

Evaluation of Jadelle use in Teaching hospital in Niger Delta, Nigeria

Nonye-Enyidah Esther Ijeoma ^{1,*}, Lebara L.B ¹ and Enyidah Nonyenim Solomon ²

¹ *Department of Obstetrics and Gynaecology, Rivers State University Teaching Hospital, Port Harcourt, Rivers State, Nigeria.*

² *Department of Medicine, Rivers State University Teaching Hospital, Port Harcourt, Rivers State, Nigeria.*

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Abstract

Background: Jadelle (Norplant 2) is a levonorgestrel contraceptive implants that is safe, reversible, convenient, very effective and suitable for many women. Although it has numerous benefits, its use is still discontinued due to various reasons including side effects in the body of acceptors.

Objective: To determine the prevalence rate, side effects, discontinuation rate and reasons for discontinuation of Jadelle at Rivers State University Teaching Hospital (RSUTH), Port Harcourt, Nigeria.

Methods: A retrospective study of 874 clients attending birth control clinic at the RSUTH from 1st January, 2015 – 31st December, 2019 was conducted. Their records were recovered from the clinic and studied. Data was extracted, coded and investigated using the statistical package for social sciences (SPSS) IBM version 25.0 (Armonk, NY).

Results: Of 874 acceptors of contraceptives within the study period, one hundred and forty two used Jadelle giving an uptake rate of 16.2%. Jadelle use accounted for third most used contraceptive after implanon and intra uterine contraceptive device (IUCD) during the study period. The mean age was 32.9+4.21 years. Most age group was 30-34 years accounting for 57.8%. Age range was 20-48 years and most (81.7%) were multiparous. Christians accounted for 99.3% and 98.4% were married. All the clients had formal education. Thirty nine (27.5%) acceptors discontinued the use. Most were due to menorrhagia (33.3%) and desire for pregnancy (23.1%). Two unintended pregnancies occurred giving a Pearl index of 0.28 per 100 women-year.

Conclusion: Jadelle is safe and effective. Menstrual abnormalities were the commonest side effects complained by the clients. Menstrual abnormalities and desire for pregnancy were the commonest reasons for discontinuation of Jadelle use.

Keywords: Jadelle; Prevalence Rate; Side Effects; Discontinuation Rate; RSUTH

1. Introduction

Contraception is the intentional prevention of pregnancy using different methods. It involves the interruption of the events that lead to conception [1]. Subdermal contraceptive implants research began in 1996 at the population council laboratories in New York which led to the discovery of the biocompatibility of silicon in the human body. This led to the development of Norplant and Norplant 2 (Jadelle) [1,2]. Contraception directly contributes to reduction in maternal morbidity and mortality by preventing unwanted pregnancies and unsafe abortions [3,4].

* Corresponding author: Nonye-Enyidah Esther Ijeoma

Department of Obstetrics and Gynaecology, Rivers State University Teaching Hospital, Port Harcourt, Rivers State, Nigeria.

Jadelle is a long acting reversible contraceptive that provides contraception for a long period of time without requiring user action [5]. It is licensed for use for 5 years [6]. It consists of a set of 2 flexible cylindrical rods consisting of dimethylsiloxane/methylvinylsiloxane co-polymer core enclosed in thinned-walled silicone tubing. Each rod is approximately 43mm long and 2.5mm in diameter. It contains 75mg of Levonorgestrel with a mean daily release of 100microgram/day in the first month of insertion [7]. This reduces to about 40 microgram/day within 1 year and 30 microgram /day within 3 years and 25 microgram/day at the end of the 5th year [4,8]. The 2 rods are inserted into the medial aspect of the less dominant arm (middle third of the upper arm) in a V-shaped manner through a minor surgical procedure under local anaesthesia. This is done within the 1st few days of the woman's menstrual cycle and at the latest 7th day from the onset of menses. Removal of implant also requires minor surgical procedure [9].

Jadelle prevents pregnancy by thickening the cervical mucus, suppression of estrogen maturation of follicles, endometrial atrophy and inhibition of ovulation due to high plasma level of progestin [6,7,10]. As a contraceptive, it prevents unwanted pregnancy and by extension unsafe abortion, septic abortion and maternal mortality. It has the benefit of non-interference with intercourse and immediate return to fertility after removal with no impact on long term fertility. The annual pregnancy rate per 100 users is 0.1 for the first 3 years, 0.4 in the 4th year and 0.85 at the end of the 5th year. The pearl index by the end of the 5th year is 0.17/100 women-years [8].

