ORIGINAL RESEARCH ARTICLE

Predictors of Discontinuation of Subdermal Levonorgestrel Implants (Jadelle) at the Lagos University Teaching Hospital, Lagos, Nigeria: An Analytic Cohort Study

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Abstract

Uptake and continuation of long acting reversible contraceptives (LARC) such as subdermal levonorgestrel implants are pivotal to the achievement of some sustainable development goals (SDG). We evaluated Jadelle uptake and factors affecting its discontinuation in the first three years of initiation at the Family Planning Clinic of the College of Medicine, University of Lagos (CMUL), Nigeria. A retrospective cohort study was conducted among 517 consecutive new Jadelle acceptors, at the family planning clinic of CMUL, between 1 October 2007 and 30 September 2010, who were followed up till 30 September 2011. Survival life table analysis, Kaplan-Meier plots and multivariable Cox proportional hazard regression were conducted to evaluate factors affecting time to Jadelle discontinuation. Stata version 13 statistical software (StataCorp USA) was used for analysis. The mean age of Jadelle acceptors was 32.9 (S.D: ±5.4) years and uptake rate of Jadelle was 61.8%. The overall discontinuation rate was 19 per 100 women-years while the 1-year, 2-year and 3-year Jadelle discontinuation rates were 7.1%; 27.0% and 58.1% respectively. Increased age, (P=0.047) and previous contraceptive use (P <0.001) were independent predictors of Jadelle discontinuation. Menstrual irregularity (51.4%) and intention to get pregnant (40.3%) were the commonest reasons for discontinuation. The failure rate was low at 0.27 per 100 women-years. This study showed that Jadelle had a high uptake rate complimented by a low failure rate; and is quite suitable for postpartum childbirth spacing as well as ongoing long term contraception. *(Afr J Reprod Health 2020; 24[2]: 48-63).*

Keywords: Clinical experience, Jadelle, Lagos, long acting reversible contraceptives (LARC), progestogen only implant, survival analysis, Nigeria

Résumé

L'adoption et la poursuite de contraceptifs réversibles à longue durée d'action (LARC) tels que les implants sous-cutanés de lévonorgestrel sont essentiels à la réalisation de certains objectifs de développement durable (ODD). Nous avons évalué l'adoption de Jadelle et les facteurs affectant son arrêt au cours des trois premières années d'initiation à la Clinique de planification familiale du Collège de médecine de l'Université de Lagos (CMUL), au Nigéria. Entre le 1er octobre 2007 et le 30 septembre 2010, une étude de cohorte rétrospective a été menée auprès de 517 nouveaux accepteurs Jadelle consécutifs, à la clinique de planning familial du CMUL, suivis jusqu'au 30 septembre 2011. Une analyse de la table de survie, des parcelles de Kaplan-Meier et une régression proportionnelle multivariable du risque de Cox ont été réalisées pour évaluer les facteurs affectant le délai avant l'arrêt de Jadelle. Le logiciel statistique Stata version 13 (StataCorp USA) a été utilisé pour l'analyse. L'âge moyen des accepteurs de Jadelle était de 32,9 ans (ET: ± 5,4) et le taux d'absorption de Jadelle était de 61,8%. Le taux global d'abandon était de 19 pour 100 femmes-années tandis que les taux d'abandon Jadelle 1 an, 2 ans et 3 ans étaient de 7,1%; 27,0% et 58,1% respectivement. L'augmentation de l'âge (P = 0,047) et l'utilisation antérieure de contraceptifs (P <0,001) étaient des prédicteurs indépendants de l'arrêt de Jadelle. L'irrégularité menstruelle (51,4%) et l'intention de tomber enceinte (40,3%) étaient les raisons les plus courantes de l'arrêt. Le taux d'échec était faible à 0,27 pour 100 femmes-années. Cette étude a montré

que Jadelle avait un taux d'absorption élevé complété par un faible taux d'échec; et est tout à fait adapté à l'espacement des naissances post-partum ainsi qu'à la contraception à long terme en cours. *(Afr J Reprod Health 2020; 24[2]: 48-63).*

Mots-clés: Expérience clinique, Jadelle, Lagos, contraceptifs réversibles à longue durée d'action (LARC), implant progestatif seul, analyse de survie, Nigéria

Introduction

Effective contraception reduces unintended pregnancy, unsafe abortion and maternal and child morbidity and mortality[1–3]. However, overall contraceptive prevalence in Nigeria is low at about 15%[4.] and this is associated with high fertility rate (5.5 per woman)[4], coupled with high maternal and child mortality estimates[5–7]. Also, failure to use effective contraception leads to unsafe abortion which accounts for 18-25% of maternal morbidity and mortality in the country[1,7,8]. In addition to a dysfunctional reproductive health system, the aforementioned poor reproductive health indicators also suggest some degree of discrimination against women and denial of the sexual and reproductive health rights to girls and women in Nigeria. Therefore, efforts must be made to increase the prevalence and continuation rates of effective contraception among Nigerian women in order to achieve the sustainable development goals (SDG) 3 and 5[9].

Long acting reversible contraceptives (LARC) such as levonorgestrel (Jadelle) have the advantages of being effective, convenient, cost effective, independent of coitus and generally safe[11,12]. With LARC, women would have reduced risk of situational barriers to contraceptive use and thus be in control of their fertility[10] . However, there are possible side effects of levornorestrel. Women mainly experience menstrual irregularity during the first year of levonorgestrel insertion but the abnormal bleeding pattern improves afterwards[10,11,13]. Other possible side effects are headaches, weight gain, acne, hair loss, hirsutism, dizziness, breast tenderness, fatigue, nausea and lower abdominal pain[10,11,13]. Occasional complications may be related to levonorgestrel rod insertion and removal[10,11,13]. The menstrual irregularities following levonorgestrel insertion can be managed expectantly with proper counselling or with low dose estrogen, combined oral contraceptive pills (COCP), mifepristone or COX 2 selective inhibitors[14]. Nonetheless, some clients would discontinue progestin only implants at different times of follow-up for varying reasons[2,10,13–21]. Given the high risk of unintended pregnancy associated with abrupt discontinuation of a contraceptive method[13,15,18,21–23] and the fact that early removal of implants prevents the maximization of the cost effectiveness of the method[18], it is appropriate to determine the associated risks of discontinuation in our setting to aid proper counselling and improve practice.

