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SAFETY AND EFFICACY OF THE ETONOGESTREL SUBDERMAL IMPLANT (IMPLANON-NXT): A PROSPECTIVE STUDY IN A TERTIARY CARE CENTER IN GUJARAT, INDIA

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ABSTRACT

Background: Implanon-NXT is a long-acting reversible contraceptive (LARC) introduced into India's national program in 2023. This study evaluated its safety and efficacy in women attending a tertiary care center in Gujarat. **Methods:** A prospective observational study was conducted with 100 women. Follow-up data were available for 88 participants. Outcomes included pregnancy rate, side effects, continuation, and removal rates over a one-year period. **Results:** No pregnancies occurred (Pearl Index = 0). Side effects were reported by 65.9% of participants, with menstrual disturbances being most common (55.5%). Non-menstrual side effects occurred in 18.2%. The 12-month continuation rate was 88.6%. The main reason for removal was side effects (77.8%), primarily menstrual bleeding irregularities. **Conclusion:** Implanon-NXT is a highly effective and well-tolerated contraceptive. Its safety profile and high continuation rates support broader implementation in India's family planning services.

KEYWORDS

Implanon-NXT, LARC, etonogestrel, contraceptive implant, safety, efficacy, India

INTRODUCTION

Implanon-NXT, a single-rod subdermal contraceptive implant, delivers etonogestrel and provides contraception for up to three years. Its introduction into the Indian public sector represents a milestone in expanding access to LARCs. This study aimed to evaluate the safety and efficacy of Implanon-NXT in a real-world clinical setting.

MATERIALS AND METHODS

Study Design: Prospective and Retrospective observational study

Sample Size: 100

Sampling Technique And Site: All consecutive consenting postnatal patients admitted in postnatal ward after c- section (G1) and postnatal ward after normal vaginal delivery (J1), all reproductive age women who has Implanon as a choice of contraceptive and all women who has been inserted with Implanon and come for follow up at tertiary health care center of South Gujarat.

Total Study Period: 12 months for data collection + 2 months for analysis + 2months of writing.

Participant Recruitment Site: Medical case records review in postnatal ward and all women of reproductive age as well as women coming to PPOPD of NCHS for follow-up postnatally and after Implanon insertion at Tertiary health care center of South Gujarat.

Inclusion Criteria: All consenting uncomplicated postnatal women and reproductive age women wanting effective contraception and all women who has been inserted with Implanon.

Exclusion criteria: (MAC- 4 criteria of exclusion)

1. Unusual vaginal bleeding
2. Liver disease or liver cancer
3. breast or uterine cancer
4. heart attack
5. Stroke
6. Bleeding disorders
7. Pregnancy
8. Non consenting women

Outcome Parameter:

1. Failure rate
2. Common side effects

RESULTS

The Implanon-NXT implant demonstrated perfect efficacy with no pregnancies during the follow-up period. Menstrual side effects were common but manageable. The low rate of non-menstrual complaints further affirms the implant's favorable safety profile.

The continuation rate of 88.6% compares favorably with international benchmarks. These findings support continued integration of Implanon-NXT into India's contraceptive services, especially with appropriate user counseling.

Table-1: Age Wise Distribution Of The Study Participants. (n=100):

Age (In years)	Frequency	Percentage	Mean ± SD
18 – 20	16	16.0	25.66 ± 4.835
21 – 25	42	42.0	
26 – 30	29	29.0	
31 – 35	9	9.0	
>35	4	4.0	
Total	100	100	

Range	26
Minimum	18
Maximum	44

The Age of participants ranged from 18 years to 44 years of age, with a mean of 25.66 ± 4.835. The majority of women (42%) were aged between 21-25 years, followed by 29% in 26-30 years group, indicating a preference for Implanon use in early reproductive years.

Table-2: Education Wise Distribution Of The Study Participants. (n=100):

Education	Frequency	Percentage
ILLITERATE	2	2.0
PRIMARY EDUCATION	61	61.0
SECONDARY EDUCATION	25	25.0

This distribution of data according to educational level suggests that 61% had only primary education and just 12% were graduates.

