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SUBDERMAL CONTRACEPTIVE IMPLANTS - A 10 YEAR EXPERIENCE IN SOKOTO NORTH WESTERN NIGERIA
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SUBDERMAL CONTRACEPTIVE IMPLANTS - A 10 YEAR EXPERIENCE IN SOKOTO NORTH WESTERN NIGERIA

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ABSTRACT

Background: **Contraceptive implants are long acting reversible hormonal contraceptives. They are one of the most effective modern family planning methods and they are available and well accepted.**

Objectives: **The study wishes to report our experience with the implants especially regarding the sociodemographic characteristics of acceptors the side effect profile and the discontinuation rates since inception of the new Fertility Research Unit of UDUTH sokoto.**

Methods: **A 10-year review of all the records of new clients from 1st January 2008 to 31st December 2017. The data extracted was analyzed using IBM SPSS version 23.**

Results: **There were 5762 new acceptors of modern contraception during the study period out of which 3640(63.2%) chose the contraceptive implants. The modal age was 20 to 24 years (29.6%) and two thousand four hundred and forty-seven of them (67%) had at least secondary level of education. All the clients were married and an overwhelming majority (84.1%) of the clients were spacers. A third of clients (33.1%) had side effects. Principal among these was irregular vaginal bleeding (71%). Discontinuation rates were high (49%) and the main reason for this was the desire to conceive.**

Conclusion: **The implants are the most popular methods of modern contraception in the fertility research unit of UDUTH Sokoto. Most clients were young, educated spacers of low parity. Most clients did not report side effects. Of those that did irregular vaginal bleeding was the most common. Discontinuation rats were high and the desire to conceive was the main reason for this.**

INTRODUCTION

Contraceptive implants are long acting reversible hormonal contraceptives. They are available acceptable and one of the most effective modern family planning methods world wide[1]. They contain only progestogens and are placed sub dermally. The discovery of the biocompatibility of silicone with the human body has made it possible to develop different generations of long term highly effective contraceptive implants for women to use[1-2]. Implants are very effective, safe, convenient, require little user compliance and return to fertility is prompt[1-3]. Furthermore, subdermal implants are independent of coitus and are devoid of oestrogenic side effects so can readily be used by breastfeeding mothers and others in whom such use is contraindicated[2, 3,4]. In addition they reduce the risk of pelvic inflammatory disease, improve dysmenorrhea and may even reduce the severity of sickle cell crises[2]. Implants are discreet, inconspicuous, do not require pelvic examinations and repeated hospital visits. They are therefore a good choice for adolescents, those with medical disorders, anemia, endometriosis and grand multiparous women[1,2]

The first-generation implant Norplant has gradually been phased out on account of difficulties in insertion and removal of its 6 rods[2]. The two commonly available implants are Jadelle[R] and Implanon[R]. They work primarily by inhibition of ovulation, thickening of the cervical mucus and suppression of endometrial growth. The new generation biodegradable implants are not yet available[2,3].

Jadelle developed by the population council is manufactured by Bayer sherring pharma in Finland[2.] It has two thin flexible rods each of which is 43mmlong and 2.5mm wide. Its thin walled silicone tubing encases a metheylvinylsiloxane copolymer core. Each rod contains 75mg of levonorgestrel[1, 2,] It's effective for 5 years and is highly effective with a pearl index of 0.2/100women years[1, 2.] Implanon was developed by NV organon in New Jersey[3]. Its single rod is 40mm long and 2mmwide. Its ethylene vinyl acetate copolymer core contains 68mg of etonorgestrel it's highly effective for 3years and has a pearl index of 0[2,3].

Side effects of implants are minor but often bothersome. They include menstrual abnormalities, emotional lability, increase in weight, depression, acne, headache, breast pain and vaginitis[1-7]. In addition, at the time of insertion, there may be pain, slight bleeding, hematoma formation and even sepsis. Both initiation and discontinuation of use are provider dependent[2-5]. The process of insertion itself requires trained health care providers.

Both implants were introduced in Nigeria in 2006. The fertility research unit (FRU) of the department of obstetrics and gynaecology Usmanu Danfodiyo university teaching hospital (UDUTH) Sokoto was established in November 2007. Implanon was introduced into the teaching hospital at the same time while Jadelle was introduced into the contraceptive method mix in 2010.

The objectives of this study therefore are to report our experience especially regarding the sociodemographic characteristics of acceptors the side effect profile and the discontinuation rates of the subdermal contraceptive implants since inception of the FRU in UDUTH sokoto Nigeria.