Although about eleven million women are reported to be using levonorgestrel implant globally[10], but previous Nigerian studies showed that male condom and Intrauterine Contraceptive Device (IUCD) were the most popular contraceptive methods chosen by women who attended the family planning clinic of the College of Medicine, University of Lagos, (CMUL) Nigeria[13,14]. The high prevalence of human immunodeficiency virus (HIV) infection and the fear of perceived "deleterious" effects of hormonal contraceptives on fecundity were reasons adduced for the previous contraceptive choice pattern[13,14]. However, this pattern was before the incorporation of the two-rod levonorgestrel (Jadelle) implant into clinical practice at the centre. The two-rod levonorgestrel (Jadelle) implant was introduced at the family planning clinic of the CMUL in 2007 after several workshops were held to train healthcare providers in the art of counseling of clients, insertion and removal of Jadelle. The commodity was also provided at subsidized rates. Such efforts were likely to increase the acceptance and continuation rates of Jadelle at the centre[12,25,26]. Information about the pattern of uptake, reported side effects and discontinuation of Jadelle implant in the centre is required to aid proper counseling and further implementation research on the method. This study aimed to evaluate the uptake of Jadelle and factors affecting

its discontinuation among a cohort of family planning clients at a foremost publicly owned family planning clinic in Lagos, South Western Nigeria. This would serve to provide data for programmatic public health evaluation and interventions aimed at improving contraceptive practice.

Methods

This study was a retrospective cohort study of consecutive new clients who attended the family planning clinic of the CMUL, Lagos, South Western Nigeria, from 1 October 2007 to 30 September 2010. This study covers the period of the first three years of initiation of Jadelle at the clinic. The family planning clinic is located adjacent to the ante natal clinic of Lagos University Teaching Hospital (LUTH) and is open to all clients from Lagos state. 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 contraceptive methods to enable them make an informed choice. Afterwards, insertion of Jadelle rods was performed for the acceptors according to the protocol of the association for voluntary surgical contraception (AVSC) for Jadelle®. 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 follow-up visit, the clients' weight and blood pressure are measured. Clients that complained about any side effect are attended to as appropriate. Events at each visit were clearly documented.

The records of all contraceptive acceptors at the clinic during the study period of 1 October 2007 to 30 September, 2010 were reviewed. The total number of clients and their choice of contraceptive method were determined. The records of new Jadelle acceptors from 1 October 2007 to 30 September 2010 were then retrieved in October 2011 for further analysis. This ensured that all the clients would have had at least one year of follow-up. Anonymized data that were obtained from the records included clients' age, parity, number of children alive, desire for more children at baseline, educational status, marital status, religion, occupation, previous contraceptive use, duration of Jadelle use (in months), side effects and reasons for discontinuing Jadelle®.

Statistical analysis

The time-variable outcome of interest was 'time to discontinuation of Jadelle (in months)' and all clients that were lost to follow-up or continued Jadelle beyond September 2011 were right censored. All descriptive statistics of the variables were conducted while normally and non-normally distributed variable(s) were presented as mean ±standard deviation (SD) and median (Interquartile range (IQR) respectively. Association between categorical and continuous variables and Jadelle discontinuation was conducted with the aid of Pearson's Chi –square and students t-test (or Wilcoxon rank sum test in case of non-normally distributed variable) respectively.

For time to event analysis of Jadelle discontinuation, survival analysis, Kaplan-Meier plots and life table probabilities were utilized to describe the overall risk of discontinuation of Jadelle at 6 months, 12 months, 24 months and 36 months respectively. Similar risk analysis was conducted according to age, ethnic groups, educational status, and reasons for discontinuation. A log-rank test of equality of survivors was also conducted to check for differences in discontinuation risks among the categories of a variable.

The overall discontinuation rate (in women-years) was also calculated by dividing the number of clients who discontinued Jadelle over the 48 months of follow-up by the women-years of follow-up. The pregnancy rate (cumulative failure rate) was also calculated as number of pregnancies while on Jadelle divided by the women-years of follow-up. Univariable Cox proportional hazard regression analysis was conducted and baseline variables with overall Wald's P-value <0.2 were

included in the multivariable analysis using a stepwise forward regression process. Age group and 'desire for more children' were selected *a priori* based on literature and experience of the researchers[3,14,16,21,26]. Two models were built: (i) with and (ii) without the variable "previous contraceptive use" since this variable can potentially have collinearity with other variables such as "current contraceptive use" and" desire for more children". Also, 'parity' or 'child alive' and 'educational level' or 'occupation' respectively was not included in the same model because there was collinearity when they were added together. The best model was the model with smallest statistically significant Wald's overall P-value. The final model was tested for violation of the assumption of Cox proportionality by utilizing the Global test of Schoenfeld. Statistically significant levels were set at 95% confidence interval (P-value<0.05). Variance estimator with the robust option (VCE [robust]) was utilized for analysis to obviate for any misspecification and violation of regression analysis. Two-tailed test of hypothesis was assumed. All analyses were conducted using Stata 13 (Stata Corporation TX USA) statistical software.

Results

Cohort characteristics

Figure 1 shows that 837 clients accepted various contraceptive methods at the family planning clinic during the study period. Majority (n=517, 61.8%) of the clients accepted Jadelle. Ninety (17.4%) of the Jadelle acceptors, were lost to follow-up and were right censored while 283 (54.7%) of the acceptors who continued using Jadelle beyond the end of the study period were also right censored. However, 144 (27.9%) Jadelle acceptors discontinued during the study period.

The mean age of Jadelle acceptors was 32.9 (±5.4) years. Majority of the acceptors were married (n=505, 97.7%), had post-secondary education (n=366, 70.8%), were professionals or skilled individuals (n=360, 69.7%) and of the Christian faith (470, 90.9%). (Table 1)

From Table 1, marital status, religious belief, occupational class, ethnic group and educational attainment were not statistically different among those that discontinued Jadelle and those that continued or were lost to follow-up.

From Table 2, the median parity of the cohort was 3 (Interquartile range (IQR): 2- 4) while the number of living children ranged from 0 – 11 with a median of 3 (IQR: 2-4). Almost all the Jadelle acceptors had used a contraceptive method before Jadelle uptake (486/517, 93%). At baseline, majority 459 (88.8%) of the clients wished to have more children in the future. The mean age (34.8 (±4.9) Vs. 32.1(±5.4), P-value<0.001) and median number of children alive (4 (IQR: 3-5) Vs. 3 (IQR: 2-5), (P-value <0.001)) were slightly higher among those that discontinued Jadelle as compared to others that continued or were lost to follow up (Table 1 and Table 2). Nearly half (44.7%, n=200/447) of the Jadelle acceptors with complete data reported side effects (Table 2). Further, complete case analysis showed that there was no difference in the distribution of side effects among clients that discontinued Jadelle and those that did not (P-value = 0.479). Data not shown

Table 3 shows that the commonest complaints were menstrual problems (60.5%) and menorrhagia was the leading menstrual problem. Two of the women became pregnant while on Jadelle giving a failure rate of 0.39% and Pearl index of (cumulative pregnancy rate) of 0.27 per 100 women-years.

