# Jadelle® Subdermal Implants. Preliminary Experience in a Teaching Hospital in the Niger Delta Region of Nigeria

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#### **ABSTRACT**

BACKGROUND: The reproductive health hazards of unwanted pregnancies and unsafe abortions have been reduced with modern contraceptive use. The purpose of this review is to highlight the acceptability and side effects of Jadelle; a modern subdermal contraceptive implant in Port Harcourt

**METHODS:** Case files of acceptors of Jadelle<sup>®</sup> subdermal implants between 4<sup>th</sup> January 2008 and 30th June 2010 were retrieved. Information obtained were sociodemographic characteristics, insertion and post insertion complications. Data analysis was done with Microsoft Excel and EPI info statistical software 14.0.

RESULTS: Of the seven thousand, eight hundred and eighty four (7884) clients who accepted contraceptive during the study period; 75 chose Jadelle constituting 0.95% of acceptors. The mean age and parity of acceptors were 33,1 years and 4.05 respectfully. Majority of the clients (89.33%) were married while 10.67% were single mothers. Similarly most of the acceptors had secondary and tertiary education, 26.67% and 69.33% respectively. Prevalent side effects were amenorrhoea (41.33%), intermenstrual bleeding (6.67%), intermenstrual spotting (4.00%). None of the acceptors discontinued the method. There was no accidental pregnancy.

**CONCLUSION:** Jadelle® appears to have been accepted in our centre. About two third of the clients switched from their other methods to Jadelle; with a zero percent discontinuations rate among acceptors.

**KEY WORDS:** Jadelle, Experience, Niger delta, Nigeria.

## INTRODUCTION

Progestin releasing subdermal contraceptive implants are used by increasing numbers of women worldwide. This is because they offer high contraceptive efficacy, long term contraception following a single intervention and a few adverse effects that represent no risk to the health of users<sup>1,2</sup>. The most widely used contraceptive implants are the levonorgestrel releasing implants (Norplant and Jadelle) and the etonogestrel releasing implant (Implanon)<sup>3</sup>. They interfere with the penetration of spermatozoa in the cervical mucus, preventing fertilization and interfering with the ovulatory process. Progestin contraceptive methods have been found to be tolerated by many users because of the absence of estrogenic effects.

Jadelle<sup>®</sup> is a newly introduced contraceptive implant into the country. It is manufactured by Schering oy. It contains two flexible rod like implants; each contains 75mg levonorgestrel and is 2.5 mm in diameter and 4.3cm in length<sup>4</sup>. It is a long acting reversible progestin only contraceptive which is inserted under the skin and provides contraception for up to five years.

It is inserted subdermally into the medial aspect of the less dominant upper arm (mid 1/3) in a v shape by a minor surgical procedure under local anaesthesia. This is done in the first few days of a woman's menstrual cycle and at the latest on the 7<sup>th</sup> day from the onset of menses. Removal of implants also requires a minor surgical procedure.

Norplant capsules and Jadelle® rods release levonorgestrel at similar rates for 5 years, which is the approved life span of the two implants<sup>5</sup>. The only difference appears to be the duration of effectiveness. Clinical trials have shown that Norplant is highly effective through to seven years <sup>6</sup>, whereas Jadelle

appears to loose effectiveness after five years <sup>7</sup>, though both are still labeled for 5 years of use <sup>8</sup>. The main practical advantage of Jadelle® over Norplant is that of having two rods instead of six capsules. This was confirmed by objective studies that showed that both insertions and removal took longer with Norplant than with Jadelle® and that local complications after insertion and removal were less frequent with Jadelle® than with Norplant. Levonorgestrel serum level falls fairly rapidly during the first month after insertion and then declines much more slowly through the remaining implants lifespan. Levonorgestrel is cleared from circulation within 120 hours following removal<sup>5</sup>.

Jadelle® contraception started was at the family planning clinic of the University of Port Harcourt Teaching Hospital (UPTH), Port Harcourt in January 2008. This family planning unit is one of the largest in the Niger delta region of Nigeria. The Niger delta forms the south south geopolitical zone of Nigeria, and is rich in crude oil. Appropriate counseling of clients was done and informed consent obtained prior to insertion of implants.

