



EVALUATION OF SAFETY, EFFICACY, AND USER PROFILE OF SINGLE ROD ETONOGESTREL IMPLANT AS A LONG-ACTING REVERSIBLE CONTRACEPTIVE: A RETROSPECTIVE STUDY

Obstetrics & Gynaecology

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ABSTRACT

Background: The investigation of unintended pregnancies is of significant public health importance, since such pregnancies are adversely linked with multiple demographic indicators and contribute substantially to hindering a country's economic development. **Aim:** To assess Single rod etonogestrel implant user profile, and its safety and efficacy, and to evaluate the association between user profile and adverse effects or discontinuation. **Method:** This is a retrospective study evaluated medical records of 50 Single rod etonogestrel implant contraceptive users. The demographic variables, reproductive profile were recorded. The single rod etonogestrel implant-related details such as timing of insertion, and duration of use were recorded. The safety outcomes like menstrual disturbances, weight changes, local complications, and systemic side effects were recorded and assessed. The efficacy outcome in terms of occurrence of pregnancy during use of Single rod etonogestrel implant was evaluated. **Results:** The mean (\pm SD) age of participants was 27.5 (\pm 4.4) years with majority of the subjects i.e., 52% were primiparous. 50% of the participants having history of previous contraceptive use. Single rod etonogestrel implant was inserted in major proportion of subjects during postpartum period (54%). Following insertion of Single rod etonogestrel implant pregnancy was not achieved in all the 50 cases (100%) showing excellent efficacy. Menstrual disturbances were observed in only in 5 cases (10%). 3 Single rod etonogestrel implant users out of 50 discontinued due to amenorrhea (two cases) and heavy bleeding (one case). Chi-square analysis showed non-significant association between single rod etonogestrel implant removal and parity ($X^2 = 0.275$; $p = 0.600$) and timing of Single rod etonogestrel implant insertion ($X^2 = 0.368$; $p = 0.832$). **Conclusion:** this study clearly establishes the safety and effectiveness of the single-rod, subdermal, progestin-only, non-biodegradable, long-acting, and reversible contraceptive implant, "Single rod etonogestrel implant". The findings may aid clinicians in counselling women regarding potential bleeding irregularities and other side effects associated with Single rod etonogestrel implant, thereby supporting informed decision-making about the use of this highly effective contraceptive method.

KEYWORDS

Single rod etonogestrel implant, Contraceptive, Pregnancy, Bleeding, Amenorrhea, Menstrual disturbances

INTRODUCTION

Unintended pregnancies place a substantial burden on healthcare systems, as they are associated not only with increased social costs arising from maternal and/or fetal morbidity, but also with expenditures related to legal abortion services. Contraceptive methods serve as safe and effective tools that enable women of reproductive age who wish to avoid pregnancy to do so. Accordingly, all women seeking contraception should be provided with comprehensive counselling regarding available contraceptive options.¹

Short-acting contraceptive methods, including oral contraceptives, transdermal patches, and vaginal rings, are often associated with suboptimal adherence due to poor compliance and/or incorrect use.² This limitation contributes to a comparatively higher risk of unintended pregnancy. In contrast, long-acting reversible contraceptives (LARCs), such as intrauterine devices (IUDs), copper (Cu)-IUDs, and subdermal contraceptive implants, offer continuous protection against pregnancy for at least three years and require minimal user involvement.^{1,2} LARCs provide long-term yet reversible contraception and are associated with high continuation rates.³ Consequently, they represent an effective strategy for preventing unintended pregnancies among women who do not desire future conception and prefer to avoid permanent contraceptive methods.⁴

Since their introduction in the United States in 1991, progestin-only subdermal implants have emerged as a safe and widely accepted contraceptive option,⁵ offering long-acting and highly effective reversible contraception.⁶ These implants are particularly favored because they eliminate the need for user action at the time of sexual intercourse. Subdermal contraceptive implants are approximately the size of a matchstick and function by releasing hormones that inhibit pregnancy.⁷

Single rod etonogestrel implant (etonogestrel [ENG] implant) is a single-rod, subdermal, progestin-only, non-biodegradable, long-acting, and reversible contraceptive device containing etonogestrel, the biologically active metabolite of desogestrel. Following subdermal

insertion of Single rod etonogestrel implant, it provides effective contraceptive protection for up to three years.^{8,9}