Jadelle discontinuation risks from life tables and Kaplan Meier plots

About half (n=74, 51.4%) of the 144 women that discontinued Jadelle did so because of the side effects/complications they experienced after Jadelle insertion. While another considerable proportion (n=58, 40.3%) discontinued Jadelle because they desired to get pregnant (Table 4). The majority (102/144, 70.8%) of clients that discontinued Jadelle did not switch to another contraceptive. Most of those that did, (15/32, 46.9%), switched to IUCD followed by injectable (8/32, 25%); Condom (6/32, 18.8%) and combined

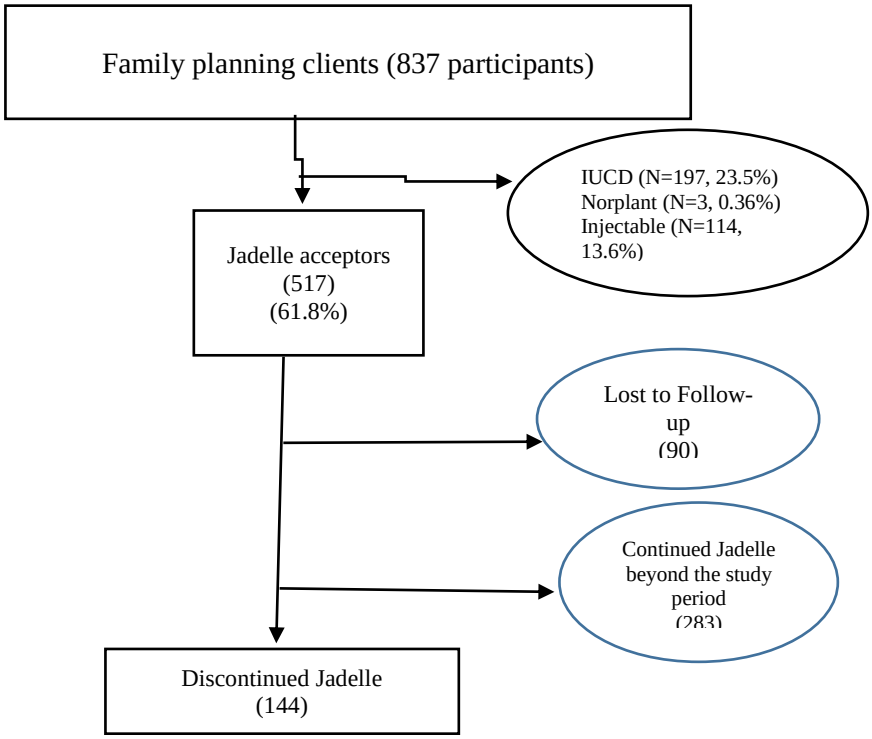

Figure 1: Flow chart showing clients' choice of Contraceptive Methods at the Family Planning Clinic, College of Medicine, University of Lagos (CMUL), Nigeria

Table 1: Comparison of the Socio-biological characteristics of the Jadelle acceptors who discontinued Jadelle and those who were censored

Characteristics	**Participants that were right censored N=373 (%)**	**Participants who discontinued Jadelle N= 144 (%)**	**Total N=517 (%)**	**P-value**
Age (mean±sd)	32.1(± 5.4)	34.8 (±4.9)	32.9 (±5.4)	<0.001*#
<20	4 (1.1)	0 (0.0)	4 (0.8)	<0.001*
20-24	23 (6.2)	3 (2.1)	26 (5.0)	
25-29	88 (23.6)	14 (9.7)	102 (19.7)	
30-34	141 (37.8)	53 (36.8)	194 (37.5)	
35-39	84 (22.5)	49 (34.0)	133 (25.7)	
40-44	27 (7.2)	20 (13.9)	47 (9.1)	
45-49	6 (1.6)	5 (3.5)	11 (2.1)	
Marital status				
Married	382 (97.1)	143(99.3)	505 (97.7)	0.306
Single	10 (2.7)	1 (0.7)	11 (2.1)	
Divorced	1 (0.3)	0 (0.0)	1 (0.2)	
Religion				
Christianity	335 (89.8)	135 (93.8)	470 (90.9)	0.344
Islam	37 (9.9)	9 (6.3)	46 (8.9)	
Others	1 (0.3)	0 (0.0)	1(0.2)	
Occupation				
Professional	43 (11.5)	9 (6.3)	52 (10.1)	0.302
Skilled	216 (57.9)	92 (63.9)	308 (59.6)	
Semi-Skilled	26 (7.0)	11 (7.6)	37 (7.2)	
Unskilled	88 (23.6)	32 (22.2)	120 (23.2)	

Tribe				
Hausa	2 (0.5)	0 (0.0)	2 (0.4)	0.552
Igbo	119 (31.9)	43 (29.9)	162 (31.3)	
Yoruba	209 (56.0)	79 (54.9)	288 (55.7)	
Others	43 (11.5)	22 (15.3)	65(12.6)	
Educational attainment				
Primary	24 (6.43)	5 (3.5)	29 (5.6)	0.368
Secondary	85 (22.8)	37 (25.7)	122 (23.6)	
Post-secondary	264 (70.8)	102 (70.8)	366 (70.8)	

*IQR: Interquartile range; !P-value for Mann-Whitney test; [#] P-value for student's t-test.

Table 2: Comparison of the Contraceptive and reproductive history of women who discontinued Jadelle and others

Characteristics	**Participants that were right censored N=373 (%)**	**Participants who discontinued Jadelle N= 144 (%)**	**Total N=517 (%)**	**P-value**
Parity (Median±IQR)	3(2-4)	3(2-4)	3(2-4)	<0.001[!]
None	15 (4.1)	1 (0.7)	16 (3.1)	0.014*
1-4	315 (85.4)	117 (81.3)	432 (84.2)	
5 and above	39 (10.6)	26 (18.1)	65 (12.7)	
Desire for more children				
Yes	333 (89.3)	126 (87.5)	459 (88.8)	0.566
No	40 (10.7)	18 (12.5)	58 (11.2)	
Ever used contraceptive before accepting Jadelle				
Yes (IUCD)	19 (5.1)	29 (20.1)	48 (9.3)	<0.001*
Yes, (Pills)	16 (4.3)	24 (16.7)	40 (7.7)	
Yes, (Norplant)	21 (5.6)	6 (4.2)	27 (5.2)	
Yes, (Injectable)	34 (9.1)	58(40.3)	92 (17.8)	
Yes, (Barrier/condom)	13 (3.5)	21(14.6)	34 (6.6)	
Yes, (Not specified)	234 (62.7)	6 (4.2)	240 (46.4)	
No	36 (9.7)	0 (0.0)	36 (7.0)	
^Complaints after Jadelle use				
Yes	136(36.5)	64 (44.4)	200 (36.7)	<0.001
No	147(39.4)	80(55.6)	227 (43.9)	
Missing data	90 (24.1)	0(0.0)	90 (17.4)	
$Specific complaints after Jadelle use				
Menstrual irregularity	88(23.6)	51 (35.4) 51	139 (26.9)	<0.001
Weight gain	18 (4.8)	4 (2.8)	22 (4.3)	
Other complaints	30 (8.0)	9 (7.3)	39 (7.5)	
No complaints	147(39.4)	80 (55.6)	227 (43.9)	
Missing data	90 (19.8)	0 (0.0)	90 (17.4)	