Complications and side effects of Jadelle can cause discontinuation of the contraceptive depending on the severity and this includes abnormal vaginal bleeding, vaginal discharge, abdominal pain, vomiting headaches, chest pain, amenorrhoea, application site reaction, dizziness, breast pain, premenstrual syndrome, neurovascular injury and mood changes. Others are weight gain, pelvic pain and anxiety [8]. Disruption of the menstrual bleeding pattern, especially in the early months after insertion accounts for most numbers of early discontinuation [10-12]. Despite the improvement in availability and utilization of long acting reversible contraceptives, early discontinuation is a major problem and majority within the first year even without side effects [13]. High discontinuation rate is a public health concern. Contraindications include abnormal vaginal bleeding, liver disease, breast tumours, endometrial cancer, thrombo-embolic disorders and allergy to levonorgestrel [8,14,15]. The side effects, use effectiveness, discontinuation rate and reasons for discontinuation of Jadelle implant in RSUTH, Port Harcourt have not been evaluated since the inception of the family planning clinic; thus the need for this study to aid in proper counseling and further implementation research on this method of contraception.

2. Material and methods

This is a retrospective study carried out at the family planning clinic of the RSUTH in Port-Harcourt, southern Nigeria. The clinic gets its clients from within Port Harcourt and its environment. The clinic is headed by a consultant Gynaecologist, with the support of trained family planning nurses and resident doctors. At the first visit, the baseline socio-demographic and reproductive health information of each client was entered into a structured health record file after obtaining informed consent. The clients were counseled by the family planning nurse practitioners, registrars or consultants on the various methods of contraceptives available and were allowed to make informed choice based on their needs and available contraceptives suitable for them. Thereafter medical history and clinical examination were done to exclude contraindications to the use of subdermal contraceptive implants. Urine analysis and pregnancy test were also done for the clients. The nurses inserted two rods of jadelle 8-10cm above the medial epicondyle of the humerus subdermally, to avoid the risk of neurovascular damage at insertion and removal. The insertion was done within 7 days of normal menstrual period after excluding pregnancy. They were also inserted within 21 days post-partum in breastfeeding mothers who were yet to resume menstruation. Following insertion, the service provider confirmed the presence of the implant by palpation and also asked the client to do so. Thereafter the procedure was documented including the arm the implant has been inserted into and that it was felt. The date of the removal of the implants was also documented. In the absence of complications, routine post insertion follow up visits are at one week, six weeks, three months, six months and then annually. Clients were advised to visit the clinic at any time if there are complaints. At each visit, the client's complaints were documented and appropriate treatment given. The weight, blood pressure and results of urinalysis were also noted. The record cards of all the clients that accepted Jadelle subdermal implant between 1st January, 2015 and 31st December, 2019 were retrieved and studied. The information extracted from the cards included the socio-demographic characteristics of the clients, side effects and complaints, discontinuation and the reasons for discontinuation of the contraceptives, previous contraceptives used and their sources. Also any unintended pregnancy following the use of Jadelle was also documented in the cards. The data was analyzed with the statistical package for social sciences (SPSS) IBM version 25.0 (Armonk, NY) using frequency counts and percentages.

3. Results

One hundred and forty two clients chose Jadelle out of 874 contraceptive acceptors during the study period giving the acceptance rate of 16.2%. It is the 3rd most accepted contraceptive after implanon and intrauterine contraceptive device (IUCD). The age range of the clients was from 20 to 48 years. Majority of the clients 82 (57.8%) were between 30-34 years. The mean age was 32.9 + 4.21 years. Multiparous women accounted for 116 (81.7%) and Christians were 141 (99.3%). The parity range was 0 to 7 and modal parity was para 2. Thirteen (9.1%) grandmultipara, one (0.7%) nullipara and 12 (8.5%) primipara accepted and used Jadelle during the study period. All the clients had formal education out of which 83 (58.5%) had tertiary level of education while 54 (38%) and 5 (3.5%) had secondary and primary levels of education respectively. Majority of the clients were married 141 (99.3%) while 1 (0.7%) were single. The socio-demographic characteristics of Jadelle acceptors are shown in table 1.

