

Jadelle® sub-dermal implant: evaluation of acceptance, effectiveness, side effects and discontinuation in Ilorin, Nigeria

Balogun OR^{1,2}, Afolabi MA², Adeniran AS^{1,2}, Saidu R^{1,2}

¹Department of Obstetrics and Gynaecology, University of Ilorin, PMB 1515, Ilorin, Nigeria.

²Department of Obstetrics and Gynaecology, University of Ilorin Teaching Hospital, PMB 1459, Ilorin, Nigeria.

Corresponding author:

Dr. AS Adeniran,
Department of Obstetrics and Gynaecology,
University of Ilorin
Teaching Hospital, PMB
1459, Ilorin, Kwara State,
Nigeria.

E-mail: acrowncord@hotmail.com

Abstract

Objective: To determine the safety, efficacy, acceptability, side effects and discontinuation pattern of Jadelle® subdermal implant.

Design: A retrospective descriptive study.

Setting: The Family Planning Clinic of the University of Ilorin Teaching Hospital [UITH], Ilorin, Kwara State, Nigeria.

Subjects: All clients who accepted Jadelle® sub-dermal implant between 1st January 2008 and 31st December 2012. Data was collected from the individual patient case files and analysed using SPSS version 20.

Main outcome measures: The prevalence, efficacy, side effects and discontinuation among users of Jadelle®.

Results: Of the 2,324 clients during the study period, 108 chose Jadelle® with prevalence of 4.7%. Among these acceptors, 23 (21.3%) had side-effects following insertion. The commonest side effect was menstrual irregularities (60.9%). Twelve acceptors (11.1%) discontinued before the due date for the removal of the insert. Insertion after one year from last childbirth (p 0.021) and two or more side effects (p 0.001) were significant predictors of discontinuation while previous contraceptive use, number of children alive and age were statistically insignificant. The pearl index was 0 during the study period.

Conclusion: Jadelle® is an acceptable contraceptive and the side effects are tolerable to most clients in the study.

Keywords: Jadelle® sub-dermal implant, Contraceptive effectiveness, Discontinuation.

Introduction

Implants are contraceptive options for delaying a first pregnancy, space subsequent birth or end child bearing [1]. The effectiveness of a method of contraception is expressed by the associated failure rates, the safety is a measure of the adverse effects while the acceptability and extent of use are the final determinants of its usefulness [2]. Norplant II [Jadelle®] is a second generation contraceptive implant consisting of two small (2.5 mm × 43 mm) silicone rods each containing 75 mg of levonorgestrel in a polymer matrix [3]. Plasma levels of levonorgestrel from Jadelle® are 0.4 to 0.5ng/ml within 24 hours after insertion; 0.35 ng/mL during the first 6 to 12 months and 0.35 ng/mL by the fifth year [4]. Jadelle® is implanted under the skin of the upper arm through a small incision under local anaesthesia and inserting the capsules in a fan-like shape. It causes thickening of the cervical mucus, making it impenetrable to spermatozoa [5], inhibit ovulation and alters endometrial maturation resulting in hypotrophic uterine lining unsuitable for implantation [6]. After insertion, it provides continuous, non-coitus-related protection, may be safely used by women with contraindications to oestrogen-containing steroid contraceptives and the contraceptive effect is easily reversible with almost undetectable plasma levonorgestrel levels 48 hours after its removal [7]. Although implants do not protect against sexually transmitted infections [STIs], the constant serum progestin level leads to thickened cervical mucus, which may protect against upper

genital tract infection [8]. Jadelle® is contraindicated in women with allergy to levonorgestrel, undiagnosed vaginal bleeding, liver disease, breast cancer, or blood clotting disorders. The common side effects are similar to those of other hormonal contraceptives; it is removed after five years, if pregnancy is desired, when a different birth control is preferred or unbearable complications arise.

Materials and Methods

Study setting: The Family Planning Clinic of the University of Ilorin Teaching Hospital, Ilorin, Nigeria. It is headed by a gynaecologist who is responsible for insertion of implants supported by trained nursing staff and counsellors. Clients have multiple counselling from the attending nursing staff, the trained counsellors and the attending gynaecologist before insertion. In addition, counselling and motivation are conducted at each subsequent visits to enhance continuation.

Study design: A retrospective descriptive study.

Subjects: All acceptors of Jadelle® for contraception at the clinic between 1st January 2008 and 31st December 2012 were included in the study. All women who had other forms of contraceptives were excluded.

Procedure for data collection: A list of all women who had Jadelle® inserted during the study period was compiled and their case files retrieved. Relevant data extracted were age, parity, number of living children, last child birth, educational status, religion, marital status, previous use of contraceptive, side effects and reasons for removal of Jadelle® in those who discontinued.

