Safety, effectiveness and acceptability of the single-rod subdermal contraceptive implant in a public health setting in Argentina: observational cohort study

Maria Daniela Faranna, Maria Guillermina Amestica, Jose Retamozo Caceres, Miguel Angel Huespe

D. F. Santojanni Public Hospital, Buenos Aires, Argentina

ABSTRACT

Background and purpose: Teenage pregnancies account for 15% of newborns delivered each year within the public health system in Argentina; 67% of these pregnancies are unintended. The consequences of unplanned pregnancies include social exclusion and an increase in the school drop-out rate. This study presents experience with the use of the single-rod implant in a public health setting in Argentina.

Methods: This prospective observational single-centre cohort study was performed using medical record data on low-income women in whom the Implanon® was placed between February 2015 and September 2019. Follow-up information on side effects, effectiveness, reasons for discontinuation, and patient satisfaction with the method was collected 12 months and 3 years after implant placement.

Results: Within the study period, 995 implants were placed. The median follow-up duration was 998 days (IQR 359–1098 days). The single-rod implant was 100% effective in preventing pregnancy. 75.8% of the women were very satisfied with this contraceptive method.

Amenorrhoea was the most commonly reported bleeding pattern (47%). Side effects were documented in 121 women (12%); of which 4.1% (n= 5) corresponded to arm insertion-site infection, which necessitated implant extraction. Weight gain was present in 27.7%, headache was reported in 14.1%, acne worsened in 20.4%, decreased libido was reported by 31.7% of women, and 42.1% presented mood changes.

Thirty-seven implants were removed before completing the three years from placement. In 84.2%, this was due to implant-related side effects. The median time to implant removal was 210 days (IQR 136–585 days). The main reason for discontinuation was prolonged bleeding (27%, n=10).

Conclusions: The single-rod subdermal implant is an effective long-term method for reducing unplanned pregnancies. Its side effects are rare and usually mild and it has a high satisfaction rate. The main reason for discontinuation is bleeding-pattern change.

KEYWORDS

Single-rod implant, contraceptives, effectiveness, side effects.

Introduction

Teenage pregnancies account for 15% of newborns delivered each year within the public health system in Argentina [1], and 67% of these pregnancies are unintended. The consequences of unplanned pregnancies include social exclusion and an increase in the school drop-out rate [2].

The single-rod subdermal contraceptive implant containing etonogestrel (Implanon® MSD Merck Sharp & Dohme; Cazadores de Coquimbo 2841, Buenos Aires, Argentina), approved by the Food and Drug Administration in 2006 [3], offers long-lasting reversible contraception, with high efficacy over years of use [4]. It has a dual mechanism of action: inhibiting ovulation and thickening the cervical mucus [5]. It can be prescribed during the breastfeeding period [6] and is ideal for women with low adherence to oral contraceptive methods. It has few contraindications and has high rates of satisfaction and continuation [7]. A few complications may arise from insertion and removal procedures [8,9]. Its most common side effects include changes in bleeding patterns, headache, weight gain, mood disorders and acne [10], which could lead to discontinuation of the method [11]. With the aim of reducing unplanned pregnancies, the National Programme of Sexual Health and Family Planning provides Implanon®, free of charge, to both Argentinian and immigrant women.

Article history
Received 17 Jul 2020 - Accepted 7 Apr 2021

Contact
María Daniela Faranna; faranna_maria25@yahoo.com.ar
Gynecologist; executive committee of AMAdA, ESCRH member Gynecology Department; Sexual and Reproductive Health and Climacteric section
D. F. Santojanni Public Hospital. Pilar 950 CABA, Buenos Aires Argentina

Objectives

This study examines the use of the single-rod implant in a public health setting in Argentina, analysing side effects, effectiveness, reasons for discontinuation, and patient satisfaction with the method.

Methods

A prospective observational cohort study was carried out using medical record data of low-income women of reproductive age seeking contraception who accessed the Santojanni Hospital, Buenos Aires, Argentina, and in whom Implanon® was placed between February 2015 and September 2019.

The device placement and replacement technique was performed according to Merck Sharp & Dohme Corp instructions, hands-on training and guidelines, after prior patient counselling and pregnancy testing and after patients had given their written informed consent. The variables analysed were: age, parity, previous contraceptive methods, prior medical treatment and personal disease history, weight, height, body mass index (BMI), pregnancies (including pregnancies carried to term and abortions), removal of the single-rod implant, reason for discontinuation, and side effects.

Follow-up information was collected 12 months and 3 years after implant placement. Patients who did not attend scheduled follow-up appointments were contacted by phone. The follow-up duration was calculated from implant placement to extraction of the device, or until the last outpatient consultation or telephone check-up, whichever was the later.

Side effects were defined as those occurring from implant placement to extraction (or last consultation/check-up). The manufacturers' guidelines were used to define the occurrence of these side effects. Arm insertion-site infection that motivated implant extraction was considered a severe side effect.

Bleeding patterns were based on the original World Health Organisation-recommended definition [9], and categorised as follows: amenorrhoea, infrequent bleeding, regular/normal frequency, frequent bleeding, prolonged bleeding.

