ORIGINAL ARTICLE

Frequency of irregular vaginal bleeding in women using Femplant

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ABSTRACT

Aim: To determine frequency of irregular vaginal bleeding in women using femplant.
Methods: This study was carried out in the Department of Obstetrics and Gynecology, Nishtar Hospital Multan from July 2013 to January 2014. Ninety one clients meeting inclusion criteria were enrolled in the study. The researcher herself performed the insertion of femplant. Clients were advised for a follow up visit every month up till 3 months after use of femplant. Presence or absence or irregular vaginal bleeding was inquired from the client by the researcher & noted on the proforma along with demography of the client. Data will be entered and analyzed by using computer software SPSS 10.
Results: Majority of the clients (38.46%) was in age group 21-40 years and were multipara i.e., 96.70%. Among 91 women, majority of cases (79.87%) were none lactating. Irregular bleeding was reported in 23.07% of women using femplant.
Conclusion: Sino-implant (II) is one of the most effective contraceptives available today. The present study indicates a favorable level of safety, effectiveness and acceptability during the first three months of use.
Keywords: Sino-implant (II), femplant, irregular vaginal bleeding

INTRODUCTION

Contraception means prevention of conception without abstinence from couitis[1]. Contraceptive methods are broadly divided into two major groups i.e., temporary methods and the permanent methods. These methods include, natural (Rhythm, Lactational amenorrhea), barrier (Condoms, Diaphragm, Cervical cap), hormonal (Oral, Injectible, Implants), intrauterine devices (Copper containing, Hormonal), sterilization (Tubal ligation, Vasectomy) and emergency contraception.

Implants are thin, flexible rods that are inserted just under the skin of a women upper arm and provide sustained contraception ranging generally from 3 to 5 years[2].

Jadelle–a contraceptive implant-consists of two rods (2.5mm×43mm) each containing 75mg of levonorgestrel. Sino-implant (II), a similar two rod implant with the same amount of active ingredients as jadelle, was introduce in china. This was followed by implanon, single rod contracentive implant (2mm × 40mm) resembling progesterone, which was developed in the Netherlands. Norplant was discontinued later[3].

Contraceptive implants provide long lasting contraception by suppressing ovulation, impeding sperms transit by thickening the cervical mucous & altering the endometrial structure[3]. The duration of contraceptive production varies by brand. Jadelle is register to provide contraception for five years, sino-implant (II) (Femplant) for four years and implanon for three years[3]. After removal, return to fertility is usually rapid as the synthetic hormones in implants have a short half life and there is no delayed return to fertility for implant users as compared to women who do not use contraception[4]. Implants are best suited for women who desire a use–independent contraceptive method for birth spacing and limiting.

Implants should not be inserted in women during the first 6 weeks after child birth if they are exclusively or partially breast feeding; those with serious liver disease, problems with blood clots or unusual vaginal bleeding and women that have or have had protection from sexually transmitted infections.

Low dose progesterone method (pills or implants) are associated with high incidence of irregular vaginal bleeding. This is due partly to their effect on ovarian function. In the normal cycle, ovulation determines regular menstruation. Inconsistent ovulation and fluctuating endogenous estrogen production from irregular follicle growth provide a recipe for irregular bleeding. Bleeding pattern differ according to dose of progestrerone. Menstural disturbance is the norm and upto 20% of users experience amenorrhea & almost all the rest will have irregular, unpredictable bleeding. Heavy bleeding is uncommon & menstrual blood loss is

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much less than that experienced during a normal menstrual cycle[5].

Annual pregnancy rate are less than 1% with all implants[6.] Contraception rate are often better than those for other hormonal contraceptive or intrauterine devices[7]. In regard of evaluation of bleeding pattern, efficacy & discontinuation rate of etonogestrel implant inserted in postpartum adolescents, it is safe & effective contraceptive method that is well accepted by adolescents after a pregnancy[8]. Etonogestrel subdermal contraceptive implant demonstrated high efficacy & an acceptable continuation rate. Counselling potential users explicating about the side effects will minimize patient's success with this long acting contraception[9].

The insertion of etonongestrel releasing contraceptive implants during the immediate postpartum period was not associated with deleterious meternal clinical effects or with significant maternal metabolic alteration or decreasing infant weight gain[10]. In one study, frequency of irregular bleeding was38.6% in women using etonongestrel implants (which is 3rd generation progesterone while femplant is 2nd generation)[11].

This study was designed to determine magnitude of irregular vaginal bleeding in women using sino-implant (femplant).