Table 1 Socio-demographic characteristics of the clients

Variable	No.	Percentage (%)
Age		
20-24	2	1.4
25-29	18	12.7
30-34	82	57.8
35-39	32	22.5
40-44	5	3.5
45-49	8	2.1
Educational status		
Primary	5	3.5
Secondary	54	38.0
Tertiary	83	58.5
Religion		
Christianity	141	99.3
Islam	1	0.7
Parity		
Nullipara	1	0.7
Primipara	12	8.5
Multipara	116	81.7
Grand multipara	13	9.1
Marital status		
Single	1	0.7
married	141	99.3

The sources of previous contraceptives used by the clients are shown in figure 1. Forty seven (33.1%) clients got their previous contraceptives from government hospitals, 18 (12.7%) got theirs from private hospitals and 77 (54.2%) did not get from either of the two sources, possibly from drug shop. Majority of the clients (13.4%) previously used barrier methods of contraception, 15 (10.7%) previously used oral contraceptive pills, 9 (6.3%) previously used IUCD and 8 (5.6%) each used implants and injectables respectively. Previously used calendar, postinor and withdrawal methods accounted for 2.8%, 3.5%, and 4.2% of Jadelle users respectively. Sixty eight (47.9%) Jadelle users did not use any method of contraception prior to the family planning visits. This is shown in table 2.

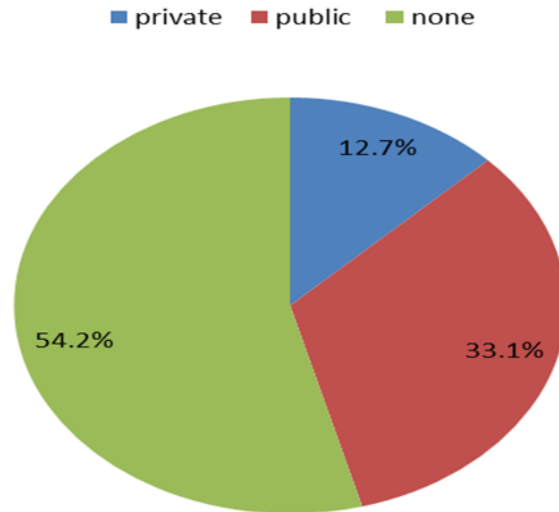


Figure 1 Sources of previous contraceptives used by clients

Table 2 Previously used contraceptives by the clients.

Methods	Frequency	Percentage
IUCD	9	6.3
Withdrawal	6	4.2
Calendar	4	2.8
Postinor	5	3.5
OCPs	15	10.7
Barrier	19	13.4
Injectable	8	5.6
Implant	8	5.6
No method	68	47.9

Side effects associated with the use of Jadelle during the study period are shown in table 3. Eighty one (57%) clients did not have any complaints and did not discontinue the use of Jadelle while 61 (43%) had side effects. Twenty one (34.4%), 16 (26.2%) and 13 (21.3%) clients had menorrhagia, irregular vaginal bleeding and secondary amenorrhoea respectively. Seven (11.5%) women had headache while 3 (5%) and 1 (1.6%) women had weight gain and lower abdominal pains respectively. Figure 3 shows the discontinuation rate of Jadelle. Thirty nine women discontinued the use of Jadelle during the study period giving a discontinuation rate of 27.5%. Throughout the study period there were two accidental pregnancies giving a failure rate of 1.4/100 women year. The reasons for discontinuation of Jadelle are shown in table 4. Menorrhagia, desire for pregnancy and irregular vaginal bleeding accounted for 13 (33.3%), 9 (23.1%) and 7 (17.9%) of the reasons for discontinuation respectively. Others are headache 3 (7.7%), weight gain 2 (5.1%), lower abdominal pain and waist pain 1 (2.6%). One woman attained menopause and discontinued the use of jadelle while another had breast cancer and stopped its use.

Table 3 Side effects of Jadelle (n=61)

Side effects	frequency	Percentage
Headache	7	11.5
Lower abdominal and waist pains	1	1.6
Weight gain	3	5.0
Menorrhagia	21	34.4
Irregular vaginal bleeding	16	26.2
Secondary amenorrhoea	13	21.3

■ continuation rate ■ discontinuation rate

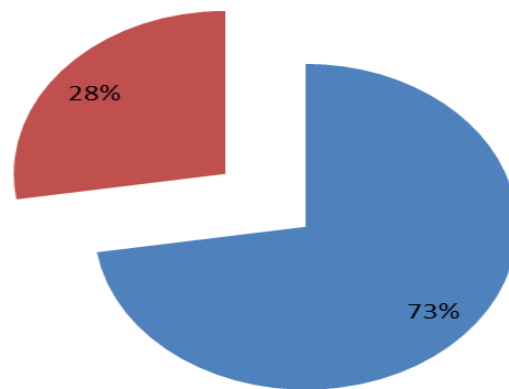


Figure 2 Continuation and discontinuation rates of Jadelle.