Discontinuation was defined as removal of the single-rod implant prior to completing the three years from placement. Reasons for discontinuation, i.e., patient-perceived reasons, were recorded. The effectiveness of the method was determined by the absence of pregnancies during the follow-up period. Satisfaction was assessed at the 12-month follow up or, in those who completed three years of follow up, was computed prior to implant removal. Satisfaction with the method was measured with the use of a visual analogue scale, with patients rating themselves from 1 (completely dissatisfied) to 10 (very satisfied); patients were then divided into three groups on the basis of their responses: 1-4 "dissatisfied", 5-7 "neither satisfied nor dissatisfied", and 8-10 "very satisfied". For continuous variables, mean, standard deviation (SD) and/or minimum and maximum, or median and interquartile interval (IQR) were used, according to distribution. For categorical variables the number and corresponding percentages were reported. Statistical analysis was performed with Excel.

Results

Within the study period, 995 implants were placed. The patients had a mean age of 25.8 years (14-47 years) and a mean BMI of 25.7 kg/m^2 (SD 5.4 kg/m^2), ranging from 14.9 to 50 kg/m^2; 29% were overweight and 19% obese at the time of implant placement.

With regard to previous contraceptive use, 53.2% of women had used some contraceptive method prior to implant placement: oral contraceptives were the most frequent method (39.9%; n=211), followed by the use of condoms (30.3%; n=160), injectable contraceptives (11.5%; n=61) and copper intrauterine device (9.8%, n=52).

As for obstetric history, 16.9% had no children, in 1/3 of cases due to abortion; 83.1% (n=753) already had children, of which 25.4% (n=191) had three or more children.

Median follow-up duration was 998 days (IQR 359-1098 days). Complete three-year follow up was achieved in 207 women (20.8%).

The single-rod implant was 100% effective in preventing pregnancy.

Amenorrhoea was the most common bleeding pattern, reported in 47%, (n=177); infrequent bleeding was present in 20% (n=84), followed by prolonged bleeding (n=51) and regular bleeding (n=43), each reported in 11%, and frequent bleeding in 10% (n=40).

Side effects were documented in 121 women (12%); of which 4.1% (n=5) corresponded to arm insertion-site infection.

Weight changes were present in 36.6% (n=140). Of these, 24.3% lost weight (n=34), 43.6% gained up to 5kg (n=61), 20% gained 5–10kg (n=28), and 12.1% gained more than 10kg (n=17).

Headache was reported in 14.1% of women (n=112). It was always present in 55 (49.1%) and sometimes present in 37 (33%), while 20 (17.9%) had headaches only at the beginning.

Acne worsened in 20.4% (n=30) and showed no changes in 79.6% (n=117); 68.3% had no changes in libido; whilst decreased libido was reported by 31.7% of women (n=46).

Of the 42.1% patients whose mood changed (n=61), 82% reported bad moods, 8.2% became irritable, 1.6% felt depressed, and 8.2% experienced both irritability and depression.

Arm pain was reported in 26% of women (n=95). It was always present in 29.5% (n=28) and occurred occasionally in 2.1% (n=2), whereas in 68.4% (n=65) it was present after implant placement but disappeared within 20 days.

Arm insertion-site infection was recorded in 5 patients, and necessitated implant extraction. Skin changes at the insertion site were observed in one patient and were treated conservatively with outpatient oral antibiotic treatment. Thirty-seven implants were removed before completing three years from placement (discontinuation rate: 3.7%), in 83.8% this was due to implant-related side effects.

The median time to implant removal was 210 days (IQR 136-585 days). The main reason for discontinuation was prolonged bleeding (n=10), accounting for 27% of implant removals, followed by weight gain (21.6%, n=8). The reasons for discontinuation are summarized in Table 1.

Table 1 Patient-perceived reasons for discontinuation.

Diagnosis	Number
Prolonged bleeding	10 (27%)
Weight gain	8 (21.6%)
Arm insertion-site infection	5 (13.6%)
Headache	3 (8.1%)
Arm pain	3 (8.1%)
Pregnancy desire	2 (5.4%)
Amenorrhoea	2 (5.4%)
Other	4 (10.8%)

The analysis of patient satisfaction showed that 75.8% were very satisfied with the single-rod subdermal contraceptive implant and 21.9% were neither satisfied nor dissatisfied. The patients who were dissatisfied with the method (2.3%) included those who presented prolonged bleeding, weight gain or severe side effects.

Discussion

Despite increasing availability of contraceptive methods, unplanned pregnancies remain a global problem, accounting for up to 30% of all known pregnancies. Various strategies have been proposed to reverse this worrying trend, especially increased use of long-lasting reversible contraceptives [12,13].

Implanon® is an effective contraceptive method with a similar Pearl index during typical (0.05-3.0%) versus perfect use (0.05-0.6%); it shows the highest efficacy of all contraceptive methods [7]. Although no pregnancies were recorded in our study, others have reported pregnancies associated with failure during implant insertion, implant expulsion and interaction with hepatic enzyme-inducing medicines [14]. These findings reinforce the need to provide doctors with guidelines and training in Implanon® insertion.

