ($P > 0.05$.

Key words: *safety, efficacy, implanon implant, Iraqi women*

Introduction

Control of the number of family members and regulation and timing of child birth become well accepted issue in our community since decades. This because of economic concern partly, as increasing family size is by itself an economic burden [(1-3)]. In addition some cultural attitudes have been positively directed toward the quality of siblings, their education and their positive participation in the society [4]. So that having little number of well educated children and of good socioeconomic status becomes the goal of Iraqi family since 80s of the previous century. Thus various methods of contraception became sought by Iraqi couples. Indeed, none of contraceptive methods is free from failure rate or adverse health issues [(5, 6)]. The methods of contraception are diverse; however, they can be grouped into two major groups, hormonal and non hormonal methods. Hormonal methods include oral birth control pills [7], skin patches [8], vaginal ring [9] and hormone releasing contraceptive coils [10]. Non hormonal methods included male condom, female condom [11], copper coils [12], diaphragms [13], chemical creams, gel or suppositories [14] and natural control methods [15]. The intrauterine device (IUD) is on top of the list of contraceptive methods used worldwide and it is estimated to be used by more than 168 million women globally [16]. Recently in the United States, IUD gains wide acceptance by women within all ages and parities as an efficient method of avoided unintended pregnancy [17]. In addition, researchers have shown that pregnancy rates in association with oral contraceptive pills and implants are about 20 times more frequent when

compared with IUD [17]. As it was mentioned previously, there are basically two forms of contraceptive methods, hormonal based and non hormonal ways ([7-5]). Implanon is one of the relatively newly introduced hormonal based contraceptive methods. It is an etonorgestrol implant. It is composed of a single road that is to be inserted in the upper arm [18]. Etonorgestrol is a synthetic active metabolite derived from a synthetic progestin and has high affinity to bind progesterone receptors. It acts to prevent pregnancy by several ways including the inhibition of luteinizing hormone (LH) secretion, an important hormone for natural ovulation, making the cervical mucus more viscous thereby inhibiting passage of sperm, and rendering the uterine mucosa less receptive for embryo thereby interfering with implantation [18] . Implanon was recently introduced into our country and its efficacy and safety is yet to be determined since published national research work with this regard is somewhat lacking. Therefore, we planned and conducted the current cohort study to evaluate the safety and efficacy of this new contraceptive method in a sample of Iraqi women.

Patients and methods

This cohort study was carried out at some governmental health institutes such as Al-Diwaniyah Maternity and Child Teaching hospital and Al-Shamiyah teaching hospital and some private clinics. The beginning of the study is dated back to the 2nd of January 2016; the study continued till end of June 2019 and included 53 women. Inclusion criteria included any women with implanon implant that was recently impanted. The variables to be evaluated included age, residency, gravidity, parity and abortions in addition to principal outcomes, complications (amenorrhea, bleeding and development of ovarian cysts) and pregnancy six months following removal of the implant. All women participating in the current study were followed up till at least six months after implant removal. The study was approved by the institutional approval committee and verbal consent was obtained from all participants following full illustration of the aim and procedures of the current study. Data were then transformed into an SPSS (version 23) spread sheet. Numeric data were expressed as mean, standard deviation, median, inter-quartile range (IQR) and range, whereas, categorical data were expressed as number and percentage. Correlation was calculated using Spearman correlation test and the level of significance was chosen at $P \leq 0.05$.

Results

The demographic characteristics of women enrolled in the current study were demonstrated in table 1. The study included 53 women with an age range of 17 - 40 years and a mean age of 26.70 ±6.27 years. Women less than 20 accounted for 5 (9.4 %), women between 20 and 39 accounted for 42 (79.2 %) and women older than 40 accounted for 6 (11.3 %). According to residency there were 47 (88.7 %) women from urban areas and 6 (11.3 %) from rural areas. Regarding obstetric history, the range of gravidity was from 0 to 9 with a median of 4, the parity was ranging from 0 to 8 and the median was 3 and abortion ranged from 0 to 5 with a median of 0. Regarding mode of delivery the range of vaginal delivery was from 0 to 9 with a median of 1 per woman, whereas, the range of cesarean section was from 0 to 5 with a median of one cesarean section per woman, as shown in table 1.

The outcome of implanon use was assessed following a period of follow up that ranged from 2 to 3 years with a mean of 2.89 years, as shown in table 2. Contraceptive failure was no seen in any case with a failure rate of 0.0 %. Amenorrhea was the most frequent side effect and it has been seen 18 (34.0 %). Ovarian cyst was seen in 6 cases accounting for (11.3 %) and bleeding was seen in 2 cases only accounting for (3.8 %), as shown in table 2.

Complications, amenorrhea, ovarian cysts and bleeding were not significantly correlated to any of demographic or obstetric characteristics of the study group ($P > 0.05$), as shown in table 3. Pregnancy after removal of the implant was seen in 17 women (32.1 %).

