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RESEARCH ARTICLE

EFFICACY AND SAFETY OF A SINGLE ROD – CONTRACEPTIVE IMPLANT (IMPLANON)

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ABSTRACT

Background: Implanon is a subdermal contraceptive implant involves the delivery of a steroid progestin (68 mg of etonogesterel) from a single rod placed under the skin at the inner side of the non-dominant upper arm and the hormone diffuses out slowly at a stable rate providing contraceptive effectiveness for 3 years. Advantages of Implanon includes long term contraceptive action without requiring the user's or provider's attention, low dose of highly effective contraception without use of estrogen and fertility is readily reversible after the removal of implant. **Objectives**: to assess contraceptive efficacy, safety and acceptability of Implanon. **Materials and methods**: the study was conducted in Iraq- Al-Samawa and Al- Diwaniya maternity and pediatrics teaching hospital, family planning clinics and privet clinics from the period of October 2012 – October 2014 that includes 41 sexually active women 18-45 years seeking for contraception with normal menstrual cycles, no history of ischemic heart disease or stroke and no history of breast or genital tract malignancy. **Results**: contraceptive efficacy of Implanon was 98% over 2 years follow up and the most common adverse experience was abnormal bleeding pattern in 100% of women, as amenorrhea affects 51.22%, infrequent bleeding 26.82%,prolonged bleeding 12.20% and metromenorhagia 9.76%.. Discontinuation rate was 2.44% because of menstrual bleeding abnormality. Other adverse experiences after Implanon insertion were weight gain of ≤ 5kg in7.32% after 2 years follow up, acne in 31.71%, mood changes in 21.95% and headache in 12.20%. **Conclusions**: Implanon is a safe, highly effective and rapidly reversible new method of contraception and the safety profile is acceptable and not essentially different from progestogens in general.

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INTRODUCTION

Contraception means prevention of pregnancy, and contraceptive methods work in a variety of ways as they may prevent the sperm from fertilizing the ovum, prevent ovulation, or change the endometrium so the fertilized ovum can't implant. Different people have different attitudes towards contraception, they may decide not to use contraception for cultural, religious or life style reasons but most people want to plan when they have children and the number of children they would like to have (1). There are a number of safe and effective methods of contraception available in the market and the effectiveness of different methods can be measured by "perfect-use" where rules of the method are rigorously followed and the action of contraception can range from a permanent method, long acting method (three, five or ten years), a medium acting method (four to twelve weeks) or a short acting method (daily) (Trussell, 2011; Trussell, 2011). Etonogestrel contraceptive implant sold under the brand name "Implanon", is a single-rode subdermal contraceptive implant that is inserted just under the skin of women's upper arm and contains etonogestrel (Raymond, 2011).

Implanon is a type of long acting reversible contraception that was first approved for use in Indonesia in 1998, then approved for use in the united states in 2006 and now it is used by more than 11 million women around the world and approved for use in over 60 countries since 2003 (Winner, 1998-2007; Raymond, 2011). Implanon is a progestin only contraception (doesn't contain estrogen or latex) and it is not radio-opaque and it is a single rode implant made of an ethylene-vinyl-acetat copolymer with a core containing 68mg of etonogesterel (3-ketodesogestrel), and the release rate of progesterone 60-70µg/day within 5-6 weeks of insertion decreased to 35-45µg/day at the end of 1st year and to 30-40µg/day at the end of 2nd year, then 25-30µg/day at the end of 3rd year(5). The implant has a length of 40mm and a diameter of 2mm and is provided in a sterile disposable inserter for subdermal application (Makarainen *et al.,* 1998). Contraceptive action of Implanon is primarily by inhibition of ovulation and lasts for 3 years, and secondary mechanism of action is the progestogenic increase in cervical mucus viscosity which inhibits sperm penetration (Makarainen *et al.,* 1998; Rivera *et al.,* 1999). Implanon should be removed after 3 years, however. They can be removed at any time if pregnancy is desired, and within a week of removal the hormones from the device leave the body

and etonogestrel is undetectable in most users and most women will begin to ovulate within six weeks of removal and fertility levels will return to what they were before Implanon insertion (Raymond, 20117). It may be replaced by a new implant at the time of removal if continued contraceptive protection is desired (Davies, 1993). Although the failure rate of Implanon is 0.05%, there are a number of advantages of using it in addition to offering a long term contraception without requiring the user's or provider's attention, estrogen free, can be removed at any time followed by quick return to fertility and provide menstrual pain relief (dysmenorrhea) and pelvic pain caused by endometriosis (Funk, 2005; Flores *et al.,* 2005). Objectives of our study were to assess contraceptive efficacy, safety and acceptability of the single-rode contraceptive implant (Implanon).