This retrospective study is the first to be carried out in this centre, evaluating our experience with Jadelle® during the first two years of use. The objective of the study is to determine the acceptability of Jadelle® as a method of contraception, the effectiveness and side effects among our clients.

## **METHOD**

The case files of all the clients who accepted Jadelle® contraception after counseling between January 2008 and June 2010 were retrieved from the family planning records of the University of Port Harcourt Teaching Hospital. The family planning clinic has its own records that are not in the main hospital records. This makes it easier for the retrieval of records of these clients. Data collected from the files included clients age, parity, educational status, marital status, side effects and reasons for removal or discontinuing Jadelle® (if any). The clients were counseled by the family planning nurse practitioners and physicians. Insertion of Jadelle rods were carried out in strict compliance with the Association for

Voluntary Surgical Contraception (AVSC) protocol for Jadelle<sup>®</sup>.

In the absence of complications, post insertion follow up visits were at the first four weeks, at three and six months, then annually. Subsequently, clients were encouraged to come to the clinic if there were complaints and/or complication, all of which were documented. The clients' weight and blood pressure were recorded at each follow up visit and complications managed as appropriate. A client was considered lost to follow up if she defaulted for more than six months. Data analysis was done with Microsoft Excel and EPI info statistical software 14.0.

#### **RESULTS**

Seven thousand, eight hundred and eighty four (7884) clients accepted contraception during the study period. Out of these 53 clients accepted Jadelle<sup>®</sup>, constituting 0.95% of acceptors. This excluded those who collected condoms and other barrier methods of contraception. The clients ages ranged between 24 and 47 years with a mean age of 33.81 years and a modal age of 37 years. The parity of the clients was from 2 to 7 with an average of 4.05. The modal parity was 4. Multiparous clients constituted 64.00% while grand-multiparous clients were 34.67%. (Table 1)

TABLE 1 Socio-demographic Characteristics of Women that Accepted Jadelle

CHARACTERISTICS	NUMBER	PERCENTAGE (%)	
A) Age			
20-24	4	5.33%	
25-29	7	9.33%	
30-34	30	40.00%	
35-39	26	34.67%	
<u>&gt;</u> 40	8	10.67%	
B) Parity			
1	1	1.33	
2	11	14.67	
3	21	28.00	
4	16	21.33	
<u>≥</u> 5	26	34.67	
C) Marital status			
Married	67	89.33	
Single	8	10.67	
D) Educational status			
No formal education	0	0	
Primary	3	4.00	
Secondary	20	26.67	
Tertiary	52	69.33	
E) Religion			
Christianity	71	94.66	
Islam	2	2.67	
Others	2	2.67	

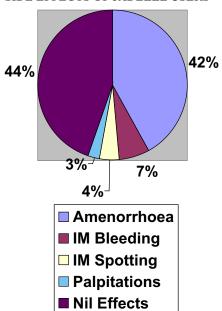
Majority of the women (89.33%) were married while 10.67% were single mothers. Similarly most of the clients had secondary and tertiary education; 26.67% and 69.33% respectively. The total number of living children among the clients were 2 to 6 with a mean of 4.02 children. The clients weighed between 52 and 109kg with a mean weight of 73.16kg. Fifty seven (76.00%) of these clients would not want to have more children on discontinuation of the method, 16(21.33%) desired more children while 2 (2.67%) were uncertain. (Table 2).

TABLE 2
The women's desire for more children in future or otherwise

Desire to have children	Number	Percentage (%)
Would not want to have more children	57	76.00
Would like to have more children	16	21.33
Not certain	2	2.67

Complications associated with insertion of implants such as itching, bruising, induration, expulsion or infections were absent. The most common side effect was amenorrhoea (41.33%), followed by intermenstrual bleeding (6.67%), intermenstrual spotting (4.00%), palpitation (2.6%) and lower abdominal pains (1.33%). Thirty-three (44.00%) of the acceptors had no side effects (Fig 1)

FIGURE 1 SIDE EFFECTS OF JADELLE USERS



Twenty four (33.96%) of the clients were using contraceptives for the first time while 51(68.00%)

were switching from other methods of contraception to Jadelle<sup>®</sup>. None of the acceptors so far discontinued the method while one client was lost to follow up.

