



A Promising Hope Among Long Acting Reversible Contraceptives for The Indian Population

KEYWORDS

Veena Gupta

Professor, Department of obstetrics and gynaecology, M.L.N. Medical College, Allahabad

Rita Shukla

Assistant Professor, Department of obstetrics and gynaecology, M.L.N. Medical College, Allahabad

*** Shweta Patel**

Senior resident, Department of obstetrics and gynaecology, M.L.N. Medical College, Allahabad
* Corresponding author

ABSTRACT *Background: The study was conducted on 200 women in the Department of Obstetrics and Gynaecology, Moti Lal Nehru Medical College, Allahabad, Uttar Pradesh, India, from August 2004 to January 2011. Method: All women, seeking family planning, after history taking, were subjected to a detailed general, systemic and gynecological examination. Then the women were offered various family planning methods in the cafeteria basket and were allowed to choose one of them as per their need and comfort. Patient opted for implanon were followed up. Results: 3.4% of women accepted implanon as a long term method of contraception. Maximum(52.7%) of users were para 2. Almost 50% users belonging to the age group of 25-29 years. The mean age among implanon users was 26 years. The efficacy of Implanon was 100% even after 36 months of use and continuation rate was 55 % at the end of 3 years duration. The most common cause of discontinuation was menstrual irregularity in the form of prolonged and irregular bleeding. After removal of implanon return of fertility was 100%. Conclusion: Implanon was accepted well by Indian women despite a high incidence of irregular bleeding. Very convenient, long-acting, reversible contraceptive method with minimal adverse effects and is accepted well by nursing mothers.*

INTRODUCTION:

Contraceptive implants were devised to provide an ideal method of contraception, and research on this technique dates back to the 1960s¹. The levonogestrel-releasing six-capsule system, Norplant, and the two-rod system, Norplant-II were the only other widely marketed implants with established efficacy and safety prior to the advent of Implanon². Implanon is a single-rod implant (4 cm long, 2 mm in diameter) containing a core of etonogestrel (3-ke-todesogestrel) 68 mg. The implant inhibits ovulation within one day of insertion and provides effective contraception for up to three years. There is no significant increase in the risk of ectopic pregnancy, fetal malformation, or impaired infant health in pregnancies conceived either during use of the implant or after its removal^{3,4}. Implanon may prove to be easily acceptable because its insertion and removal is much easier and faster than with Norplant. In addition, previous studies have shown that complications associated with its insertion and removal are rare in the hands of medical professionals familiar with the technique.

The primary objective of this study was to evaluate Indian women's perception and acceptance of Implanon as a contraceptive method in Cafeteria approach. Our aim was also to observe any change in their menstrual patterns, any adverse reaction, contraception failure, reasons for discontinuation, and its effect on return of fertility after removal.

We hope that the findings of this study will contribute to future counselling of women who wish to use Implanon. We also anticipate that our findings will help to reduce the discontinuation rate and have a good impact on future national family planning programs in terms of inclusion of Implanon in the cafeteria approach for Indian women.

AIMS AND OBJECTIVES:

The purpose of the study was

1. To observe the acceptance of IMPLANON in our community as a long acting reversible contraceptive.
2. To study the menstrual pattern.
3. To study the reason of discontinuation
4. To study its efficacy in terms of failure.
5. To study return of fertility after its removal.

MATERIAL AND METHODS:

The study was conducted in the Department of Obstetrics and Gynaecology, Moti Lal Nehru Medical College, Allahabad, Uttar Pradesh, India, from August 2004 to January 2011 after obtaining clearance from ethical committee.

All women who came to us for seeking family planning advice during the study period were thoroughly interrogated with proper history regarding their age, parity, education status, habitat, socioeconomic status, past medical and surgical history, menstrual history and obstetrical history and their need and purpose for contraception. All the women were subjected to a detailed general, systemic and gynecological examination. Then the women were offered various family planning methods like Coc, IUCD, condom, DMPA and Implanon etc in the cafeteria basket and were allowed to choose one of them as per their need and comfort and willing to come for follow up.

Out of the total 5777 women counselled for family planning method during that period 200 patients opted for Implanon. Implanon were inserted and follow up was done upto 3 years and then observed for return of fertility after removal of implanon for one year. There was no any loss to follow up.