MATERIALS AND METHODS

A cohort prospective study conducted in Iraq- Al-Samawa Maternity and Pediatrics teaching hospital, Al Diwaniya Maternity and Pediatrics teaching hospital, family planning clinics and the privet clinics in both cities from the period of October 2012- October 2014. The inclusion criteria: 41 healthy women 18-45 years who were sexually active, of childbearing potential and requesting contraception, menstrual cycle length 25-35 days, no history of heart disease or stroke medical history and gynecological history assessed with baseline physical and pelvic examination including normal cervical papanicolaou smear (pap smear) and these assessment repeated once every year at the time of follow up after insertion. All women gave their consent in writing after receiving full information on Implanon and the requirement and the protocol of the study was submitted to the local Iraqi Ethical Committee.

Exclusion criteria: Were pregnancy, breast feeding, over weight (BMI ≥29 kg/cm², taking liver inducing drugs or sex steroid drugs,history of genital tract malignancy or breast cancer and allergy to etonogestrel. The implant rode (Implanon) containing 68mg of etonogestrel was inserted subdermally in the inner aspect of the non-dominant upper arm about 8-10cm (3-4inches) above the medial epicondyle of the humors, this is to reduce the risk of neural or vascular injury. Before insertion the arm was washed with antiseptic solution and local anesthetic was applied. The time of insertion had to be on or between day 1-5 of a spontaneous menses, back-up contraception is not necessary if inserted as recommended. Follow up of the patient over 2 years after implant insertion scheduled with 3 months visit, 6 months, 1 year and 2 year visit. Contraceptive efficacy was assessed with the percentage of failure rate and safety assessment schedule was development of side effects in form of menstrual cycle abnormality, weight gain, mood changes, headache and acne.

RESULTS

Relevant characteristics of the study population were present in (table 1). Follow up of 41 women with a mean age of 34.22± 6.77 years over 2 years after Implanon insertion reveal a contraceptive efficacy of 98% as one women had a failed contraception after 9 months of insertion of Implanon and the rod removed immediately and follow up of her pregnancy and delivered a healthy baby (Figure 1).

Table 1. Demographic characteristic of the study population

Characteristic		N	%
Age	<20 years	2	4.88
	21-30 years	7	17.07
	31-40 years	23	56.10
	≥41 years	9	21.95
Parity	P1	1	2.44
	P2-4	26	63.41
	P>4	14	34.15

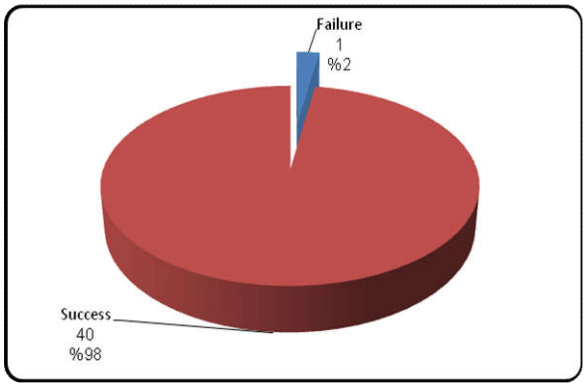

Figure 1. Failure rate (pregnancy) with Implanon use

Table 2. Bleeding pattern after Implanon insertion

Characteristic		N	%
Bleeding pattern	Infrequent	11	26.82
	Amenorrhea	21	51.22
	Prolonged	5	12.20
	Metromenorhagia	4	9.76

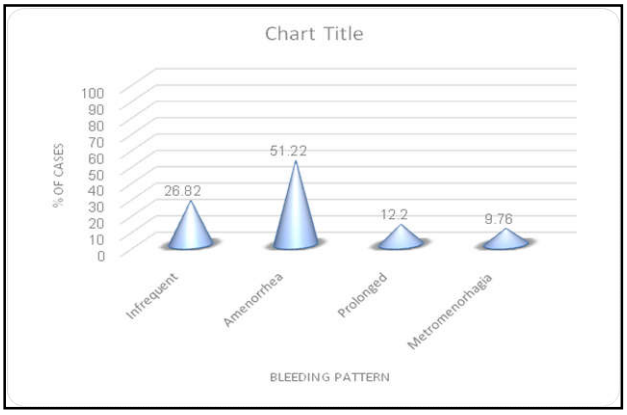

Figure 2. Bleeding pattern abnormalities after Implanon insertion

Table 3. Weight gain after Implanon insertion

Weight gain	N	%
3 months	8	19.51
6 months	11	26.83
1 year	5	12.20
2 year	3	7.32

Safety was monitored by recording the adverse experiences after insertion as there was a change in menstrual cycle pattern in all women after Implanon insertion (Table 2), ranging from amenorrhea(was defined as no bleeding or spotting throughout the reference period) in 51.22%, infrequent bleeding(fewer than three bleeding –spotting episodes starting within a reference period) in 26.82%, prolonged bleeding (at least one bleeding-spotting episode starting within a reference period and lasting > 14 days) in 12.20% and metromenorhagia (more than five bleeding - spotting starting within reference period) in 9.76%.