Literature reports delineated that the ENG implant is easy to insert and remove,^{10,11} and is highly effective in preventing pregnancy.⁹ Alterations in bleeding patterns, most commonly amenorrhea or infrequent bleeding, have been reported in a substantial proportion of users across clinical studies.¹² Reported adverse effects, such as weight gain, mood changes or depression, headache, acne, and reduced libido, are known to be associated with progestin-only contraceptives.¹³⁻¹⁵ With these viewpoints, the present study was conducted to assess Single rod etonogestrel implant user profile, and its safety and efficacy, and to evaluate the association between user profile and adverse effects or discontinuation.

METHODOLOGY

Study Design And Patients

This is a retrospective study evaluated medical records of 50 Single rod etonogestrel implant contraceptive user women in Department of Obstetrics and Gynecology, Sri Chamarajendra Hospital, Hassan Institute of Medical Sciences (HIMS), Hassan, Karnataka.

Inclusion Criteria

1. Reproductive age group
2. Single rod etonogestrel implant insertion
3. Availability of complete medical records including follow-up data

Exclusion Criteria

1. Single rod etonogestrel implant inserted outside the study center
2. Implant removal done elsewhere without documented follow-up
3. Incomplete or missing medical records

Data Collection

Data were collected retrospectively from family planning registers, outpatient and inpatient case records, and follow-up and implant removal records. A structured data collection proforma was used to record demographic variables, reproductive profile. The single rod

etonogestrel implant-related details such as timing of insertion (interval/postpartum/post-abortal), and duration of use were recorded. The safety outcomes like menstrual disturbances, weight changes, local complications, and systemic side effects were recorded and assessed. The efficacy outcome in terms of occurrence of pregnancy during use of Single rod etonogestrel implant was evaluated.

Study Outcomes

The primary outcomes include, the efficacy of Single rod etonogestrel implant in preventing pregnancy during the study period and safety profile of Single rod etonogestrel implant which was evaluated by reported adverse effects and complications in Single rod etonogestrel implant user women. The demographic and reproductive characteristics of Single rod etonogestrel implant users, continuation and removal rates and reasons for removal, and the association between user profile and adverse effects or discontinuation were evaluated as secondary outcomes.

Statistical Analysis

Data were entered in Microsoft Excel 2021 and statistical analysis was done using IBM Statistical Software for Social Sciences (SPSS) version 20. Categorical variables were represented in the form of percentages, and frequencies. Continuous variables were presented as descriptive statistics (Mean and Standard deviation). Categorical variables were analysed using the Chi-square test. $p \leq 0.05$ was considered statistically significant.

RESULTS

The mean (\pm SD) age of subjects was 27.5 (\pm 4.4) years with primary & high school education (26% each) and pre-university (PUC) and Bachelor degree (24% each). Majority of the subjects i.e., 52% were primiparous followed by multiparous (48%). 50% of the subjects having history of previous contraceptive use for the duration of 8.8 months (Table 1).

Table 1. Demographic And Patient Characteristics

Variables	n (%)
Age	
20 - 30 years	35 (70.0)
31 - 40 years	15 (30.0)
Mean \pm SD	27.5 \pm 4.4
Education	
Primary	13 (26.0)
High school	13 (26.0)
PUC	12 (24.0)
Bachelor degree	12 (24.0)
Parity	
Primipara	26 (52.0)
Multipara	24 (48.0)
Previous contraception use	
Yes	25 (50.0)
No	25 (50.0)
Duration of use (months), Mean \pm SD	8.8 \pm 2.5

Values were n (%) unless otherwise stated

Major proportion of subjects inserted Single rod etonogestrel implant during postpartum period (54%) followed by interval period (38%), and 8% of participants inserted Single rod etonogestrel implant during post-abortal period (Figure 1).