MATERIAL AND METHODS

This study was carried out in the Department of Obstetrics and Gynecology, Nishtar Hospital Multan from July 2013 to January 2014. Ninety one clients meeting inclusion criteria were enrolled in the study. The researcher herself performed the insertion of femplant. Clients were advised for a follow up visit every month up till 3 months after use of femplant. Presence or absence or irregular vaginal bleeding was inquired from the client by the researcher & noted on the proforma along with demography of the client. Data will be entered and analyzed by using computer software SPSS 10.

RESULTS

This study was conducted in Gynaecology outpatient department of Nishtar Hospital Multan from 06-09-2012 to 19-12-2012 and from 20-03-2013 to 05-06-2013. The aim of this study was to determine the frequency of irregular vaginal bleeding in women using femplant. Majority of the clients (38.46%) was in age group 21-40 years. The age group 21-30 years was next in line. Least number of cases (12.08%) was in age group 16-20 years (Table 1). Analysis of parity distribution showed that majority of women (96.70%) was multipara i.e., having parity more than one. Among 91 patients, 3.29% were P1, 12.08% were P2, 26.37% were P3, 38.46% P4 and 19.78% were P5 (Table 2). Among 91 women, majority of cases (79.87%) were none lactating. And 20.87% were lactating (Figure 1). Among 91 women using femplant, irregular bleeding was reported in 23.07% of cases (Table 4)**.** Majority of the clients (38.46%) was in age group 21-40 years. The age group 21-30 years was next in line. Least number of cases (12.08%) was in age group 16-20 years.

Majority of women (96.70%) was multipara i.e. having parity more than one.3.29% was P1, 12.08% was P2, 26.37% was P3, 38.46% P4 and 19.78% were P5. Among 91 women using femplant, irregular bleeding was reported in 23.07% of cases.

Table 1: Age wise distribution of clients (n =91)

Age group (in years)	n	%age
16-20	11	12.08
21-30	29	31.86
31-40	35	38.46
41-50	16	17.58

Table 2: Parity wise distribution of clients (n =91)

Parity	n	%age
P1	3	3.29
P2	11	12.08
P3	24	26.37
P4	35	38.46
P5	18	19.78

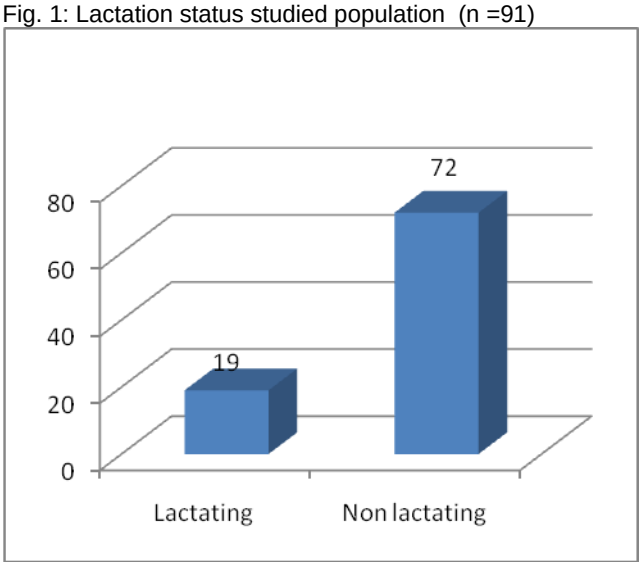
Table 3: Frequency of irregular bleeding in women using femplant (n =91)

Irregular bleeding	n	%age
Yes	21	23.07
No	70	76.92

Table 4: Stratification table

Age group (in years)	Irregular bleeding Yes	Irregular bleeding No	P value
16-20	2	9	Chi-square value=1.4440 df=3 p value=0.6952
21-30	5	24	
31-40	9	26	
41-50	5	11	
Parity			
P1	1	2	Chi-square value=0.3846 df=4 p value=0.9837
P2	2	9	
P3	6	18	
P4	8	27	
P5	4	14	
Lactational status			
Lactating	4	15	Chi-square value=0.0554 df=1 p value=0.8136
Non lactating	17	55	

Fig. 1: Lactation status studied population (n =91)



Among 91 women, majority of cases (79.87%) were none lactating. And 20.87% were lactating.