*IQR: Interquartile range;[!]P-value for Mann-Whitney U test; [#]P-value for Student's t-test
^Analysis of complete data (without the missing data): P-value = 0.479
[$]Analysis of complete data (without the missing data): P-value = 0.162

oral contraceptive pills (COCP) (2/32, 6.3%). Data not shown in table. The overall discontinuation rate of Jadelle for the study period was 19 per 100 women-years and the median time to discontinuation of Jadelle was 35 months (Figure 2). However, the overall 6-month, 1-year, 2-year and 3-year cumulative discontinuation risks of Jadelle were 2.2%, (95% CI: 1.1 - 4.1), 7.1 (95% CI: 5.0-10.2), 27.0% (95% CI: 22.3 - 32.6) and 58.1% (95% CI: 50.5 - 65.8) respectively (Figure 2). Thus, the risk of discontinuation of Jadelle during the first year was negligible but it abruptly increased and was quadrupled after 2 years of use (Table 5). Also, the risk of discontinuation after the third year of Jadelle use was doubled the discontinuation risk after the second year of Jadelle insertion (Figure 2). The other pattern of discontinuation by age group, number of children alive and desire for more children were shown in Figure 2.

Table 3: Reported side effects/ complications after Jadelle insertion

Complications/ side effects	**[#]Frequency N, (%)**
Abdominal discomfort	12 (5.2)
Acne	1 (0.4)
Breast pain	4 (1.7)
Difficult removal	3 (1.3)
Expulsion	10 (4.3)
Headache	9 (3.9)
Menstrual irregularity	141 (60.5)
Insertion site infection	8 (3.4)
Pain at site of insertion	15 (6.4)
Pregnancy	2 (0.9)
Rashes	6 (2.6)
Weight gain	22 (9.4)
Total	**233**

[#]Multiple responses allowed

Table 4: Reasons for discontinuation of Jadelle among the acceptors

Reasons for discontinuation	**Frequency**	**Percent**
Due to complications	74	55.3
Desire for more children	58	43.3
Cultural belief/myth	0	0
Personal fears	1	0.7
Pressure from spouse	1	0.7
Not stated	10	6.9%
Total	**144**	**100**

Furthermore, there was a statistically significant difference in pattern of discontinuation based on the previous use of contraception (P-value<0.001) while the pattern of discontinuation did not significantly differ based on the complaints of side effects (P-value =0.2118) Figure 3.

Although Christians appeared to discontinue Jadelle earlier than Muslims but the difference was not statistically significant (P-value = 0.0853) (Figure 4). In addition, women who had tertiary education appeared to have longer duration of continuing Jadelle as compared to others, but the difference did not reach statistical significance (P-value = 0.1494) (Figure 4)

Furthermore, Table 5 shows that teenagers though few had 100% Jadelle continuation rate (or 0.0% discontinuation risk) while women aged 35 - 39 years had the highest risk of discontinuation followed by women aged 30 – 34 years. This pattern was more pronounced from 24th month (P-value = 0.0382). Women who desired to have more children had a higher risk of Jadelle discontinuation especially after 24 months of use. Also, previously contraceptive naïve individuals had a 100% cumulative risk of Jadelle continuation (or 0.0% discontinuation risk) while those who had previously used other contraceptives had varying levels of discontinuation risk (P<0.001). Intention to get pregnant as reason for discontinuation became pronounced after 24 months (60.7% (95% CI: 43.5 - 78.3)) and 36 months (96.4% (95% CI: 84.6 - 99.7)) of Jadelle insertion respectively (Table 5).

Factors associated with Jadelle discontinuation (Cox regression analysis)

From Table 6, the univariable Cox proportional hazard regression analysis shows that women who were 30 years and older had about two-fold risk of discontinuing Jadelle contraceptive as compared with women younger than 30 years (For 30- 39 HR = 1.94, 95% CI: 1.15-3.28, P-value =0.013). Among clients with previous contraceptive experience, previous COCP users had the highest likelihood of about 2.7 fold hazards of discontinuing Jadelle (HR =2.70, 95% CI: 1.02 - 3.96, P-value = 0.044)

However, on multivariable analysis, only 'previous contraceptive use' had statistically significant association with Jadelle discontinuation (P-value <0.05) in the first multivariable model that included this variable. Of those acceptors who had prior contraceptive experience, COCP, injectable and condom users had between 2 to 3 fold likelihood of discontinuation as compared to previous Norplant implant users (Table 6). But the median time to discontinuation of Jadelle among previous COCP (22 months), injectable (27 months) and condom (29 months) users was still relatively long (Table 5).

Previous acceptors of IUCD did not have a statistically significant difference in discontinuation risk as compared with previous Norplant users. The second multivariable model without "previous contraceptive use" showed that