This reflects a reasonable level of understanding and acceptance of Implanon even among women with low literacy levels.

Table-3: Residence Wise Distribution Of The Study Participants. (n=100)

Residence	Frequency	Percentage
SURAT RURAL	22	22.0
SURAT URBAN	78	78.0
Total	100	100.0

In this distribution it is seen that most women (78%) are from Surat urban residence, however this is because majority of family planning clients of our hospital are from Surat urban area.

Table-4: Occupation Wise Distribution Of The Study Participants. (n=100):

Occupation	Frequency	Percentage
HOUSEWIFE	92	92.0
JOB	8	8.0
Total	100	100.0

Majority (92%) in this data were housewives, indicating that non-working women are more likely to opt for Implanon (LARC), possibly due to easier access through public healthcare programs.

Table-5: Parity Wise Distribution Of Study Participants (n=100):

Obstetric history	Frequency	Percentage
Multipara	66	66.0
Primipara	33	33.0
Nullipara	1	1.0
Total	100	100.0

Regarding obstetric history of the participants 66% were multiparous, 33 % were primiparous which explained the more use of Implanon as LARC method by women who have already borne children. 1 woman who got Implanon inserted was unmarried and nulliparous as she was mentally challenged, it was her family who chose Implanon to be inserted to prevent unintended pregnancy.

Table-6: Distribution According To Medical History Of Participants (n=100):

Comorbidity	Frequency	Percentage
NONE	81	81.0
NUTRITIONAL DEFICIENCY	11	11.0
NCD (NON-COMMUNICABLE DISEASES)	8	8.0
Total	100	100.0

This distribution suggests Implanon is accepted by all type of women despite of medical illness. However, in this distribution it is seen that most women (81%) are healthy ,11 % had nutritional deficiency,8% have non communicable disease which shows that Implanon is widely acceptable.

Table -7: Following Table Shows Data Of Subjects Having Side Effects On Follow Up (n=88).

Presence of Side Effects	Frequency	Percentage
NO	30	34.1
YES	58	65.9
Total	88	100

Table -7(a): Following Table Shows Data Of Subjects Having Menstrual Side Effects On Follow Up (n=88)

Side effects related to Menstruation	Frequency	Percentage
NO	40	44.5
YES	48	55.5
Total	88	100

Table -7(b): Following Table Shows Data Of Subjects Having Side Effects Which Are Not Related With Menstruation On Follow Up (n=88)

Side effects other than related to Menstruation	Frequency	Percentage
NO	72	81.8
YES	16	18.2
Total	88	100

Table – 8: Distribution According To Reason Of Removal Of Implanon (n=100):

Reason for removal	Frequency	Percentage
PATIENT WANTED SECOND CHILD	1	11.1
SIDE EFFECTS	7	77.8
PATIENT WANTED TUBAL LIGATION	1	11.1
Total	9	100.0

This shows most common reason (77.8%) of removal of Implanon is side effects.

Efficacy

Pregnancy Rate: 0 pregnancies; Pearl Index = 0.0

Safety

- **Overall Side Effects:** 58/88 (65.9%)
- **Menstrual Side Effects:** 48/88 (55.5%)
- **Heavy bleeding:** 22 (25%)
- **Continuous spotting:** 13 (14.78%)
- **Amenorrhea:** 11 (12.5%)
- **Irregular menses:** 1 (1.1%)
- **Non-Menstrual Side Effects:** 16/88 (18.2%)
- **Abdominal pain:** 6 (6.82%)
- **Elbow pain:** 6 (6.81%)
- **Insertion site pain:** 2 (2.27%)
- **Skin induration:** 1 (1.1%)

Continuation And Removal

- **Continuation Rate at 12 months:** 88.6% (78/88)
- **Discontinuation:** 11.4% (10/88)

Reasons For Removal:

- **Side Effects:** 77.8%
- **Desire For Pregnancy:** 11.1%
- **Desire For Sterilization:** 11.1%

DISCUSSION

Here Are Some Comparative Studies On Implanon:

Comparative Analysis Of Contraceptive Implant Studies:

This section presents a comparative assessment between the current prospective study conducted at a tertiary care centre in Gujarat and two widely cited international studies: Affandi et al. (1998) and Mansour et al. (2008). The comparative evaluation focuses on efficacy, continuation rates, side effects, and demographic variables, offering both short-term and long-term insights into the acceptability and performance of contraceptive implants.