Inclusion criteria:

- Reproductive age group 18 -35 years
- Willing to participate in the study
- Women who want a long term reversible contraception
- Have at least one living child

- Breast feeding more than 6 month
- Willing to come for regular follow up

Exclusion criteria

- Age more than 35 yrs
- Nullipara
- Irregular menstrual cycle
- Unexplained vaginal bleeding
- Known diabetes or cardiac disease
- Jaundice within 6 month

Method of insertion: An informed consent was taken prior to insertion. With proper aseptic precaution and under local anesthesia, the implant was inserted on the inner aspect of the left (non dominant) arm 5cm above the elbow joint between Day 1 and Day 5 of the menstrual cycle with the help of trocar and canula. The total insertion time was 1 minute. A pressure bandage was applied over the site which was removed after 2 days by the women herself. Women were followed up to the 3 years. Efficacy of implanon was noted after 12 months, 24 months and 36 months of the insertion. In the follow up patients were asked for menstrual irregularity, amenorrhoea, backache, weight gain, headache and other side effects.

After 3 years or earlier when patients wanted other methods of contraception, fertility or discontinuation for side effects, implant was removed under local anesthesia and removal time was 2-3 minutes. A stab incision was given over the lower end of implanon and with the help of artery forceps it was taken out, no stitch was required. A pressure bandage was applied after putting a water proof bandage which was removed after 2 days by the women herself. Return of fertility was noted in the patients who discontinued implanon for the fertility.

RESULTS:

Total of 5777 women were counselled for different methods of family planning. More than half of the women (57%) opted for permanent method that is tubal ligation and rest of the 43% women adopted spacing method of contraception. Condom was the method of choice among 19% of women who wanted spacing method. 3.4% of women accepted implanon as a long term method of contraception. (Graph-1)

Out of 200 subjects 33 (16.5%) women accepted implanon along with MTP and other 167 (83.5%) implanon were interval insertions.

Maximum(52.7%) of users were para 2 who opted implanon as a long term contraceptive and another significant number (28%) women who were primiparas chosen implanon as a spacing method.(Graph-2)

Graph-3 shows the age distribution among the Implanon users with almost 50 % users belonging to the age group of 25-29 years. The mean age among implanon users was 26 years.

It was clearly evident from (Table-1) that the efficacy of Implanon was 100% even after 36 months of use and continuation rate was 55 % at the end of 3 years duration.

Table -2 shows that the most common cause of discontinuation was menstrual irregularity in the form of prolonged and irregular bleeding which was not acceptable by the Indian women. 4 women discontinued as they were transferred. 10 women had amenorrhoea since insertion.

Graph-4 represents the complaints during 3 years duration of Implanon use. Most common complaint was backache which could be due to progesterone. Few women had itching at the insertion site while some had headache and vertigo.

Menstrual pattern was normal only in 6 cases out of 200. Rest of them had irregular menstrual cycle in the form of amenorrhea prolonged bleeding, heavy bleeding and continuous spotting. (Table-3)

After removal of implanon 13 women were enrolled for return of fertility because rest 183 women accepted other family planning method. Out of 13 all women conceived within in one year of removal, suggesting 100 % return of fertility.

Time taken for insertion was 1 min and for removal 1-2 min. There was no migration of rod from its original site. None of the women had infection at the site after insertion or removal.

- Average time taken for implanon insertion (mins): 1 min
- Average time taken for implanon removal (mins): 1min

-staus of implanon at removal:

Number of women with horizontal migration: none

Number of women with deep migration: none

Number of women in whom implant was not palpable: none

Number of women where in implant couldn't be removed: none

-Site of implanon insertion after one month of removal:

Site normal: 200

Infection at site: 0

Scarring at site: 0

DISCUSSION:-

The mean age of women using Implanon in our study was 28.6±5.3 years, with 40% of them being older than 25 years and mean parity was 3.2 years. Half of this group of women had already completed their family This study demonstrates that Implanon was the choice made by women who have completed their family but still want effective temporary long term reversible method of contraception They did not want a permanent method. The minimum duration of assessment in this study was three months from the time Implanon was inserted. This was because we required at least one evaluable reference period of 90 days to assess bleeding patterns, whereby users would be able to describe their experience and give their overall view of Implanon after at least three months using it.

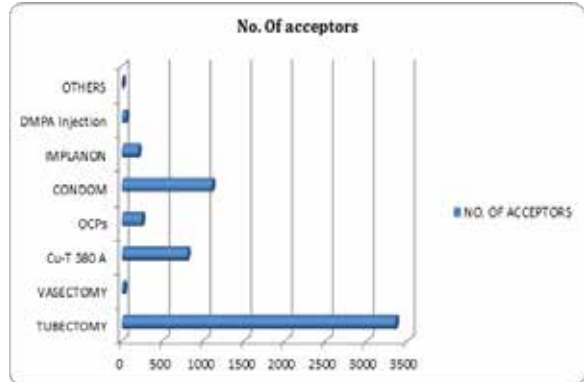
Contrary to the findings of a study from Thailand⁵, the most common bleeding change experienced by our users was prolonged bleeding but scanty. Implanon is probably a good contraceptive choice in Indian women of this age group because it is associated with an overall reduction in menstrual blood loss and may be potentially beneficial for women with heavy bleeding who wish to practice contraception. Prolonged but scanty bleeding was reported to be the most common