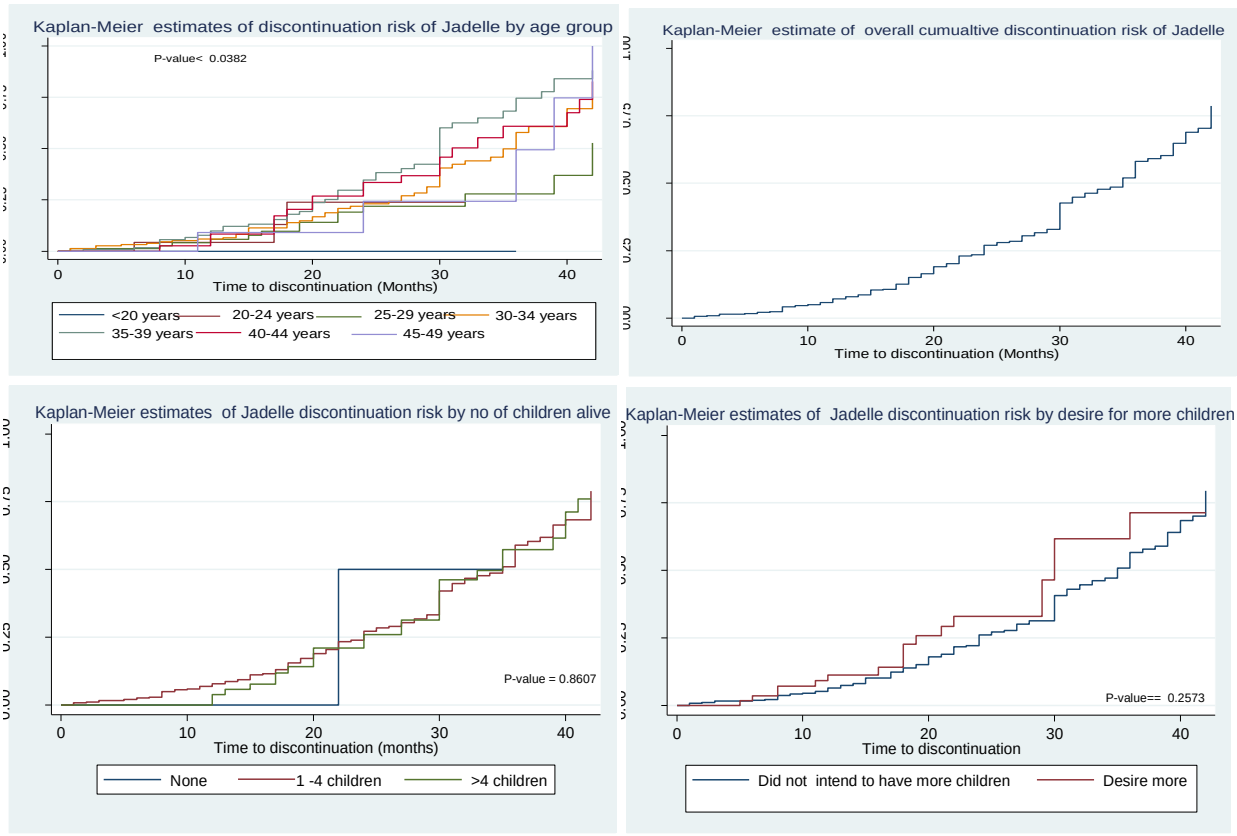

Figure 2: Kaplan Meir plot showing the overall cumulative discontinuation risk of Jadelle, by age group, number of children alive and desire for more children

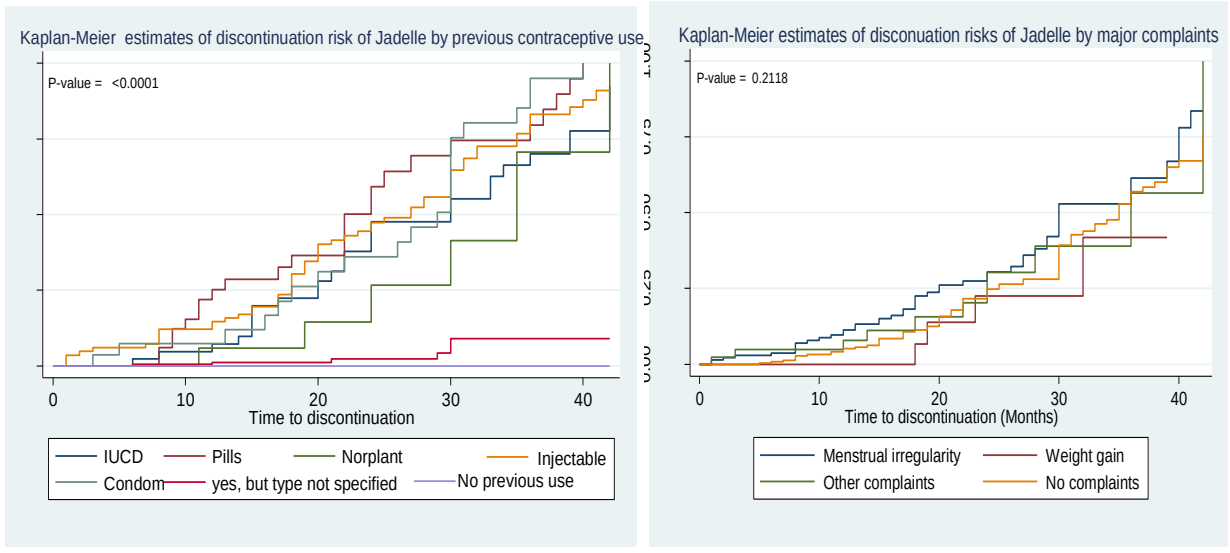

Figure 3: Kaplan Meir plots of the discontinuation risk of Jadelle by previous contraceptive use, and main complaint during Jadelle use

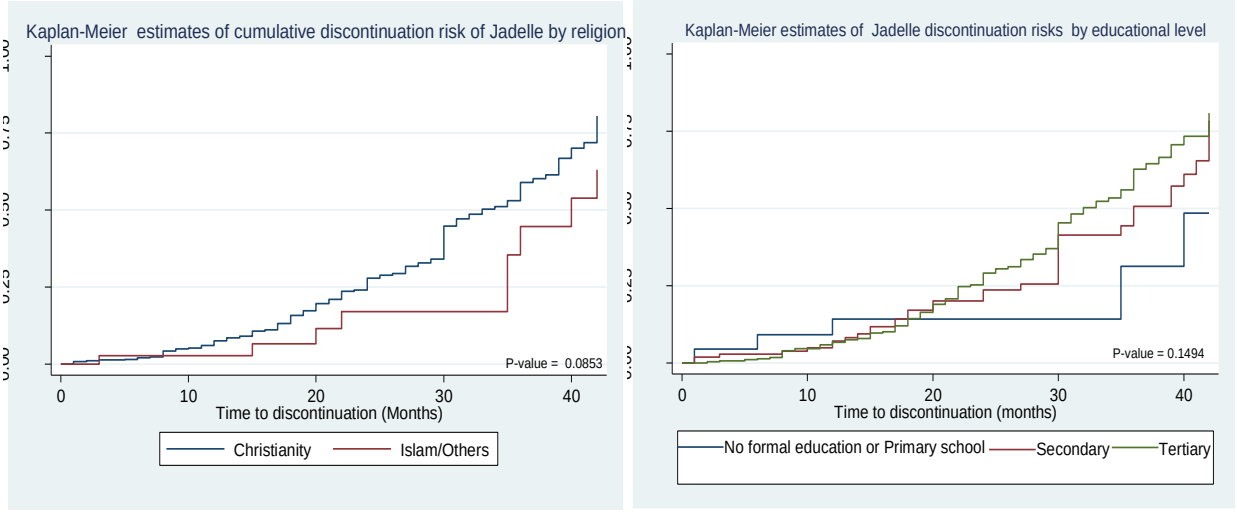

Figure 4: Kaplan Meir plots of the cumulative discontinuation risk of Jadelle by religious belief and educational attainment

the risk of discontinuing Jadelle increased with age as women older than 39 years had about 2 fold increased risk of discontinuing Jadelle as compared to women younger than 30 years (Table 6). There was no violation of the proportionality assumptions since the global P-value was greater than 0.05. (For model I: P-value = 0.4968, for model II: P-value = 0.5411).