Sample Size And Follow-up Duration:

- The **current study** enrolled 100 women with a **12-month follow-up**, allowing for a focused short-term evaluation.
- **Affandi et al.** followed **390 participants over 3 years**, while **Mansour et al.** tracked **923 women over a 2-year period**, enabling long-term observations and detection of delayed side effects or discontinuation patterns.

Demographics:

- Participants in the current study had a mean age of **25.66 ± 4.835 years**, ranging from 18 to 44 years. This reflects a young reproductive age group likely to benefit from long-acting reversible contraception (LARC).
- Affandi's study included women aged 18–40 years but did not report mean or standard deviation, while **Mansour's study did not report age data**, limiting the scope for direct demographic comparisons.
- Importantly, the **current study is the only one reporting BMI** data (Mean BMI: **24.26 ± 2.27**), emphasizing a more comprehensive baseline assessment including metabolic profiling.

Efficacy:

- All three studies consistently reported a **Pearl Index of 0.0**, indicating **no pregnancies occurred** during the respective follow-up periods. This reaffirms the **high contraceptive efficacy** of subdermal implants across varied populations and timeframes.

Continuation And Satisfaction Rates:

- The **continuation rate in the current study** was **88.6%** at 12 months, and an equal percentage of those followed expressed a **desire to continue** using the implant, suggesting **high acceptability and satisfaction** within the cohort.
- In contrast, **Affandi et al.** reported a lower continuation rate of **74%** at 3 years, and **Mansour et al.** reported **84%** continuation at 2 years. These comparatively lower figures may reflect

cumulative side effects, **extended duration of use**, and **differences in cultural or counselling practices**.

Menstrual Side Effects:

- Across all studies, **menstrual disturbances** emerged as the most common adverse effect.
- In the current study, **heavy bleeding (21%)**, **spotting (13%)**, and **amenorrhea (11%)** were reported.
- **Affandi et al.** noted **irregular bleeding in 30%** and **amenorrhea in 20%** of users.
- **Mansour et al.** also documented irregular bleeding and amenorrhea, though without quantitative detail.
- These findings underscore the need for **proactive counselling about bleeding patterns**, which significantly influence user satisfaction and continuation.

Non-Menstrual Side Effects:

- The **current study reported minimal systemic side effects**, such as **weight gain (2%)**, **elbow pain**, and **insertion site discomfort**.
- **Affandi's study** observed **insertion site reactions in 5%**, with no significant systemic symptoms reported.
- **Mansour et al.** documented **higher incidence of systemic effects**, including **weight gain (14.7%)**, **acne (13.5%)**, and **headache (16.7%)**. These differences could be attributed to **longer follow-up**, **larger sample size**, and **variability in population characteristics**.

Reasons For Discontinuation:

- The primary reason for discontinuation in all three studies was **side effects**, predominantly **menstrual irregularities**.
- The current study also identified a **desire for planned conception (11.1%)** as a cause for discontinuation, suggesting a shift from contraception to fertility planning among a subset of users.

The comparative findings reaffirm the **high contraceptive efficacy (Pearl Index: 0.0)** of implants across diverse study settings. However, **continuation and satisfaction rates are influenced by duration of use, side effect profile, and user counselling**. The **current study showed a relatively higher continuation rate and fewer systemic side effects**, possibly due to **shorter follow-up** and **targeted counselling efforts**. This emphasizes the importance of **individualized user support, side effect management**, and **comprehensive counselling** to enhance long-term adherence and user satisfaction with contraceptive implants.

CONCLUSION

Implanon-NXT is a safe, effective, and highly acceptable contraceptive. Its zero-pregnancy rate and high continuation validate its role as a reliable LARC option. Enhanced counseling can help mitigate discontinuation due to menstrual side effects.

Conflicts Of Interest
None declared.

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None.

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