DISCUSSION

Subdermal implants are contraceptive systems that release low, stable amounts of synthetic progestins from Silastic or other materials for periods of months to several years. Unlike other hormonal delivery systems, they do not cause unnecessary peaks in progestin levels and do not use estrogens, and thus their health risks are minimal[12]. Levonorgestrel-releasing implants are long acting contraceptives. Randomised clinical trials and controlled cohort observations indicate that for the first 3 years, when pregnancy rates are at or almost zero, no other contraceptive system is more effective, although etonogestrel implants provide equal effectiveness. Levonorgestrel implants provide low progestogen doses; 40-50 microg/day at 1 year of use, decreasing to 25-30 microg/day in the fifth year. Serum levels of levonorgestrel at 5 years are 60-65% of those levels measured at 1 month of use. Adverse effects with levonorgestrel implants are similar to those observed with progestogen only and combined oral contraceptives[13].

Sino-implant (II) is a low-cost subdermal contraceptive implant containing levonorgestrel that is currently labeled for 4 years of use. Widely used in China and Indonesia, it has been little studied elsewhere. This study was conducted in Gynaecology outpatient department of Nishtar Hospital Multanfrom 06-09-2012 to 19-12-2012 and from 20-03-2013 to 05-06-2013. The aim of this study was to determine the frequency of irregular vaginal bleeding in women using femplant.

Table 4 & 5 is revealing age and parity wise distribution of women using femplant. Majority of the clients (38.46%) in our study was in age group 21-40 years. The age group 21-30 years was next in line. Least number of cases (12.08%) was in age group 16-20 years. Analysis of parity distribution showed that majority of women (96.70%) was multipara i.e. having parity more than one. Among 91 patients, 3.29% were P1, 12.08% were P2, 26.37% were P3, 38.46% P4 and 19.78% were P5.

Among 91 women, majority of cases (79.87%) were none lactating (Figure 1) and irregular bleeding was reported in 23.07% of cases (Table 4).

The acceptability of bleeding patterns in terms of its menstrual cycle regularity is comparable with other International study. In this study on Sino-implant (II), a total of 384 women returned for an earlier visit, and 351 returned for a later visit, for a total of 419 woman-years of observation. No postinsertion pregnancies or serious adverse events were observed. Twenty-eight implant removals were reported by 12 months, a cumulative removal probability of 7.3 per 100 women. Acceptability of the implants was very high, as was satisfaction with clinic services[14].

In another study, A total of 754 women returned for at least one follow-up visit[15]. The overall Pearl pregnancy rate was 0.4 per 100 woman-years (95% confidence interval [CI] 0.1, 0.9) from 1 confirmed post-insertion pregnancy in Kenya and 4 in Pakistan; country-specific pregnancy rates were 0.2 (95% CI 0.0, 0.9) in Kenya and 0.6 (95% CI 0.2, 1.6) in Pakistan. Four serious adverse events (SAEs) occurred in Kenya and none in Pakistan; one SAE (i.e. ectopic pregnancy) was possibly related to Sino-implant. Two removal complications were reported, both in Pakistan. Twenty-three Kenyan women and 77 Pakistani women had implants removed; the cumulative probability of removal at 12-months was 3.4% in Kenya (95% CI 1.9, 4.8) and 10.8% in Pakistan (95% CI 8.5, 13.2). Most common reasons for removal were: medical including heavy bleeding, irregular bleeding, infection, discomfort/pain, other side effects and pregnancy (n=16 in Kenya; n=56 in Pakistan); desired pregnancy (4 Kenya; 8 Pakistan); implant came out by itself (2 Kenya; 2 Pakistan); and husband or in-law's opposition (2 Kenya; 10 Pakistan). The most common side effect in both countries was headaches (6.1% Kenya and 36.6% Pakistan). Other side effects included mood changes (1.0% in Kenya; 18.1% in Pakistan), weight gain (3.9% Kenya; 11.7% Pakistan), and hair loss (7.7% Pakistan only). Bleeding patterns were generally acceptable with 93% of Kenyan participants and 73% of Pakistani participants reporting acceptable bleeding patterns during follow-up. Approximately

97% of Kenyan women and 82% of Pakistani women would recommend Sino-implant (II) to a friend[15].

To understand the changes of menstrual bleeding patterns of women using two types of subdermal sino - implant and compare to that of Norplant. A total of 857 menstrual diaries, provided by three subcentres, were analyzed. They included 288 diaries for sino - implant type I, 292 for type II and 277 for Norplant. The analysis of bleeding patterns was carried out using the reference period approach and followed the guidelines published by WHO. Each index of bleeding patterns was very similar between three groups. The number of bleeding/spotting days and the number of spotting days began to decrease from the second 90 - day period. The number of bleeding days was not much changed per 90 - day period among three groups. The proportions of women experiencing clinically important bleeding patterns were no significant difference in statistics among three groups. The percentage of users experiencing "acceptable" bleeding pattern was increased obviously in the second 90 - day period, from 15%~16% to 28%~33%. The percentage of irregular bleeding, the main bleeding disturbance, was decreased from 51% ~ 60% to 34%~35% in the second 90 - day period. Women using this contraceptive again had shorter bleeding and spotting days than ones using this method first in the first and second 90 - day period[16].