Discussion

This study utilized robust analytic methods to determine the pattern of uptake and predictors of time to discontinuation of Jadelle at a public family planning clinic in Lagos, Nigeria. During the study period, Jadelle was accepted by three out of five family planning clients. The overall discontinuation rate for Jadelle was 19 per 100 women years with a median time to discontinuation of 35 months. This study showed that menstrual irregularities were the leading side effect experienced among the cohort of Jadelle acceptors, with menorrhagia being the commonest. However, the commonest reason for Jadelle discontinuation was a desire to get pregnant which applied in 40.3% of cases. The main risk factors for Jadelle discontinuation were age of the clients and previous contraceptive history before using Jadelle. On multivariable analysis, only 'previous contraceptive use' had statistically significant association with Jadelle discontinuation (P-value <0.05) in the first multivariable model that included this variable.

This study found a shift in preference from IUCD to Jadelle at the study centre[24]. A similar finding of increased uptake of progestogen implants was reported in South Eastern part of Nigeria during similar period as our study[12,17]. In contrast, the uptake of progestin implants was reported to be relatively low in the South-South[17,29] and Northern parts[21,29] of Nigeria as well as in most sub-Saharan African countries (SSA), where IUCD and progesterone injectable were more popular[10]. Provision of incentives and subsidy, availability of the commodity, proper counselling and extended clinical experience of its use were reasons proffered for the reported increased uptake of Jadelle in other parts of Nigeria[10,13,21,26,29]. The shift from IUCD to hormonal implants by clients who wished to space child birth indicates that the previous suspicion of reduced fecundity that was attributed to hormonal contraceptives may have been eliminated in our environment by education and counselling.

The modal age group in the study population was 30-34 years and majority (82.9%) were within the age range of 25 and 39 years similar to findings from previous studies in

Table 5: Cumulative probability (risk) of Jadelle discontinuation (life tables) among acceptors at 6 months, 12 months and 36 months

Characteristics	Cumulative risk of discontinuation Jadelle (%, 95% CI)			
	6 months	12months	24months	36months
Overall	2.2(1.1-4.1)	7.1(5.0- 10.2)	27.0(22.3 – 32.6)	58.1(50.5 65.8)
Age				
<20	0.0	0.0	0.0	0.0
20-29	2.0 (0.5- 7.8)	5.5(2.3– 12.7)	22.4 (13.5–35.6)	27.9(16.2– 45.5)
30-39	2.6(1.3– 5.4)	7.5 (4.8- 11.4)	27.7 (21.9– 34.7)	65.6(55.5 – 73.6)
40-49	2.1(0.3-13.9)	8.6(3.3– 21.4)	31.2 (19.3 – 47.8)	58.3 (41.1– 76.5)
Marital status				
Married	2.2 (1.2- 4.2)	7.3 (5.1-10.4)	27.2 (22.3 - 32.8)	58.6 (51.0 - 66.4)
Single/ Divorced	0.0	0.0	25.0 (4.0 - 87.2)	25.0 (4.0 - 87.2)
Desire for more children				
Yes	0.04 (0.01 -0.13)	0.11(0.05-0.23)	0.33(0.20 -0.51)	0.71 (0.47-0.91)
No	0.02 (0.01 -0.03)	0.06(0.04- 0.10)	0.26 (0.21-0.32)	0.57 (0.49 - 0.65)
Religion				
Christianity	2.1(1.1 - 4.1)	7.5(5.2 - 10.8)	27.9 (22.9 - 33.7)	58.9 (51.1 - 66.9)
Islam/ Others	2.7(0.4-17.7)	2.7(0.4 -17.7)	17.0 (6.5 - 40.5)	44.7 (22.5- 74.8)
Occupation				
Professional	2.9(0.4-18.6)	12.6 (4.9-30.2)	42.1 (20.6 - 72.7)	71.1 (31.6- 98.2)
Skilled	1.2(0.4-3.6)	6.3 (3.8-10.2)	28.4 (22.4- 35.7)	60.1(50.6 – 69.7)
Semi-Skilled	0.00 (0.00)	3.6 (0.5– 22.8)	14.2 (4.6- 39.5)	80.0(53.0-96.8)
Unskilled	5.1(2.2–11.8)	8.6(4.4-10.4)	23.5 (15.3-35.1)	42.9 (30.3-58.1)
Tribe				
Hausa/Others	3.9(1.0-14.5)	8.0 (3.1– 19.9)	24.7(13.8-41.7)	54.3 (36.6-73.8)
Igbo	3.1(1.2-8.0)	8.9 (5.0-15.6)	30.3 (21.8-41.0)	60.2 (46.5-74.2)
Yoruba	1.7(06-4.4)	5.9(3.5-10.0)	25.8 (19.7-33.3)	58.4(48.2 – 69.0)
Educational attainment				
Primary	9.1 (2.4-31.7)	14.1 (4.8-37.8)	14.1 (4.8-37.8)	31.3(10.2-73.2)
Secondary	2.9(0.9-8.6)	7.1 (3.4 -14.3)	23.7 (15.6 – 35.1)	50.6(37.1 – 65.8)
Post-secondary	1.4 (0.5-3.6)	6.6(4.2 – 10.3)	29.1 (23.3 – 36.0)	62.7(53.5 – 71.9)
Parity				
Nulliparous	0.0	0.0	50.0(9.0-99.4)	50.0(9.0-99.4)
1-4	1.8 (0.8-4.3)	7.0(4.5 – 10.9)	27.1 (21.2 – 34.3)	54.7(45.2 – 64.9)
5 and above	3.0(1.1– 7.7)	7.8(4.4 – 13.9)	26.6 (19.1 – 36.2)	62.9(51.0 – 74.8)
Type of contraceptive used prior to Jadelle				
IUCD	2.4 (0.3 – 15.7)	7.3 (2.4 – 20.9)	47.7 (32.5 – 65.6)	70.1 (53.3 – 85.3)
Pills	6.1 (1.6 – 22.1)	25.2(13.5– 44.2)	59.2 (40.9 – 78.3)	79.6 (60.8 – 93.3)
Norplant	0.00	5.9 (0.9 – 35.0)	26.7 (8.8 – 64.6)	70.7 (30.3 – 98.5)
Injectable	7,2 (3.3 – 15.4)	14.6 (8.6 – 24.3)	47.4 (36.8 – 59.3)	83.1 (72.0 – 91.7)
Condom	7.4 (1.9 – 26.5)	12.0 (4.0 – 33.1)	41.0 (23.6 – 64.4)	95.1 (79.8 – 99.7)
Type (Not specified)	0.6 (0.11 – 3.9)	1.2 (0.3 – 4.6)	2.3 (0.7 – 7.2)	9.0 (3.7 – 20.7)
Never used any	0.0	0.0	0.0	0.0
Reasons for discontinuation of Jadelle				
Menstrual irregularity	7.1 (1.8 - 25.7)	25.0(12.8 - 45.4)	67.7 (50.7- 83.9)	85.7 (70.5-95.5)
Weight gain/abdominal pain	12.5 (1.9 - 61.3)*	25.0(6.9-68.5)**	75.0(44.2 -96.3)***	100.0****
Wants to get pregnant	3.6 (0.5 - 22.8)^	17.9(7.9 - 37.7)	60.7 (43.5-78.3)	96.4 (84.6-99.7)
Other reasons	8.8 (4.3-17.5)	18.8(11.8-29.2)	51.3 (40.9 - 62.6)	87.5 (79.3 - 93.6)