Data analysis: Data analysis was with SPSS- version 20.

Results

A total of 2,324 clients accepted contraceptives during the 5 year study period. Of these, 108 accepted Jadelle® constituting 4.7% of contraceptive users during the period. The mean age of the participants was 34.6 ± 5.69 years [range 20-49 years] and the modal age group was 35-39 years. All the clients except one were married, 82 (76%) had at least secondary school education and 59(54.6%)

were Christians. The mean parity was 3.7 ± 1 , the modal parity was 4, 26(24.1%) were grand-multiparous while 3(2.7%) were nulliparous. The mean number of children alive was 3.56 ± 1.36 (Table 1).

Table 1: Socio-demographic characteristics of women that accepted Jadelle®

Socio-demographic characteristics	Frequency (%)
Age	
20-24	2 (1.9)
25 – 29	12(11.1)
30 – 34	39(36.1)
35 – 39	40(37.0)
40 – 44	13(12.0)
45 – 49	2(1.9)
Mean age = 34.6 ± 5.69	
Parity	
0	3(2.7)
1	2(1.9)
2	12(11.1)
3	31(28.7)
4	34(31.5)
≥5	26(24.1)
Mean = 3.7 ± 1.0	
Number of children alive	
0	3(2.7)
1	2(1.9)
2	16(14.8)
3	31(28.7)
4	32(29.6)
≥5	24(22.3)
Mean= 3.56 ± 1.36	
Marital status	
Married	107(99.1)
Single	1(0.9)
Educational status	
None	1(0.9)
Primary	16(14.8)
Secondary	26(24.1)
Tertiary	56(51.9)
Not stated	9(8.3)
Religion	
Christianity	59(54.6)
Islam	42(38.9)
Not stated	7(6.5)

From Table 2, the last child birth was more than 12 months prior to the usage of the implant in 55 (50.9%) of the acceptors, 35(32.4%) inserted Jadelle® within 6-12 months of their delivery; 14(13%) had their last child birth less than 6 months before using Jadelle®. Side effects were experienced by 23(21.3%) of the users of Jadelle®; of these, 14(60.9%) had menstrual irregularities while weight gain was experienced in 6(26.2%) of them. Discontinuation was in 12(11.1%); of these, 6(50%) discontinued because of unacceptable weight gain, 3(25%) desired to get pregnant while one user had discomfort in the hand with inability to use it for domestic work.

Table 2: Time of insertion, side effects and reason for discontinuation among Jadelle® users

Parameter	Frequency (%)
Time of insertion from last delivery (months)	
<6	14(13.0)
6-12	35(32.4)
>12	55(50.9)
No previous delivery	4(3.7)
Side effect profile	
No side effect	85(78.7)
Side effect present	23(21.3)
Menstrual irregularity	14(60.9)
Weight gain	6(26.2)
Abdominal bloating	1(4.3)
Amenorrhoea	1(4.3)
Abdominal pain	1(4.3)
Discontinuation pattern	
Did not discontinue	96(88.9)
Discontinued	12(11.1)
Weight gain	6 (50.0)
Desire for pregnancy	3(25.0)
Menorrhagia	1(8.3)
Persistent pain at site of insertion	1(8.3)
Not stated	1(8.3)

Figure 1 showed that 9(8.3%) of the acceptors of Jadelle® were using contraceptives for the first time while 70(64.8%) were switching from other methods of contraception to Jadelle®. Among them, 23(21.3%) had used injectable contraceptives in the past, 19(17.6%) used Intra-Uterine Contraceptive Device, 13(12%) used oral contraceptive pills while 9(8.3%) used Implanon.

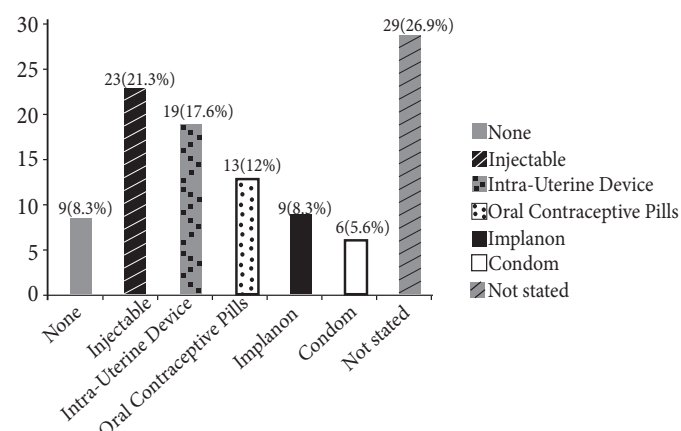


Figure 1: Previous contraceptive use among acceptors of Jadelle®

In 48(44.4%) of the clients, the source of information about Jadelle® was from the clinic personnel; other sources were radio/television in 16(14.8%), friend/relative in 12(11.1%), the print media in 11(10.2%) and other health workers in 7(6.5%) (Figure 2).