## **DISCUSSION**

Contraceptive implants provide long lasting highly effective reversible contraception. They offer an excellent contraceptive option for women who have contraindications to combined hormonal methods because of its progestin only content. They also offer an option for any woman who desires long term contraception that is rapidly reversible. Their major advantages are their effectiveness, safety, long term contraception and immediate return to fertility following reversal<sup>10</sup>. None of the users of Jadelle implant discontinued the method during the period of study. This suggests a very high level of acceptance of this method of contraception. Acceptors of Jadelle constituted 0.95% of contraceptive users within the study period, which is less than 5.2% reported for Norplant users in the same centre<sup>11</sup>. The latter was however over a period of seven years. Similarly the cost of the Jadelle implant and occasional non availability may be responsible for this low prevalence rate. This was reported earlier in the same centre with the study on levonorgestrel implants (Norplant) where decreasing availability and increasing cost of the Norplant implants reduced the total number of clients that accepted the method 11. Poor outreach and communication of this method to the women by providers could also be responsible.

The socio-dermographic characteristics of jadelle users especially parity, efficacy in preventing pregnancy and pattern of side effects agree with three of previous studies with levonorgestrel implants in Nigeria and elsewhere <sup>6,12,13.</sup>

Majority of the women in this study were multiparous and in their thirties with a mean age of 33.81 years which is similar to earlier reports in other Nigerian centres <sup>12,13</sup>. Their high parity, preacceptance counseling, ongoing information during use by family planning providers and other clients who benefited from the method could have been other factors that accounted for the level of acceptability. Fewer implants and its practical implications, that is, easier insertion and removal and diminished appearance in the arm, may have also been the reason for acceptability of this method as reported in other studies <sup>14</sup>. The clients had 2 to 6 living children in an

average of 4.02 children of which 76.00% of them would not want to have more children on discontinuation of the method. This suggest that Jadelle implants, if available will be a popular alternative to female sterilization which is the ideal method for this group of women who qualify for it but are reluctant to accept it.

Majority of the women (89.33%) were married while 10.67% were single mothers. A greater proportion of the clients also had secondary and tertiary education constituting 26.67% and 69.33% of the study group respectively. This suggests a more urban base clientele in our centre. It could also suggest a suspicion of this method by non literate women or poor communication of the method to women by contraception providers.

The most common side effect of hormonal contraceptives is the disruption in the menstrual cycle <sup>15</sup>. Menstrual irregularities were the common side effects in this study with amenorrhoea constituting 41.33% and intermenstrual bleeding 6.67% among others. Prolonged amenorrhoea was however infrequent. Insertion site infection was not reported which is in contrast to earlier reports on Norplant in the same centre <sup>11</sup>. This could be as a result of the reduced number of rods that Jadelle has.

Annual pregnancy rates for each year of use up to the end of 5 years for both Norplant and Jadelle are well below 1 per 100. Five year cumulative pregnancy rates for both implants are 1.1 per 100 . There was however no pregnancy reported during the period of the study. Insertion of Jadelle implants in this study was not limited to only women of 70kg or below as initially applied for Norplant implants. This is because of its reported good pearl index 5. In this study, the clients weighed between 52kg and 109kg with a mean weight of 73.16kg. Counseling was however done about the possibility of a higher chance of failure compared with those of lower body weight. Similarly, that more than half (68.0%) of the clients were switching from other methods of contraception to Jadelle coupled with zero discontinuation rate during the study period suggest acceptability of the method.

# **CONCLUSION**

Contraception with Jadelle appears to have been accepted by women of the Niger delta region of Nigeria. It is a long lasting, safe and effective contraceptive method which women could choose as an alternative to tubal ligation. The lack of severe side effects and reduced need for frequent follow up also highlights the suitability of Jadelle as an important contraceptive method for domiciliary practice and for rural populations. Efforts should thus be made to create more awareness about it especially in the rural areas/non-literate population, as well as ensure its availability at reduced cost.

## **ACKNOWLEDGEMENTS**

We wish to acknowledge Prof A. O. U. Okpani for his advice and criticisms, as well as staff of the family planning clinic for their support and co-operation.

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