! There was no risk calculated at required months: *Risks at 8 months, **Risks at 15 months, *** Risk at 28 months, **** Risk at 28 months. ^ Risk at 9 months

Table 6: Univariate and multivariate Cox proportional hazard regression analysis of the risk factors of discontinuation of Jadelle among acceptors

Characteristics	Unadjusted Cox proportional hazard regression analysis			Multivariable Cox proportional hazard regression analysis		
	HR	CI	P-value	^AdjHR	CI	P-value
Age						
<30	1.00	Ref	Ref	1.00	Ref	Ref
30-39	1.94	1.15-3.28	0.013*	1.93	1.13 - 3.29	0.016*
40-49	1.89	1.03 -3.46	0.040*	1.93	1.01- 3.67	0.047*
Parity						
Nulliparous	1.00	Ref	Ref	1.00	Ref	Ref
1-4	1.41	0.21-9.65	0.725	0.82	0.13 - 5.17	0.838
5 and above	1.51	0.22-10.40	0.676	0.83	0.13-5.23	0.832
Desire for more children						
No	1.00	Ref	Ref	1.00	Ref	Ref
Yes	1.32	0.78-2.25	0.300	1.42	0.83 - 2.42	0.203
Complaints with Jadelle use						
No complaint	1.00	Ref	Ref	1.00	Ref	Ref
Menstrual irregularity	1.41	0.98 - 2.00	0.062	1.41	1.00 -1.99	0.05
Weight gain	0.71	0.26 -1.89	0.488	0.74	0.26 - 2.07	0.567
Other complaint	1.10	0.61-1.96	0.758	0.92	0.45 - 1.87	0.818
Ever used Contraceptives before Jadelle						
Norplant	1.00	Ref	Ref	#1.00	Ref	Ref
IUCD	1.52	0.75 -3.10	0.248	1.83	0.90 -3.72	0.093
Pills	2.70	1.31-5.58	0.007*	2.82	1.34 - 5.94	0.007*
Injectable	2.01	1.02-3.96	0.044*	2.07	1.01 - 4.24	0.047*
Condom	2.38	1.20 -4.74	0.014*	2.22	1.08 - 4.57	0.031*
Not specified	0.10	0.04- 0.28	<0.001*	0.10	0.04-0.29	<0.001*
No	1.8e-20	7.8 e-21-4.4e-20	<0.001*	4.8e-17	1.8e-17-1.3e-16	<0.001*
Educational qualification						
At least Primary	1.00	Ref	Ref			
Secondary school	1.81	0.68-4.80	0.231			
Tertiary	2.19	0.85-5.64	0.106			
Religion						
Islam/others	1.00	Ref	Ref			
Christianity	1.77	0.94-3.34	0.077			
Marital status						
Single/Divorced	1.00	Ref	Ref			
Married	2.48	0.35-17.72	0.367			
Number of children alive						
None	1.00	Ref	Ref			
1-4	1.70	0.25-11.42	0.586			
5 and above	1.66	0.24 -11.46	0.608			
Occupation						
Unskilled	1.00	Ref	Ref			
Professional	1.89	0.87-4.13	0.110			
Skilled	1.33	0.88 -2.01	0.173			
Semi-skilled	1.26	0.73- 2.19	0.408			
Tribe						
Hausa/Others	1.00	Ref	Ref			
Ibo	0.97	0.59-1.57	0.889			
Yoruba	0.90	0.58-1.38	0.626			

[#] Multivariable estimates from model I. ^Adjusted hazard ratio estimates are for model II. *P-value statistically significant. CI: 95% confidence interval

Nigeria and elsewhere[10,12–14,17,19–21,28,29]. It is apparent that our family planning clinic was not commonly used by teenagers and young adults possibly due to socio-cultural and other barriers. This suggests that teenagers have unmet contraceptive needs that might increase prevalence of unintended pregnancies and unsafe abortion among them[1,8]. This calls for strategies to make the family planning clinic to be adolescent and youth friendly[12]. Nonetheless, Jadelle continuation rate was 100% among the few teenagers in the study. This confirms the position of the American College of Obstetrics and Gynecology (ACOG) that Jadelle and other progestin implants are safe and acceptable among teenagers[11]. Teunissen *et al* also provided evidence that LARC drastically reduced unintended pregnancy and abortion among teenagers[14]. In our environment where young women are not empowered to negotiate sex because of socio-cultural reasons[8], Jadelle would be useful to them since it is independent of coitus and discrete. However, because of the high prevalence of sexually transmitted infections especially HIV in our setting, the double Dutch system incorporating Jadelle and condom should be advocated among young women[31].

Cox multivariable analysis showed that the likelihood of discontinuing Jadelle increases with age and the discontinuation risk among women at the end of the reproductive spectrum (40-49 years) was about two folds compared to women younger than 30 years. However, the Kaplan Meier plot showed that women older than 45 years had relatively low chance of early discontinuation until close to the 38th month of use when the risk abruptly increased. Such a pattern may suggest that women of that extreme age used Jadelle to limit family size and/ or discontinue as they approach menopause. The higher likelihood of Jadelle discontinuation of about 1.9 folds among women within the ages of 30 and 39 years as compared to women younger than 30 years may be because the former were eager to have more children.

It was expected that women with very high parity (five or more) would use Jadelle as 'limiters' while those with parities less than five would use Jadelle as 'spacers'. Surprisingly, there was no statistically significant difference in discontinuation pattern among the two groups (Kaplan Meier log rank P-value = 0.8). Both groups behaved like child spacers because less than 10% discontinued after 12 months of use and the median time to discontinuation was about 36 weeks among the two groups. However, each group would have discontinued for different reasons. Lower parity group may discontinue so as to have more children while higher parity (who may be older) may discontinue because of peri-menopausal symptoms. Nonetheless, since this study was for 48 months, the expected difference in discontinuation pattern between the two parity groups may only become apparent with prolonged follow-up. Nulliparous women who accepted Jadelle are likely to be neither spacers nor limiters and may not be married. Thus, discontinuation risk was low among them.

