

## **JADELLE SUBDERMAL CONTRACEPTIVE IMPLANT IN AMINU KANO TEACHING HOSPITAL KANO, NORTHERN NIGERIA.**

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### **ABSTRACT**

**Background:** Jadelle is a set of two flexible cylindrical implants consisting of a dimethylsiloxane/methylvinylsiloxane copolymer core enclosed in thin-walled silicone tubing. It is an improved version of Norplant. Worldwide, it is found to be effective, safe, reversible and convenient for many users.

**Objective:** To determine the acceptance rate, the Socio-demographic profile of the clients, post insertion complications and reason for discontinuation of the method among its acceptors in Aminu Kano Teaching Hospital, Kano.

**Study design:** This is a retrospective descriptive study, involving all acceptors of Jadelle Subdermal implant in the family planning unit of Aminu Kano Teaching Hospital Kano, North western Nigeria.

**Results:** A total of 1505 clients accepted contraceptive methods during the study period. Out of these, 102 had Jadelle inserted, giving a rate of 6.8%. All the clients who accepted Jadelle had it inserted for child spacing. The mean age of the clients at insertion was 28.9 years  $\pm$  6.1, the mean parity at insertion was 3.3  $\pm$  1.8, while the mean weight at insertion was 63Kg  $\pm$  11.4.

About 94% of the clients had secondary and tertiary education. 42.2% of the clients had used a modern contraceptive method previously while the remaining 57.8% were using a modern method for the first time. Nine clients reported post insertion complication, pain at the site of insertion was reported by three clients, and pruritus was reported by one client and intermenstrual bleeding by five of the clients. Five women discontinued the method; 3(60%) was due to menorrhagia.

**Conclusion:** The continuation rate of the method is high (95.1%). Majority of the acceptors (98%) had formal education, only 2% of the acceptors were illiterate. Public enlightenment will improve its use among the non literate women. **Keywords:** Jadelle, Subdermal implant, Kano, Northern Nigeria

### **INTRODUCTION**

Jadelle is a set of two flexible cylindrical implants consisting of a dimethylsiloxane/methylvinylsiloxane copolymer core enclosed in thin-walled silicone tubing. Each rod contains 75 mg of the progestin levonorgestrel. The core of each rod is a mixture, half of levonorgestrel, half of the elastomer. The rods are sealed with polydimethylsiloxane adhesive and

sterilized. Each rod is approximately 2.5 mm in diameter and 43 mm in length<sup>1</sup>

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Jadelle is a progestin-only product and does not contain oestrogen. The sole active ingredient in the rods is levornogestrel. It has a molecular weight of 312.45. Medical grade silicone rubber materials, including the type used in Jadelle, have been employed in various implantable devices for humans since 1950<sup>2</sup>

The levornogestrel in Jadelle is released at an initial rate of about 100 µg/day at one month, declining to about 40 µg/day at 12 months and to about 30 µg/day at 24 months, stabilizing thereafter at about 30 µg/day. This rate of release results in sufficiently high plasma levels of the progestin to inhibit ovulation and provide effective contraception for up to five years.<sup>1,2</sup>

Jadelle rods can be inserted just below the skin of the woman's inner upper arm through a small incision made either with a scalpel or a disposable pre-loaded inserter. The two rods are placed in the shape of a V opening toward the shoulder. Strict asepsis must be observed to avoid infection. Training of health care providers is essential for proper placement and removal. The better the placement, the easier removals will be<sup>2</sup>.

The annual pregnancy rate per 100 users was 0.1 at one, two, and three years, 0.0 at four years, and 0.8 at five years. The Pearl Index pregnancy rate was less than 0.2 pregnancies per hundred woman-years.<sup>3</sup>

Adverse events that have been reported include, irregular menstrual bleeding in the form of prolonged episodes of bleeding or spotting, heavy bleeding, bleeding or spotting between periods, no bleeding at all for several months or a combination of these patterns,<sup>4</sup> fortunately, for most women, these menstrual irregularities will diminish gradually with continuing use.<sup>5</sup>

Other adverse events reported in 10% of women in the Jadelle clinical trials were pain, discolouration or other skin reactions at the site of implant, dizziness, leucorrhoea, mastalgia, nausea, pelvic pain and

weight gain; which are common with progestin only contraceptives.<sup>5</sup>

The objectives of this study is to determine the acceptance rate, the socio-demographic profile and post insertion complications among clients using this method of contraception in our centre and to report the rate and reasons for discontinuation of the method.