Table 1: General characteristics of the study sample

Characteristic	Value
Number of cases	53
Age	
Range	17 - 40
Mean ± SD	26.70 ±6.27
< 20, n (%)	5 (9.4 %)
20-34, n (%)	42 (79.2 %)
≥ 35, n (%)	6 (11.3 %)
Residency	

Cont.... **Table 1: General characteristics of the study sample**

Urban, n (%)	47 (88.7 %)
Rural, n (%)	6 (11.3 %)
Gravidity	
Range	0 - 9
Median (IQR)	4 (3)
Parity	
Range	0 - 8
Median (IQR)	3 (2)
Vaginal delivery	
Range	0 - 7
Median (IQR)	2 (3)
Cesarean section	
Range	0 - 5
Median (IQR)	1 (2)
Abortion	
Range	0 - 5
Median (IQR)	0 (2)

n: number of cases; SD: standard deviation; IQR: inter-quartile range

Table 2: Outcome of implanon use

Outcome	**n**	**%**
Contraceptive failure	0	0.0
Complication		
Amenorrhea	18	34
Ovarian cyst	6	11.3
Bleeding	2	3.8
Pregnancy following 6 moths implanon removal	17	32.1
Duration of implant (years)		
2	3	5.7
2.5	6	11.3
3	44	83
Range	2	3
Mean ±SD	2.89	0.27

Table 3: Correlations of complications to demographic and obstetric characteristics of women enrolled in the study

Characteristic	**Amenorrhea**		**Ovarian Cyst**		**Bleeding**	
	r	**P**	**r**	**P**	**r**	**P**
Age	0.029	0.838	0.178	0.203	-0.029	0.835
Residency	-0.005	0.973	-0.128	0.362	-0.071	0.615
Gravidity	0.038	0.786	0.256	0.064	0.023	0.871
Parity	0.029	0.836	0.259	0.061	0.033	0.815
Vaginal delivery	0.097	0.491	0.201	0.068	0.114	0.418
Cesarean section	-0.003	0.984	-0.083	0.555	-0.007	0.961
Abortion	0.043	0.762	0.015	0.916	0.014	0.920
Duration	0.223	0.108	-0.015	0.916	0.089	0.525

Discussion

The avoidance of unintended pregnancy by Iraqi couples became well known trend in our community and the search for a suitable method for contraception with minimal adverse effects and almost zero percent failure rate became an urgent need in daily obstetric clinical practice. For that reason, now and then new modalities of contraception enters into daily obstetric practice, but basically they are always of either hormonal or non hormonal principle of action.

Implanon is well recognized as an effective mode of contraception in developed countries. It is a single road etonorgestrol implant that is can be inserted in the upper arm and remains for a period of 3 years [18]. The active ingredient is Etonorgestrol which is a synthetic active metabolite derived from a synthetic progestin and has high affinity to bind progesterone receptors. It produces its effects by several mechanisms suchas the inhibition of luteinizing hormone (LH) secretion, an important hormone for natural ovulation, making the cervical mucus more viscous thereby inhibiting passage of sperm, and rendering the uterine mucosa less receptive for embryo thereby interfering with implantation [18].

In the current study, impalnon use was evaluated in a cohort study and women were followed up for a period that lasted for an average of 2.89 years. The use of implanon was associated with zero percent failure rate and minimal anticipated side effects such as amenorrhea and bleeding in addition to 6 cases of ovarian cyst that have resolved spontaneously. In addition, pregnancy was successful after implanon removal in 32.1 % of cases with in a period of six months after implant removal.

In addition, the cost of impalnon was also satisfactory for all participants. The safety and efficacy of impalnon has been reported by several previous reports [19-22]. Some side effects has been previously reported. Damage to antebrachial cutaneous nerve at time of insertion or removal has been observed by Wechselberger et al. [23]. Damage to ulnar nerve at time of insertion has been seen by Osman et al. [24]. There was spontaneous extrusion of Implanon in one case 3 days after insertion. Extrusion has also been seen by Harrison-Woolrych and Hill [25]. Splitting of Implanon in 2 halves in situ more than one year after insertion has been observed by Agrawal and Robinson [26]; however, none of these adverse outcomes has been seen in our study.

Therefore, in view of available data of the current research and previously published data about impalnon single rod contraceptive implant, a conclusion can be inferred as following: Implanon is effective and safe mode of contraception and recommended to be used in daily obstetric practice in our community.

Conclusion

The use of impalnon is highly effective as a contraceptive mode since it was associated with 0 % risk of contraceptive failure and it was safe because of minimal tolerable side effects in almost all included women.

Financial Disclosure: There is no financial disclosure.

Conflict of Interest: None to declare.

Ethical Clearance: All experimental protocols were approved under the Al-Diwaniyah child and maternity hospital / Department of Obstetrics and gynecology / Al-Diwania / Iraq and all experiments were carried out in accordance with approved guidelines.

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