Marital status, religion and educational attainment did not affect the discontinuation risk in this study and the life table analysis still suggests prolonged use of Jadelle. This contrasts with findings from a study in Northern Nigeria where Muslims had a higher risk of discontinuing Jadelle, probably because of its menstrual side effects that may debar them from attending the mosque[21]. Ironically, another hormonal contraceptive (progesterone injectable) was said to be popular in the Northern part of the country[21,29], supposedly because of its association with periods of amenorrhea. This study also had relatively few Muslims. However, adequate motivation and counseling may have played a role in the low discontinuation rate of Jadelle among Muslims in our cohort.

Despite the fact that many of the clients complained about menstrual irregularities, the overall risk of Jadelle discontinuation among our clients was less than 10% in the first 12 months of insertion and the median time to Jadelle discontinuation was 35 months. The relatively low overall discontinuation rate of 19 per 100 women-years recorded throughout the 48-month follow-up was similar to reports from other Low and middle income countries[13,19,28] but lower than implant

discontinuation rates of most studies from High income countries (40-60%) [13,30]. This study found that one in three women was likely to request for Jadelle removal, two years after insertion and about half may stop after three years of use. This may not be far-fetched since the majority (88%) of our clients had the desire to have more children at baseline and the median parity of the cohort was 3 (which was relatively low in the African context). Also, a considerable proportion (40.3%) of those that discontinued Jadelle did so because they wanted to get pregnant. However, the Kaplan Meier plot and life table showed that the difference in discontinuation risk between those that wanted to have more babies and those that did not was not apparent until after the 24th month of use, when the former group discontinued abruptly. The foregoing suggests that most of the clients used Jadelle to space child-birth.

More than 93% of Jadelle acceptors had previously used other contraceptive methods. They might have switched from other methods to Jadelle, possibly because of side effects or because of the publicity and promotion of Jadelle at its initiation at our centre. Furthermore, the clients are well educated, highly skilled and mostly Christians, attributes that have been previously reported to increase contraceptive prevalence in our environment[24,31]. Surprisingly, the previous contraceptive naïve Jadelle acceptors had 100% continuation rate during the study. Further study is therefore required on the motivation for the Jadelle continuation rate among the contraceptive naïve clients. However, women who previously used COCP had an increased likelihood of discontinuing Jadelle of about 2.8 folds as compared with previous Norplant users. But the life table still showed that the median time to discontinuation of Jadelle among previous COCP users was still relatively long (22 months). Thus, the previous pill users are also child birth spacers and not long term users as 10 out of 24 (41.7%) of them stopped because of their desire to get pregnant and none of them stopped on account of menstrual or abdominal side effects.

This study found that menstrual irregularities were the leading side effect experienced among our cohort of Jadelle acceptors, with menorrhagia being the commonest. This pattern is similar to findings from previous studies[10,12–14,17,19–21,28,29]. However, in contrast to previous studies that reported side effects as playing significant roles in implant discontinuation[14], we found that there was no statistically significant difference in discontinuation risk among those who had complaints and those that did not after multivariable analysis. This may be due to a difference in statistical analysis but may indicate that the clients were better counseled and motivated; and that the side effects were managed to their satisfaction. The failure rate of less than 1% (0.39%, with Pearl index of 0.27 per 100 women-years) over the four year study period. This is within the low range of failure rate of 0-1.1% obtained both in Nigeria and elsewhere[13,30], such that the effectiveness of progestin implants is comparable to permanent contraceptive methods[30]. It is noteworthy that the two clients who became pregnant got pregnant in the first month of Jadelle insertion. This raises the suspicion that they might have been pregnant before the insertion since the effect of Jadelle commences within 12 to 24 hours after insertion [10]. Similar experience has also been reported in Jos, North Central Nigeria and elsewhere[19]. Comprehensive menstrual and sexual history is therefore necessary before Jadelle insertion and if in doubt, a blood β-HCG test may be necessary to rule out pregnancy [19].

Strengths and Limitations

This was an ongoing cohort study of family planning acceptors which utilized survival analysis, life tables and person-year approach to evaluate discontinuation risk of Jadelle contraceptives. Previous studies in Nigeria utilized descriptive statistics without considering the person-years of follow-up in contrast to the more robust survival analysis methods employed in this study[10,12,13,17,19–21,28,29]. It may therefore be difficult to strictly compare the results with other previous local studies.

However, the results should be interpreted in the context of recognized limitations. Our clients were

generally well educated, skilled professionals and of high socio-economic status and may not be representative of the general population. Medical/obstetric conditions such as HIV, hypertension, sickle cell disease may affect discontinuation rate of Jadelle but were not reviewed in this study. A significant proportion (17.4%) of the clients was lost to follow-up and was right censored. This pattern was also reported at Benin City, Nigeria[13]. But since the insertion and removal of Jadelle was provider dependent, those lost to follow-up might have continued with Jadelle without any complication to warrant their visiting the clinic[13]. However, when we compared the baseline characteristics of the right censored participants and those that discontinued there was no difference.

Conclusion

Jadelle is an effective and safe LARC and the uptake increased dramatically at our centre after its initial introduction. The discontinuation risk of Jadelle was minimal in the first 12 months but quadrupled after 24 months and its discontinuation risk increased with increasing age of the client. Although intention to get pregnant and menstrual irregularities were common reasons for discontinuation, menstrual irregularities appear not to play major role in the Jadelle discontinuation pattern after considering all other associated factors. Thus, it appears that most of the acceptors of Jadelle in this study used it to space child-birth. This represents a paradigm shift since there was a previous suspicion of reduced fertility by hormonal contraceptives among child spacers in our environment. Proper counselling, commodity availability, cost reduction and appropriate motivation can improve uptake and continuation of Jadelle in Nigeria. This will support the efforts to protect the reproductive and sexual rights of women and contribute towards achieving the SDG 3 and 5 [10,21]. A further follow-up study throughout the life span of Jadelle (5 years) would be necessary to provide additional relevant information. In addition, a multi-centre pooled analysis of various family planning centres in Nigeria (currently in process) can further provide insight into the subject *in lieu* of a large population study that addresses some of the highlighted limitations.

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Conflict of Interests

None

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Contribution of Authors

EOO: Research conceptualization, research design, data collection, data acquisition, literature search, writing of draft manuscript.
JAO: Research conceptualization, research design, data collection, data acquisition, critical review of manuscript for intellectual content and structure
LI: Research design, Data analysis and manuscript review for intellectual content.
GO: Contributed to research concept and study design. Data analysis and literature search. Manuscript review for intellectual content
AAO: Research conceptualization, research design and manuscript review for intellectual content.

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