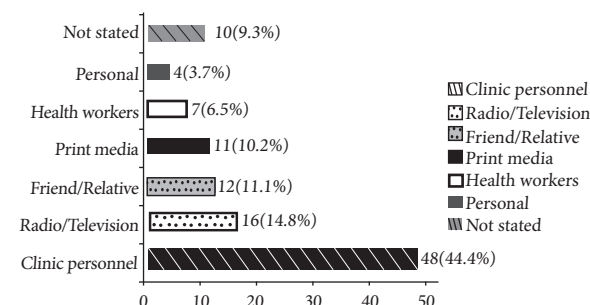


Figure 2: Source of information about Jadelle® among users

Table 3: Predictors of discontinuation among Jadelle® users

Parameter	Clients		RR (95% CI)	χ^2 (P value)
	Continued	Discontinued		
Time of insertion				
<1year from last childbirth (n= 52)	50	2		
>1year from last childbirth (n= 56)	46	10	1.17 (1.02 – 1.34)	5.36 (0.021)
Previously used contraceptive				
*Yes (n= 70)	62	8	1.33 (0.83 – 2.12)	3.19 (0.106)
No (n= 9)	6	3	0.92 (0.82 – 1.02)	1.58 (0.276)
No response (n=29)	28	1		
Side effect profile				
*No side effect (=85)	83	2	0.98 (0.94 – 1.01)	0.22 (0.999)
1 side effect (n= 9)	9	0	3.42 (1.49 – 7.83)	53.84 (0.001)
≥2 side effects (n= 14)	4	10		
Number of children alive				
*0 – 2 (n=21)	19	2		
3 – 4(n=63)	56	7	1.02 (0.86 – 1.20)	0.04 (0.999)
≥5(n= 24)	21	3	1.03 (0.84 – 1.27)	0.10 (0.999)
Age (years)				
<20 (n= 0)	0	0		
20-35 (n= 53)	44	9		
>35 (n= 55)	52	3	0.88 (0.77 – 1.01)	3.63 (0.056)

From Table 3, the significant predictors of discontinuation of Jadelle® were insertion after 12months from last childbirth [RR 1.17, 95% CI 1.02-1.34, p 0.021] and multiple side effects [RR 3.42, 95% CI 1.49-7.83, p 0.001]. The age of the client, number of children alive and previous use of contraceptive were not statistically significant in predicting discontinuation of Jadelle®. The Pearl Index for Jadelle® was zero during the study period.

Discussion

The prevalence of Jadelle® subdermal implant usage from this study was 4.7%; similar to 6.9% from Aba, South-eastern Nigeria [9] but higher than 0.95% from Port-Harcourt, South-South Nigeria [10]. The differences may be because the Port-Harcourt study was a preliminary report of Jadelle® in the first two years of its use in the centre compared to this centre where it has been available since the year 2007 and more people have accepted it. The modal age group of 35-39 years (mean 34.6 ± 5.69 years) was comparable to reports from Port-Harcourt, Nigeria with modal age 37 years (mean age 33.81 years) [10]. It shows that most of the users were at the peak of their reproductive age and the absence of adolescents among the acceptors may be due to cultural and religious restrictions, lack of knowledge, poor access and concern over side effects, especially fear of future infertility among adolescents [11]. The mean parity in this study was four; this was similar to other study reports [9, 10]. This may be a reflection of the concerns about

sterilization in developing countries with preference for long term reversible contraceptives like Jadelle® as an alternative [12].

Women education was seen as an important factor in acceptance of Jadelle® with comparable figures to other reports [10]. This could be because educated women have better access to information on innovations, are likely to be empowered financially and of independent mind as well as being more receptive to newer innovation with regards to their health. Clinic staff as the commonest source of information about Jadelle® highlights the increasing importance of clinic staff in disseminating information on contraception [13]. However, Chigbu *et al* [9] reported that friends were the leading source of information in 48.2% of the acceptors, followed by the health care personnel (28.4%) in Aba, South-Eastern Nigeria. Majority of clients switched from other contraception to Jadelle® in this study similar to a study by Enyindah *et al* [10] which showed that 68% of the acceptors in Port-Harcourt, Nigeria changed to Jadelle®. This was attributed to its effectiveness, long-acting, user independence, easier insertion and removal as well as diminished appearance in the arm [10]. The cultural and attitudinal restriction of single women with regard to contraceptive choice in a developing country like Nigeria was demonstrated as only one unmarried client accepted Jadelle®. Menstrual irregularities as the commonest side effect in this study was comparable to reports on other sub-dermal implants [14-16] although the commonest reason for discontinuation was unacceptable weight