bleeding change in women, followed by infrequent bleeding/spotting⁶. Systemic analyses of randomized trials report that the bleeding pattern changes vary in different geographic regions^{6,7}. On the other hand, prolonged bleeding/spotting affected more than one-third of our study population and was found to be a major concern among discontinuers. They felt that their sex life was affected by this undesirable event. Menstrual changes would be expected with any form of progestin-only contraception, including Implanon. This led to discontinuation in 18% of Implanon users and was the main reason given by the discontinuers, which is consistent with previous findings^{3,8}. Overall, the majority of the users in our center experienced no serious adverse events while on Implanon. This favorable finding may be useful in future contraception counseling. The most commonly reported non menstrual adverse events observed in users were backache, followed by itching at insertion site. The less common adverse events were nausea, mood swings, breast tenderness, and loss of libido, which affected 4.3% to 5% of the users. Many of these symptoms are known side effects of hormonal contraception and of progestin contraceptive methods^{9,10}. An integrated analysis of non menstrual adverse events with Implanon reported that there were no consistent differences between countries, except that far fewer adverse events were reported in Indonesia and many more in Chile than in other regions⁷. The countries involved in that study were Europe, Chile, Thailand, Singapore, and Indonesia.

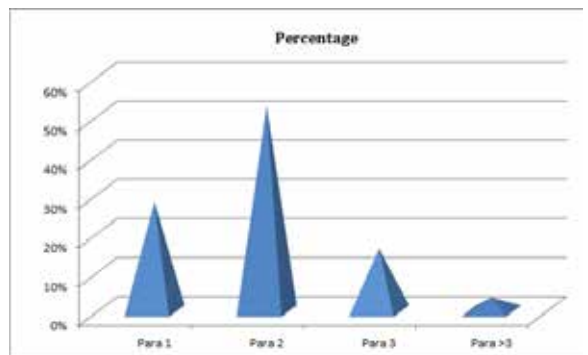
No insertion- and removal related side effects including infection, scarring were reported by our users, as in previous Implanon studies^{3,5}. Although insertion and removal of Implanon only involves a minor surgical procedure, medical professionals are strongly advised to familiarize themselves with the technique before undertaking these procedures on patients. The women should be adequately counselled, including the usual information on general advantages and disadvantages of implants, as well as knowledge of the insertion and removal procedures. The counseling should include the right to discontinue Implanon at any time, informing patients that implant site-related adverse events could occur, as well as clarification of the rapid return to fertility once the implant is removed. Implanon can be considered as one of the best contraceptive methods in the modern world, because insertion is simple and rapid, with immediate contraception when inserted on days 1–5 of the menstrual period, with contraceptive efficacy of 100% for a period of three years¹¹⁻¹³. Not a single failure was observed during the study period.

CONCLUSION:

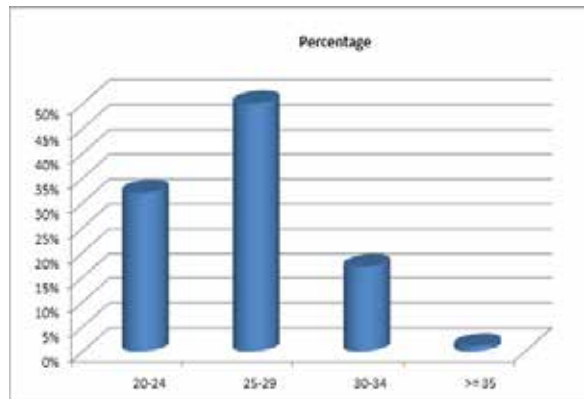
We found that Implanon was accepted well by Indian women despite a high incidence of irregular bleeding, which was found to be a major concern among discontinuers. Nevertheless, it is a very convenient, long-acting, reversible contraceptive method with minimal adverse effects and is accepted well by nursing mothers. In order to improve Implanon acceptance and to reduce its discontinuation rate, we suggest that counseling prior to insertion should include its advantages, disadvantages, management of adverse effects and return of fertility with strong emphasis on the expected changes in bleeding pattern.