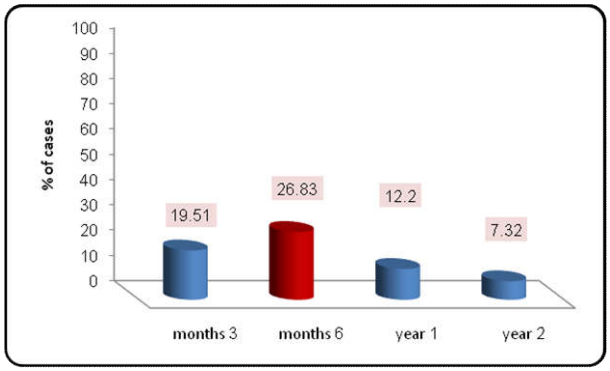

Figure 3. Weight gain within two years of Implanon insertion

Table 4. Adverse effects after Implanon insertion

Side effects	N	%
Abnormal menstrual cycle	41	100.00
Acne	13	31.71
Mood change	9	21.95
Dizziness and headache	5	12.20
Subjective satisfaction	0	0.00

Table 5. Follow up table

Characteristic		N	%
Follow up visits	1 visit	23	56.10
	>2 visits	18	43.90
Cause of removal	Bleeding	1	2.44
	Other adverse effects	0	0.00

A bleeding-spotting episode was defined as any set of ≥ 1 consecutive bleeding or spotting days bounded at each end by at least 1 bleeding-free day). Coding of adverse experiences was done using the WHO adverse reactions terminology (World Health Organization, 1994). Menstrual cycle abnormality was a cause for discontinuation of the contraception in 2.44% of women (Table 5). Weight gain of ≤ 5 kg observed in 19.51% of women within 3 months after insertion and in 7.32% after 2 years follow up (Table 3). Acne was one of the most frequently reported adverse experience and it affect 31.71% of women in our study group. Other adverse effects after Implanon insertion were headache in12.20% and mood changes and emotional liability in 21.95% of women (Table 4). So, subjective satisfaction was 0% and this was because of the adverse effects after insertion (Table 4). No complication related to implantation site insertion and no allergic reaction. No change in blood pressure reading during the follow up period after insertion and no change in pap smear screening results.

Statistical analysis: Data were analyzed using SPSS version 20 and Microsoft Office Excel 2007. Numeric variables were expressed as mean±SD (standard deviation) while categorical variables were expressed as number and percentage

DISCUSSION

Implanon is a single contraceptive implant with an effective life span of 3 years, it provide excellent contraceptive cover for the full period to women of wide ranges of ages, weight and cultural background (Funk *et al.,* 2005; Sivin *et al.,* 1997). Total contraceptive protection is rarely observed even among the most effective methods including tubal ligation and this fact allow us to use the new implant's in the youngest, most fertile women as well as those who were overweight (Sivin *et al.,* 1997).

Although the failure rate in our study was 2% which was probably related to failure of the method itself, but still Implanon is a type of long-acting reversible contraception which has been shown to be the most effective form of birth control available with a failure rate of 0.05% (Guttmacher, 2012). Prospective follow up studies of Implanon which include over 2,465 women have no pregnancies (Winner, 1998-2007; Davies, 1993; Kiriwat *et al.,* 1999). But other studies have found some failures with this method, some attributed to failures of the method itself and others to improper placement, drug interactions or conception prior to insertion (Harrison-Woolrych, 1993). Other multicenter study by Horacio *et al.,* (1998), that involved 635 young healthy women from 21 centers in nine different countries participated in the study with Implanon insertion as contraception reveal no pregnancy occurred during follow up period resulting in a pearl index of (95% confidence interval :0.0-0.2) during the 3 years, with excellent contraceptive action and the safety profil was accepted and not essentially different from progestogens side effect (Haracio *et al.,* 1999).