gain unlike menstrual irregularities reported from Aba, Nigeria [9]. This supports the inference that women in developing countries may be more willing to accept the inconvenience of menstrual irregularity in the face of implants as an effective, user-independent contraceptive unlike those in developed countries [17]. The significant predictors of discontinuation were insertion after one year from last childbirth and multiple side effects. This may be because of the cumulative inconveniences of the multiple side effects. The continuation rate of 88.9% in this study was similar to 91.4% from other developing countries [17] and none of the clients had problems during removal. The Pearl index for Jadelle® in this study was 0%; this was same as that reported from other studies [14, 15] which reflect its effectiveness.

In conclusion, Jadelle® is an acceptable, long-acting, reversible hormonal contraceptive with tolerable side effects and high continuation rate in the presence of adequate counselling and motivation.

References

1. World Health Organization Department of Reproductive Health and Research [WHO/RHR] and John Hopkins Bloomberg School of Public Health Centre for Communication Programs [CCP]. Family Planning: a Global Handbook for Providers [2011 Update]. Baltimore: CCP and WHO; 2011 [Assessed 2013 Sept 20].
2. Okpere E. Contraception and family planning. In: Okpere E, ed. Clinical Gynaecology. Revised edition. Benin City: Mindex Publishing Company Ltd. 2007; 253-271.
3. Sivin I, Lahteenmaki P and Ranta S. Levonorgestrel concentrations during use of levonorgestrel rod [LNG ROD] implants. *Contraception*. 1997; **55**:81.
4. Orme ML, Back DJ and Breckenridge AM. Clinical pharmacokinetics of oral contraceptive steroids. *Clin. Pharmacokinet*. 1983; **8**: 95.
5. Croxatto HB, Diaz S and Salvatierra AM. Treatment with Norplant sub-dermal implants inhibits sperm penetration through cervical mucus in vitro. *Contraception*. 1987; **36**: 193.
6. Darney PD, Klaisle CM and Tanner S. Sustained release contraceptives. *Curr Problem Obstet Gynecol Fertil*. 1990; **13**: 90.
7. Sivin I. International experience with Norplant and Norplant-2 contraceptives. *Stud Fam Plann*. 1988; **19**:81.
8. Clerk NT, Ladipo OA. Contraception. In: Agboola A. ed. Textbook of Obstetrics and Gynaecology for Medical Students. 2nd ed. Ibadan; Heinemann Educational Books [Nig.] Plc. 2006; 149-150.
9. Chigbu B, Onwere S, Aluka C, Kamanu C, Okoro O and Feyi-Waboso P. Contraceptive choices of women in rural South-Eastern Nigeria. *Nig J Clin Pract*. 2010; **13**(2): 195-199.
10. Enyindah CE and Kasso T. Jadelle® Sub-dermal Implants: Preliminary experience in a Teaching Hospital in the Niger Delta Region of Nigeria. *Niger J Med*. 2011; **20**(2): 270-274.
11. Williamson LM, Parkes A, Wight D, Petticrew M and Hart J. Limits to modern contraceptive use among young women in developing countries: a systematic review of qualitative research. *Reprod Health*. 2009; **6**:3.
12. Fakeye O. Contraception with subdermal levonorgestrel implants as an alternative to surgical contraception at Ilorin, Nigeria. *Int J Gynaecol Obstet*. 1991; **35** (4): 331-336.
13. Abasiattai AM, Bassey EA and Udoma EJ. Profile of intrauterine contraceptive device acceptors at the University of Uyo Teaching Hospital, Uyo, Nigeria. *Ann Afr Med*. 2008; **1**: 1-5.
14. Aisien AO. Contraception with Levonorgestrel sub-dermal implants (Norplant) in Benin-city, Nigeria: A 12-year review. *Afr J Reprod Health*. 2007; **11**(1): 90-97.
15. Haggi DN. The Norplant experience in Zaria: A ten-year review. *Afr J Reprod Health*. 2003; **7**(2): 20-24.
16. Ogedengbe OK, Giwa-Osagie OF, Adeboye M and Usifoh CA. The acceptability and role of Norplant as a long acting contraceptive in Lagos, Nigeria. *Trop J Obstet Gynaecol*. 1997; **14**(1): 28-33.
17. Bahamondes L. Interventions: Subdermal implantable contraceptives versus other forms of reversible contraceptives or other implants as effective methods of family planning. The WHO Reproductive Health Library Commentary. Geneva: WHO; 2008.