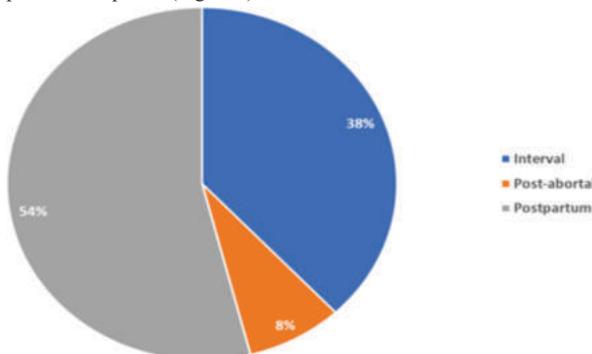


Figure 1. Distribution Of Subjects Based On Timing Of Single Rod Etonogestrel Implant Insertion

Following insertion of Single rod etonogestrel implant pregnancy was not achieved in all the 50 cases (100%) showing excellent efficacy. Menstrual disturbances were observed in only 5 cases out of 50 (10%). However, there were no other adverse effects such as weight changes, local complications or systemic side effects. In 3 cases out of 50 Single rod etonogestrel implant was removed due to amenorrhoea in two cases and heavy bleeding in only one case (Table 2).

Table 2. Primary And Secondary Outcomes

Outcomes	Yes	No
Pregnancy rate	0 (0.0)	50 (100.0)
Menstrual disturbances	5 (10.0)	45 (90.0)
Weight changes	0 (0.0)	50 (100.0)
Local complications	0 (0.0)	50 (100.0)
Systemic side effects	0 (0.0)	50 (100.0)
Removal	3 (6.0)	47 (94.0)
Reason for Single rod etonogestrel implant removal		
Amenorrhoea	2 (4.0)	1 (2.0)
Heavy bleeding	1 (2.0)	2 (4.0)

Values were n (%)

The results on association between Single rod etonogestrel implant removal and parity were represented in Table 3. Results showed non-significant association between parity and single rod etonogestrel implant removal ($X^2 = 0.275$; $p = 0.600$), and reason for removal ($X^2 = 2.946$; $p = 0.229$).

Table 3. Association Between Single Rod Etonogestrel Implant Removal And Parity

Single rod etonogestrel implant Removal		Parity		X^2 -value	p-value
		Multi para	Primi para		
Single rod etonogestrel implant removal	No	Count 23	24	0.275	0.600
		% 95.8%	92.3%		
Yes	Count 1	2			
	% 4.2%	7.7%			
Reason for Single rod etonogestrel implant removal	Amenorrhoea	Count 0	2	2.946	0.229
		% 0.0%	7.7%		
	Heavy bleeding	Count 1	0		
		% 4.2%	0.0%		

The results on association between Single rod etonogestrel implant removal and timing of Single rod etonogestrel implant insertion were represented in Table 4. Results showed non-significant association between timing of single rod etonogestrel implant insertion and single rod etonogestrel implant removal ($X^2 = 0.368$; $p = 0.832$) and reason for removal ($X^2 = 1.116$; $p = 0.892$).

Table 4. Association Between Single Rod Etonogestrel Implant Removal And Timing Of Insertion

Single Rod Etonogestrel Implant Removal		Timing of insertion			X^2 -value	p-value
		Interval	Post-abortal	Postpartum		
Single rod etonogestrel implant removal	No	Count 18	4	25	0.368	0.832
		% 94.7%	100.0%	92.6%		
Yes	Count 1	0	2			
	% 5.3%	0.0%	7.4%			
Reason for Single rod etonogestrel implant removal	Amenorrhoea	Count 1	0	1	1.116	0.892
		% 5.3%	0.0%	3.7%		
	Heavy bleeding	Count 0	0	1		
		% 0.0%	0.0%	3.7%		

DISCUSSION

Globally, unintended pregnancies occur at a rate of approximately 64 per 1,000 women, indicating that nearly 6% of women experience an unplanned pregnancy each year.¹⁶ From a public health perspective, research on unintended pregnancies is particularly important, as such pregnancies are adversely associated with several demographic indicators and play a significant role in slowing a country's economic development.¹⁷ In view of this, the present retrospective study was undertaken to evaluate the user profile of Single rod etonogestrel

implant, assess its safety and effectiveness, and analyze the association between user characteristics and adverse effects or discontinuation.