## **MATERIALS AND METHOD**

### **Study Area**

Aminu Kano Teaching Hospital, Kano is one of the tertiary/ referral health facilities for Kano and its environs. It is a 500 bed hospital established in 1988. Located in Kano, the largest commercial centre of Northern Nigeria. This hospital receives clients from within Kano and neighbouring states of Bauchi, Katsina, Jigawa, Kaduna and Zamfara. The hospital has sixteen (16) departments. The clinical departments are Obstetrics and Gynaecology, Surgery, Internal medicine, Paediatrics, Ophthalmology, Orthorhinolaryngology, Anaesthesia and family Medicine. The Para clinical departments include; haematology and blood bank, microbiology, histopathology, chemical pathology, radiology, physiotherapy, community medicine and the pharmacy. The hospital operates family planning clinics five days a week seeing an average of 40 clients per day.

### **Study Design/Study Population**

This study was a retrospective descriptive study. All clients who had Subdermal Jadelle implant inserted at the family planning clinic of Aminu Kano Teaching Hospital between January 2011 and December 2012 formed the study population. The case files of the clients accepting the method in the centre were retrieved. Socio-demographic data, previous method of contraception, post insertion complications and reasons for discontinuation of the

method were obtained. None of the client reported been pregnant while using the implant. Analysis was done using absolute number and percentages.

## **RESULTS**

A total of 1505 clients accepted contraceptive methods during the study period. Out of these, 102 had Jadelle inserted, giving a rate of 6.8%. All the clients who accepted Jadelle had it inserted for child spacing. The mean age of the clients at insertion was 28.9 years  $\pm$  6.1, the mean parity at insertion was 3.3  $\pm$  1.8, while the mean weight at insertion was 63Kg  $\pm$  11.4. There was no significant weight gain during follow up.

About 89% of the clients had secondary and/or tertiary education. Four percent had only primary education, and another 5% had only Islamic education. The remaining 2% were not literate.

Forty two percent of the clients had used a modern contraceptive previously; the remaining 58% were using a modern contraceptive method for the first time.

Nine of the clients had post insertion complication. Pain at the site of insertion was reported by three clients, pruritus by one client and intermenstrual bleeding by five of the clients.

Five women discontinued the method; three of these (60%) were due to menorrhagia. Those that discontinue the method are below the age of thirty and of parity less than five.

## **DISCUSSION:**

Acceptors of Jadelle constituted 6.8% of all new users within the study period. This is higher than 0.95% reported in a similar study in Port Harcourt<sup>5</sup>. The acceptance rate is however lower than 12.5% reported for Norplant in Lagos.

The key advantages of contraceptive implant are its effectiveness, convenience, safety, long term contraceptive protection that commence within

twenty four hours and return of fertility almost immediately after its removal<sup>6</sup>. Annual pregnancy rates following typical use of Jadelle is 0.24per 100 woman years<sup>7</sup>. None of the acceptors in this study reported pregnancy during its use.

Common side effects of implants which could limit its acceptability are disruption of menstrual cycle. These include menorrhagia, spotting between periods and oligomenorrhoea<sup>6</sup>. Amenorrhoea may also occur in about 20-30 % of levornogestrel implant users compared to 30-40% of etornogestrel (implanon) users<sup>6</sup>. In our study, the complications reported are pain at the site of insertion was reported by three (3%) clients, pruritus by one(1%) client and intermenstrual bleeding by five(5%) of the clients.