Table 4 Reasons for discontinuation of Jadelle (n=39).

Reasons	Frequency	Percent
Irregular vaginal bleeding	7	17.9
Menorrhagia	13	33.3
Headache	3	7.7
Weight gain	2	5.1
Desire for pregnancy	9	23.1
Lower abdominal and waist pains	1	2.6
Breast cancer	1	2.6
Menopause	1	2.6
Pregnancy	2	5.1

4. Discussion

Jadelle is the third most frequently accepted and used contraceptive method among women attending the family planning clinic of Rivers State University Teaching Hospital (RSUTH) following implanon, intrauterine contraceptive device (IUCD). 142 women accepted jadelle during the period of the study. They were within the age range of 20-48 years with a mean of 32.9 years. The uptake rate of Jadelle in this study is 16.2% which is lower than 38.7% but higher than 13.4% in the previous study from this centre [16,17]. Women may prefer implants probably because they are convenient, long acting and can be inserted without undergoing a pelvic examination [18].

Majority of women within the age range of 30-34 accepted jadelle. This is similar to studies done in Uyo and PH where most of the women fell within the range of 30-34 years [6,15]. Other similar results were studies done by Mohammed et al and Igwebueze et al [2,16]. Adolescents are less likely to use subdermal implants which is in line with our study with no uptake from the adolescents and other similar studies [19-21]. Adolescents shy away from Government owned family planning clinics possibly to avoid stigmatization explaining the poor uptake rate in this age group [22].

Most of the women with parity of 2-4 accepted the method of contraception and 99.3% of the clients were married. This is similar to a work done in Gambia where 57.3% of the clients that accepted jadelle had a parity of 2-4 [23]. Multiparous women especially grandmultipara are more likely to use long acting reversible contraceptives (LARC) like subdermal implants. This is expected as LARC are generally seen as permanent contraceptive methods especially in this part of the world where bilateral tubal ligation (BTL) is usually not acceptable because of religious and cultural beliefs [22].

Almost all clients who accepted and used Jadelle were Christians. This is not surprising as Christians predominate the southern part of Nigeria. Most of the women had tertiary level of education. A study in Nigeria discovered that women with tertiary education are 2.10 times likely to have used a modern contraceptive method than women with no formal education. This plays out in this study where the uptake rate has improved from 13.4% of a previous study and the improved uptake rate is associated with improvement in the level of education. In this study, most of the women had tertiary level of education unlike the previous study in this centre [17]. Also Christians were 1.41 times more likely to accept contraceptives than muslims [24]. Most of the clients had tertiary level of education. This finding is similar to other studies done in Nigeria and other countries [7,8,10, 25, 26].

Most women discontinued Jadelle because they desired to have more children. Majority of the side effects were due to menstrual abnormalities which were the most frequent complaints leading to discontinuation of the contraceptives. This is similar to a study in Aminu Kano teaching hospital where menorrhagia accounted for 60% of the reason for discontinuation [7]. These menstrual disorders are due to the effect on ovarian function. Fluctuating endogenous production from irregular follicular growth leads to irregular bleeding whereas secondary amenorrhoea has been attributed to ovarian suppression and endometrial atrophy [27,28]. Secondary amenorrhoea may be beneficial to some women especially those that require reduced menstrual flow and those with sickle cell anaemia [29].

The continuation rate of Jadelle in RSUTH was 72.5%. The high continuation rate of Jadelle is based on its effectiveness as a long acting reversible contraceptive and its side effect profile compared to other methods of contraception. It is important to state that 57% of the clients had no side effects indicating a good safety profile of the contraceptive. The pearl index derived from a study in Ilorin was 0% [30] and it is comparable to our study that had a pearl index of 0.28/100 women year. A study in UCTH had a pearl index of 0.074 [8] while a study on contraceptive efficacy in the Dominican republic had a pearl index of 0.00/100 women year [31]. These demonstrate high contraceptive efficacy of Jadelle.

5. Conclusion

The acceptance rate of Jadelle is low. Menstrual disorders remain the major side effects of this method of contraception and could lead to discontinuation. Persistent counseling before and during follow up visits will go a long way to reduce the discontinuation rate of this very effective contraceptive. Also dissemination of information on subdermal implants by the government, non-government organizations (NGOs) and media will also improve the uptake rate.

Compliance with ethical standards

Acknowledgments

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Disclosure of conflict of interest

Authors have declared that no competing interests exist.

Statement of ethical approval

Ethical approval was given by the Hospital's Ethics committee.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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