In the present study, the mean age of subjects was 27.5 years, with the majority belonging to the 21–30-year age group (70%). More than half of the women were primiparous (52%), while the remaining were multiparous (48%). These observations are comparable with those reported in earlier studies, both in terms of mean age and parity distribution.¹⁸⁻²¹ Aisien and Enoslease documented that 46.9% of participants each had tertiary and secondary education, while 6.2% had primary education.²² Similar patterns were observed in our study, where 26% of participants each had primary and high school education, and 24% each had completed PUC and bachelor's degree education.

Literature reports evidenced that the most commonly used contraceptive methods prior to implant use included foam, condoms, diaphragms, or spermicides (39.1%), followed by oral contraceptive pills (24.3%).²³ Consistent with these reports, half of the women in the current study had a history of prior contraceptive use.

In this study, Single rod etonogestrel implant insertion was most frequently performed during the postpartum period, accounting for 54% of cases. No pregnancies were recorded among the 50 users following Single rod etonogestrel implant insertion, demonstrating a contraceptive efficacy of 100%. In contrast, Harrison-Woolrych and Hill reported a failure rate of approximately 1 per 1,000 insertions (218 failures among 204,486 insertions).²⁴ Implant failure-related pregnancies have also been described by Hamontri and Weerkul,²⁵ and Mansour et al. reported a case of ectopic pregnancy following implant failure.²⁶ Unlike these reports, no contraceptive failures were observed in the present study.

It was understood from the literature that the etonogestrel-releasing implant contains 68 mg of etonogestrel enclosed within an ethylene vinyl acetate rod. Etonogestrel is the biologically active metabolite of desogestrel, which is utilized in certain progestogen-only and combined oral contraceptives. The implant is designed for a duration of use of up to three years. Its contraceptive effect is mediated through interaction with specific receptors located along the hypothalamic-pituitary-gonadal axis. The implant disrupts key physiological processes required for fertilization by inhibiting ovulation and inducing thickening of cervical mucus.²⁷

Furthermore, dose-finding studies have demonstrated that suppression of ovulation requires a daily release of approximately 25–30 µg of etonogestrel.^{28,29} Single rod etonogestrel implant initially releases etonogestrel at a rate of about 60–70 µg/day, which gradually declines to approximately 30 µg/day over time.³⁰ This sustained release maintains adequate plasma concentrations to inhibit ovulation and ensure effective contraception for up to three years.³¹

In the present study, menstrual disturbances were reported in only five participants (10%). No additional adverse effects, such as weight changes, local complications, or systemic side effects, were observed. Three out of 50 women discontinued Single rod etonogestrel implant use due to amenorrhea (two cases) and heavy menstrual bleeding (one case). Chi-square analysis showed non-significant association between Single rod etonogestrel implant removal and either parity or timing of insertion. Similar to our findings, Brache et al. reported that changes in uterine bleeding patterns are common with progestin-only contraceptives.⁸ Smith and Reuter observed that clinically significant bleeding patterns, including prolonged and frequent bleeding, were most common during the initial three months of use. Infrequent bleeding was the predominant pattern throughout the study period, while frequent bleeding was least common. The incidence of amenorrhea ranged from 14% to 20% during months 4–24, and bleeding disturbances led to premature discontinuation in 13% of users, with the highest withdrawal rates occurring within the first eight months.³² To enhance acceptance and continuation rates, comprehensive pre-insertion counselling should emphasize both the benefits and potential side effects of the implant, particularly expected changes in menstrual bleeding patterns.

Certain limitations of this study should be considered. The sample size was relatively small and restricted to a single tertiary care centre, which limits the generalizability of the findings to broader populations or other healthcare settings. Consequently, larger multicentric studies

are recommended for more robust conclusions. Additionally, heterogeneity among available studies limited the ability to combine all continuation outcomes.

CONCLUSION

In conclusion, our study findings clearly confirm the safety and effectiveness of the single-rod, subdermal, progestin-only, non-biodegradable, long-acting, and reversible contraceptive implant, “Single rod etonogestrel implant”. Furthermore, the findings of this retrospective analysis may assist clinicians in providing appropriate counselling regarding possible bleeding irregularities and other associated side effects, thereby enabling women to make informed decisions about adopting this highly effective contraceptive method.

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