In comparison tubal sterilization has a failure rate of 0.5% and intrauterine contraceptive devices (IUDs) had a failure rate of 0.2-0.8% (Guttmacher, 2012). These studies suggest that Implanon is more effective contraception than tubal sterilization and IUDs, also tubal ligation is permanent and required invasive surgery whereas the subdermal implant is completely reversible, and IUDs are associated with complication as pelvic infection, perforation, excessive cyclical bleeding and ectopic pregnancy (Guttmacher, 2012; Harrison-Woolrych, 1993). Although the percentage of failure rate in our study was higher than other studies but this probably attributed to the small number of the studied group. With due consideration to these studies, the performance of Implanon can be compared with the performance of other contraceptive implants, a study by Sivi *et al.* (1997), showed no pregnancies were reported in a trial that encompassed 598 users of the six-capsule system implant(Norplant) and 600 users of the two-rod system (Norplant-II)over 3 years (Sivin *et al.,* 1997).

The annual pregnancy rate ranged from 0.0-0.3 per 100 women over 3 years which rose to 1.0 per 100 women over 5 years (Sivin *et al.,* 1998). As for the bleeding pattern, this study confirms the well-established concept that the use of continuous progesterone - only methods were associated with disturbed menstrual pattern in high proportion of users and that is the main reason for discontinuation of the method. The bleeding pattern reported here shows a shift towards amenorrhea and infrequent bleeding 51.22% and 26.82%, respectively. Some women experience prolonged bleeding 12.20% which was declined after the first 3 months of use. While these pattern are not dangerous, they are the most common reason for discontinuation of the method 2.44%, and after removal the bleeding pattern returns to previous patterns in most women. Therefore, discontinuation rate is in the first place a reflection of tolerance rather than safety. Horacio *et al.* study (1999) showed that bleeding irregularity was the main reason for discontinuation during the first 2 years of use (17.2%) (Haracio, 1999), while Funk S., et al study (2008) showed the incidence of amenorrhea range from 14% to 20% and 13% withdrew from the study because of the bleeding pattern (Funk, 2005). Sivin I., et al study (1997) showed the incidence of amenorrhea was just below 20% during most of the time and it was the reason for discontinuation in only 1.7%

of women (Sivin *et al.,* 1997). Other adverse effect of Implanon insertion in our study was weight gain with average increment of ≤ 5kg over 2 years follow up which affect 19.51% within 3 months of insertion and 7.32% after 2 years .Although some studies showed that some women experience slight weight gain when using Implanon contraception, however they are not conclusive because they do not compare the weight of women using Implanon with a control group not using it (Winner, 2007). But Funk *et al.* study (2005) showed weight gain of 3.3% which was not significant and can be controlled with diet and healthy eating pattern (Funk, 2005). Acne has been reported as a side effect of Implanon, and in our study it affects 31.71%, but a study by Funk *et al.* (2005) showed that majority of users with acne before their insertion reported that their acne had decreased and only 16% of those who did not have acne before insertion developed acne (Funk, 2005). Other adverse experiences that were reported in our study include headache 12.20%, mood changes in 21.95%. However, there have been no studies that conclusively determine that these symptoms are caused by the Implanon (Davies, 1993; Funk, 2005).

Horacio B. study (1999) showed that the incidence of headache was 69.2%, which was in contrast to the average incidence of 6.5% in other centers (Haracio, 1999), and Funk S. study (2005) showed that emotional liability and mood changes occur in 6.1% (Funk, 2005). There was no adverse experiences at the site of implant placement in our study group during the 3 years follow up, together with the fast insertion and removal stand out practical advantage over other multiple unit implant (Norplant).There was no change in blood pressure reading during the follow up period after Implanon insertion, no development of ischemic heart disease or stroke. Although some studies showed some concern about women who developed ischemic heart disease, migraines with aura or stroke while using progesterone only contraception as pills, depomedroxy- progesterone injection or implant. However these concerns are less for the implant (Implanon)and more for the depomedroxy- progesterone injection (Brache, 2002). There have been no studies to provide direct evidence that progesterone only contraception such as implant has a negative effect on breast milk production or infants and the WHO lists breast feeding under 4 weeks as category 2 concern in which the benefits outweigh the risks and cites no risk after 4 weeks postpartum.

Conclusion and Recommendation

Implanon is a safe, highly effective and rapidly reversible new method of contraception for the full period of 3 years to women with wide ranges of ages, weight and breast feeding women with easy implant insertion and removal and retune to normal menstrual cycles and fertility was rapid after removal and the adverse events were not essentially different from progesterone itself. A larger study group is recommended to study more the effectiveness of the new Implanon contraception.

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