Graph-1: distribution of women according to acceptance of method of contraception



Graph-2: Distribution of implanon users according to their parity



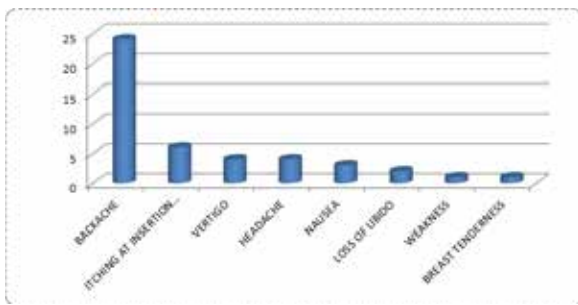
Graph-3: age distribution among the Implanon users

Table- 1: Efficacy and continuation rate among implanon users

Months of use	12months	24months	36months
Efficacy	100%	100%	100%
Continuation rate	74%	61%	55%
Number of women continued	148	122	109
Number of lost to follow up	0	0	0

Table-2: causes of discontinuation of implanon

Discontinuation causes	number	percentage
Prolonged bleeding	37	40.65%
Heavy bleeding	10	10.98%
Irregular bleeding	15	16.48%
Scanty bleeding	7	7.7%
Amenorrhoea	10	10.98%
Headache	1	1.09%
Breast tenderness	1	1.09%
Tubercular lymph node	1	1.09%
Weight gain	3	3.29%
Transfer	4	4.39%
Desire for child	2	2.19%
Total	91	100%



Graph-4 : complains among implanon users during 3 years

Table-3: menstrual pattern among implanon user women

MENSTRUAL PATTERN	200 Cases	Percentage
REGULAR	6	3%
IRREGULAR	94	47%
PROLONG BLEEDING DURING PERIODS	35	17.5%
HEAVY BLEEDING	8	4%
SCANTY BLEEDING	24	12%
AMMENORHOEA	33	16.5%

Table-4: return of fertility after removal of implanon

No. of women accepted other contraceptive method	183
No. of women transferred	4
No. of women enrolled for fertility	13
No. of women conceived within 12 months	13

REFERENCES:-

- Affandi B, Korver T, Geurts TB, Coelingh Bennink HJ. A pilot efficacy study with a single-rod contraceptive implant (Implanon) in 200 Indonesian women treated for 4 years. *Contraception*. 1999;59:167-74. Retraction in: Rekers H, Affandi B. *Contraception*. 2004;70:433.
- Biswas A, Biswas S, Viegas OA. Effect of etonogestrel subdermal contraceptive implant (Implanon) on liver function tests – a randomized comparative study with Norplant implants. *Contraception*. 2004;70(5):379-382.
- Funk S, Miller MM, Mishell DR Jr, Archer DF, Poindexter A, et al. Safety and efficacy of Implanon, a single-rod implantable contraceptive containing etonogestrel. *Contraception*. 2005;71:319-326.
- Glasier A. Implantable contraceptives for women: Effectiveness, discontin-

- uation rates, return of fertility, and outcome of pregnancies. *Contraception*. 2002;65:29-37.
- Booranabunyat S, Taneepanichkul S. Implanon use in Thai women above the age of 35 years. *Contraception*. 2004;69:489-491.
- Affandi B. An integrated analysis of vaginal bleeding patterns in clinical trials of Implanon. *Contraception*. 1998;58:99S-107S.
- Zheng SR, Zheng HM, Qian SZ, Sang GW, Kaper RF. A randomized multicenter study comparing the efficacy and bleeding pattern of a single-rod (Implanon) and a six-capsule (Norplant) hormonal contraceptive implant. *Contraception*. 1999;60:1-8.
- Harvey C, Seib C, Lucke J. Continuation rates and reasons for removal among Implanon® users accessing two family planning clinics in Queensland, Australia. *Contraception*. 2009;80:527-532. Available from: [http://www.contraceptionjournal.org/article/S0010-7824\(09\)00300-X/abstract](http://www.contraceptionjournal.org/article/S0010-7824(09)00300-X/abstract). Accessed March 26, 2010.
- Urbancsek J. An integrated analysis of nonmenstrual adverse events with Implanon. *Contraception*. 1998;58:109S-115S.
- Brachea V, Faundes A, Alvarez F, Cochona L. Nonmenstrual adverse events during use of implantable contraceptives for women: Data from clinical trials. *Contraception*. 2002;65:63-74.
- Herjan JT, Coelingh Bennink HJ. Presentation of clinical data on Implanon. *Contraception*. 1998;58:75S-77S.
- Affandi B. Long-acting progestogens. Best practice and research. *Clin Obstet Gynaecol*. 2002;16:169-179.
- Croxatto HB. Progestin implants. *Steroids*. 2000;65:681-685.