The mean age and parity of the clients in this study were 28.9 $\pm$ 6.1 and 3.3 $\pm$ 1.8; these figures are comparable to 33.81 and 4.05 reported from a similar study in Portharcourt<sup>5</sup>. The mean age of the clients in this study is also comparable to 27.2 $\pm$ 5.2 in a study in the United States; however the mean parity in our study of 3.3 $\pm$ 1.8 is higher than 1.4 obtained in the United States study<sup>8</sup>. This is probably due to higher parity of women in our environment compared to United States. The mean weight of the women at insertion of the implant was 63Kg  $\pm$  11.4; this is comparable to 56.6 $\pm$ 9.6 reported from Bangkok<sup>9</sup> and 56.1 $\pm$ 9.2 reported in Mexico<sup>10</sup> Weight gain was not a problem in our study, because only one client discontinued the method due to this reason.

Weight was not a barrier to offering Jadelle in our unit. This is because; there is no evidence that body weight affects the efficacy of implants and in our study, weight gain did not pose a problem with the clients. Although clinical trials of this method included relatively few women who weighed >90 Kg, hence the effect of increased body weight on efficacy is unknown. Serum levels of implants are inversely related to the body weight and decreased with time after insertion<sup>11</sup>. This aspect of levornogestrel

implants efficacy should be discussed when counselling overweight women.

The mean number of living children of the clients in this study is 3.1±1.7 this is similar to 2.0±0.9 obtained in a study in Mexico<sup>10</sup>.

Fifty six percent (56%) of the clients in this study had been on other form of contraception while the remaining 44% were taking a contraceptive method for the first time. The proportion of those taking contraception for the first time in this study was higher than 11%<sup>10</sup> and 20.6%<sup>11</sup> reported by other workers. This could be due to campaign on the efficacy and safety of the method during the antenatal health talk and counselling in the family planning clinic.

Majority of the clients (89%) had secondary and/or tertiary education, 5% had Islamic education, and 4% had primary education, while 2% were non literate. This is comparable to 75.8% who had secondary and/or tertiary education in Jos<sup>11</sup>. The findings contrast however with the findings in Bangkok study where majority of the clients (71.4%) had primary education, 21.4% had secondary education and 4.3 had Vocational education<sup>9</sup>. The low proportion of the non literate and those with Islamic and primary education among the acceptors in this study could be due to aversion to western oriented programs in our setting.

Nine percent of the clients had post insertion complication. Three of these had pain, and five had intermenstrual bleeding. This is comparable to findings by other workers<sup>12</sup>.

Five clients discontinued the method, three (60%) of these were due to menorrhagia, this is comparable to 57.5% of women removing implants due to menstrual disturbance in Jos<sup>1</sup>, but lower than 78.6% in Northern Ethiopia.<sup>13</sup> One (20%) of the client discontinued the implant because of weight gain, this is lower than 35.7% reported in Northern Ethiopia.<sup>13</sup> The continuation rate in this study was

95.1%, which is comparable to 98.9% obtained by other workers<sup>11</sup>

In conclusion, the acceptance rate of Jadelle was 6.8% of all new users within the study period. The continuation rate of the contraceptive implant is high (95.1%). Ninety one percent of the acceptors had secondary/tertiary education. Public enlightenment on its efficacy and safety will improve its acceptance among the illiterate women.

**Table 1: Sociodemographic profile of the clients accepting Jadelle in AKTH**

Parameter	Frequency	Percentage
a. Age		
15-20	5	4.9
21-25	23	22.6
26-30	38	37.3
31-35	25	24.5
36-40	8	7.8
41-45	2	2.0
46-50	1	0.9
Total	102	100
Age range= 18-49      mean age 28.9±6.1		
b. Parity		
1-5	90	88.2
6-10	12	11.8
Total	102	100
Parity range= 1-10,      mean parity 3.3±1.8		
c. Number of living children		
1-5		
6-10	92	90
Total	10	10
	102	100

**Table 2: Educational level of clients accepting Jadelle**

Educational level	Frequency	percentage
None	2	2
Primary	4	4
Secondary	40	39
Tertiary	51	50
Islamic	5	5
Total	102	100

**Table 3: post insertion complication**

Post Insertion Complication	Frequency	Percentage
None	93	91
Pain	3	3
Pruritus	1	1
Intermenstrual bleeding	5	5
Total	102	100

**Table 4. Reasons for Discontinuation**

Reasons For Discontinuation	Frequency	Percentage
Menorrhagia	3	60
Weight Gain	1	20
Divorced	1	20
Total	5	100

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