A review also evaluated bleeding disturbances and amenorrhoea associated with subdermal implantable contraceptives. Bleeding disturbances and amenorrhoea constitute one of the most important side-effects, which could lead to premature discontinuation of the method, possibly resulting in unintended pregnancy if the woman does not switch over to another contraceptive method. With respect to bleeding disturbances, infrequent bleeding [odds ratio (OR) 1.30; 95% confidence interval (CI) 1.04–1.63] and prolonged bleeding (OR 1.49; 95% CI 1.09–2.03), per a 90-day reference period, were more likely to occur among Implanon users compared with Norplant users (8–10). In addition, amenorrhoea was found to be statistically significantly higher in users of Implanon compared with those of Norplant (OR 1.87 and 95% CI 1.45–2.42 for 1 year of use; and OR 2.14 and 95% CI 1.63–2.81 for 2 years of use), and increased with number of years of use. Nevertheless, it is possible that the rate of amenorrhoea may be affected by the number of discontinuations. For this reason, caution is required in the interpretation of these data and women should be informed with respect to the differences between the different types of implant[17].

Levonorgestrel subdermal implants provide effective long term contraception. Despite a high incidence of menstrual adverse events, overall levels of user satisfaction are high, and 1-year continuation rates are better than those for combined oral contraceptives. Levonorgestrel subdermal implants are a good choice of contraceptive method in women who desire effective contraception, but who are unable to, or prefer not to, comply with an oral regimen[18].

Irregularity in vaginal bleeding patterns is the most common clinical side effect causing discontinuation of the method reported by the-users of the newer contraceptive methods, especially hormonal ones. An objective assessment of vaginal bleeding pattern is, therefore, critical in evaluation of a new contraceptive method for its acceptance and continued use. The menstrual diary records of women participating in clinical trials of several contraceptive methods undertaken by the Indian Council of Medical Research were analysed. It was observed that the long-acting progestogen-only hormonal contraceptives like levonorgestrel (LNG)-releasing subdermal implants Norplant or intrauterine devices (LNG-IUD) as well as injectable contraceptive NET-EN 200mg given 2 or 3 monthly produced disturbances in bleeding pattern in the majority of their users. Very heavy or prolonged bleeding, a potential health hazard was uncommon and a shift more towards infrequent bleeding was observed. In Norplant-II implants users, 75 to 80% of women had irregularities in bleeding pattern during the first year of use which improved with prolonged use. However, even at 4 years of use, about half of the users of Norplant-II implants continued to have irregular bleeding patterns. The bleeding disturbances occurred in 80% users of 200mg NET-EN injectable contraceptives also during first year of use, however unlike Norplant-II implants users, there was no improvement with prolonged use. Combined monthly injectable contraceptives containing 50mg NET-EN and 5mg estradiol valerate caused less bleeding problems with half of the users experiencing normal pattern during one year of its use. Combined low-dose oral pills, both triphasic and monophasic, produced much better cycle control as compared to any of the other hormonal contraceptive-treated groups; about 90% of combined oral pill users had normal bleeding patterns during one year of method use. The use of copper IUDs was associated with increased bleeding in 18 to 20% of women during the initial period of three months which improved with prolonged use. It was observed that the women having frequent or prolonged bleeding had discontinued the contraceptive method more often as compared to those having delayed bleeding episodes or oligomenorrhoea. However, discontinuation rates due to bleeding irregularities at one year were lower

in Norplant-II implants users as compared to other long acting hormonal contraceptive methods such as injectables or IUDs in spite of similar or better bleeding patterns in women using these methods[19].

These studies showed that the Sino-implant (II) was safe and effective in routine service delivery during the first year of use[140]. Acceptability as reported by study participants as well as continuation rates in both countries was generally high, though notably higher in Kenya. The favorable results from both countries provide further evidence that Sino-implant (II) is a safe, effective and acceptable contraceptive method. Longer follow-up of Sino-implant (II) users should be done. Further research may also elucidate factors associated with higher reported rates of side effects and lower rates of acceptability in Pakistan.

CONCLUSION

Sino-implant (II) is one of the most effective contraceptives available today. These available clinical data, combined with independent laboratory testing, and the knowledge that 7 million women have used this method since 1994, support the safety and effectiveness of Sino-implant (II). The lower cost of Sino-implant (II) compared with other subdermal implants could improve access to implants in resource-constrained settings.

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