Implanon® use reported in the international literature was associated with the following bleeding irregularities: amenorrhoea (22.2%), infrequent (33.6%), frequent (6.7%) and/or prolonged bleeding (17.7%) [10]. Conversely, the most frequent bleeding pattern in our population was amenorrhoea, accounting for almost 50% of bleeding patterns.

Treatment discontinuation rates range from 11 to 20% [11] and seem to depend on patients' socioeconomic status and level of education. Thus, more developed countries have higher discontinuation rates than those seen in developing countries [15]. Our cohort's discontinuation rate is way below the values reported in the literature, possibly due to the fact that the cohort included low-income and low educational level patients from a public health setting. As described by other authors, prolonged bleeding was the most common patient-perceived reason for early removal, accounting for 1/3 of implant-related discontinuations [10].

In our cohort, side effects were infrequent, and usually mild. Serious adverse effects were rare, but their presence was responsible for early implant removal and dissatisfaction with the method. In the international literature, Implanon® was removed prematurely in 24% of patients, primarily because of side effects (20%) [16].

The high satisfaction rate found in our study may be due to the effectiveness of the treatment, its low side-effect rate, and the fact that the subdermal single-rod implant does not require, on the part of the patient, commitment and responsibility for daily oral contraceptive intake; in Argentina, oral contraceptives show a high rate of method abandonment and are frequently used incorrectly in low-income populations. To our knowledge, this is the largest published study conducted in Argentina on the use of the subdermal single-rod contraceptive implant. However, this study has its limitations, due to possible recall and information bias.

Conclusions

Implanon® is an effective long-term method for reducing unplanned pregnancies. Its side effects are usually mild. The main reason for discontinuation is bleeding-pattern change. Side effects and modifications in bleeding patterns should be discussed with the patient prior to placement to decrease discontinuation due to non-severe side effects.

References

1. Dirección de Estadísticas e Información en Salud (DEIS) - Sistema de Información Perinatal (SIP), 2017.
2. Observatorio de Salud Sexual y Reproductiva. El embarazo en la adolescencia. Buenos Aires: CEDES; CREP, 2014. 8 p. (Hojas Informativas, 10). Available at: http://www.ossyr.org.ar/pdf/Hoja_Informativa_OSSyR_10.pdf.
3. U.S. Food and Drug Administration, November 19, 2009. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021529_implanon_toc.cfm.
4. Amico J, Kumar B, Rosenstein H, Gold M. The contraceptive implant: an updated review of the evidence. Curr Obstet Gynecol Rep. 2015;4:79-88.
5. Croxatto HB. Mechanisms that explain the contraceptive action of progestin implants for women. Contraception. 2002;65:21-7.
6. Díaz S. Contraceptive implants and lactation. Contraception. 2002; 65:39-46.
7. Arribas-Mir L, Rueda-Lozano D, Agrela-Cardona M, Cedeño-Benavides T, Olvera-Porcel C, Bueno-Cavanillas A. Insertion and 3-year follow-up experience of 372 etonogestrel subdermal contraceptive implants by family physicians in Granada, Spain. Contraception. 2009;80:457-62.
8. Rowlands S, Mansour D, Walling M. Intravascular migration of contraceptive implants: two more cases. Contraception. 2017;95:211-4.
9. Simon C, Maurier A, Gaboriau L, et al. Incidence and characteristics of intravascular pulmonary migration of etonogestrel implants: a French nationwide study. Contraception. 2020;102:186-9.
10. Mansour D, Korver T, Marintcheva-Petrova M, Fraser IS. The effects of Implanon on menstrual bleeding patterns. Eur J Contracept Reprod Health Care. 2008;13 Suppl 1:13-28.
11. Casey P, Long M, Fleming-Harvey J, Marnach M Reason for removal

of US etonogestrel subdermal implant is significantly associated with age, BMI and postpartum status. Contraception. 2012;85:319-20.
12. Fleming C, Lipetz C, Phillips CJ, Fleming CF. The cost-effectiveness of a long-acting reversible contraceptive (Implanon) relative to oral contraception in a community setting. Contraception. 2009;79:304-9.
13. Lewis LN, Doherty DA, Hickey M, Skinner SR. Implanon as a contraceptive choice for teenage mothers: a comparison of contraceptive choices, acceptability and repeat pregnancy. Contraception. 2010;81:421-6.
14. Harrison-Woolrych M, Hill R. Unintended pregnancies with the etonogestrel implant (Implanon): a case series from postmarketing experience in Australia. Contraception. 2005;71:306-8.
15. Rowlands S, Mansour D, Walling M, et al. Intravascular migration of contraceptive implants: two more cases. Contraception. 2016;95:211-14.
16. 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;80:527-32.

Acknowledgments: *J. Menin Cela contributed with data analysis and C. Chwat assisted in the drafting of this study.*
Conflict of Interest Statement: *none declared*
Funding: *none*