METHODS

Usmanu Danfodiyo university teaching hospital is a tertiary hospital in Sokoto. It has all the major clinical departments and provides all levels of care. The obstetrics and gynaecology department has 4 units which operate the antenatal, postnatal and gynaecological clinics on all weekdays. The average annual delivery rate is 3000. This was a 10-year retrospective study involving

women attending the Fertility Research unit (the family planning unit) of the department of Obstetrics and Gynaecology(O&G) of UDUTH Sokoto. The unit was fully set up in November 2007, to run family planning services and it is located within the O&G complex. Prior to this, the department of Community health was providing family planning services in the hospital thrice a week. The fertility research unit is overseen by the consultants from the fertility regulation unit of the department and a resident Doctor rotates through the unit every month. The unit is manned by three Nurses and Midwives trained in the provision of family planning services and an average of 30 patients are seen daily. The unit receives clients primarily from the postnatal gynaecological and outpatient clinics. Furthermore, clients also come from Sokoto metropolis, neighboring states and even nearby Niger republic. The clinic runs from 8am to 4pm on Mondays to Fridays. Services provided include counselling on the various modern methods of family planning, administration of such services following informed choice as well as periodic follow up after a choice has been made. Contraceptive methods available at the unit include hormonal agents like the contraceptive pills, the monthly combined injectable (Norigynon [R)], the monthly injectable norethisterone oenanthate (Noristerat [R)] the three-monthly injectable depo medroxy progesterone acetate (Depo-Provera [R)] the single rod etonorgestrel containing subdermal implant (Implanon[R)] and the two rod levonorgestrel containing subdermal implant (Jadelle [R)]. In addition, the levonorgestrel intrauterine system (LNG IUS) and copper T intrauterine devices are also available. Tubal ligation and other sterilization methods are performed by the various units within the department either during obstetric emergencies or as elective procedures from referrals from the research unit. At inception in 2007 the commodities were bought and therefore had to be paid for by the clients. However, since 2012 most commodities are provided free of charge by the federal government.

On presentation, socio- demographic data of the clients are recorded and registered. They receive detailed counselling on the various methods of contraception available, their benefits, risks and side effects, so that informed choices could be made relative to a particular method. Their bio-data is obtained, and a brief history is also taken. A general physical examination is performed, and a recording of the pulse, blood and pressure is performed. The clients' choice of contraception is noted, and a folder is opened. Where the patient chooses implants, they are re counseled again on possible side effects. All the insertions are done within 5 days of the last menstrual period or after a negative serum pregnancy test where the patient is not menstruating. Most of the insertions were done at about 6 weeks after delivery. Those that change methods usually choose another method immediately after discontinuing the index one. The registers and all the case notes are kept in the clinic and are periodically assessed for quality assurance. All the registers and case notes of all clients in the unit were reviewed. The theatre case notes of patients who preferred tubal ligation as a mode of contraception were also followed-up. The total deliveries during the study period was obtained from the labour ward and theatre records. The period of study was for the entire 10 years of existence of the unit from 1st January 2008 to 31st December 2017. Further analysis was limited to patients who chose the contraceptive implants. The data extracted was analyzed using IBM SPSS version 23. Chi square test was used to determine associations and the p-value was <0.05

RESULTS

There were 5762 new acceptors of family planning during the study period out of which 3640(63.2%) chose the contraceptive implants. Of these 2698(74.1%) accepted Implanon while 942(25.9%) accepted Jadelle. Implanon was available and the only implant until 2010. Jadelle was introduced in 2010. Implanon has however risen and remained the most accepted contraceptive method throughout the period of study.

The ages of the clients ranged from 14 to 55 years with a modal age of 20 to 24 years. (29.6%). The clients were predominantly Hausa Fulani (84.5%). Two thousand four hundred and fourty seven of them (67%) had at least secondary level of education and 2791(76.7%) were housewives. One thousand one hundred and thirty-four (31.2%) were primiparous while the rest (68.8%) were multiparous as depicted in table1

Table 1

Sociodemographic profile of acceptors of Implants

AGE	**Frequency**	**Percentage (%)**
≤14	39	1.1
15 – 19	246	6.8
20 – 24	1077	29.6
25 – 29	1036	28.5
30 – 34	704	19.3
35 – 39	394	10.8
40 – 44	110	3.0
45 – 49	28	0.8
≥50	6	0.2
Total	3640	100
TRIBE		
Hausa/Fulani	3077	84.5
Yoruba	154	4.2
Igbo	127	3.5
Others	282	7.7
Total	3640	100
PARITY		
Primiparae	1134	31.2
Multiparae	1335	36.7
Grandmultiparae	970	26.6
Great grand Multiparae	201	5.5
Total	3640	100
EDUCATIONAL STATUS		
Primary	620	17.0
Secondary	1103	30.3
Tertiary	1344	36.9
Quranic	29	0.8
No formal education	544	14.9
Total	3640	100
OCCUPATION		
Housewives	2791	76.7
Civil servants	490	13.5
Businesswomen	42	1.2
Students	317	8.7
Total	3640	100

All the clients were married and in an overwhelming majority (84.1%) of the clients spacing was the indication for the use of the implants and only 339 (15.9 %) wanted to limit their family size.

Two empty Implanon applicators were found between 2008-2009. One thousand two hundred and five clients had complications (33.1%). Of these Irregular vaginal bleeding was the most frequent side effect in 856(71.9%) clients. There were 7 pregnancies reported during the study period. Five of them were in patients who were pregnant before the insertion and had implantation bleeding mistaken for a menstrual period. In all of them the serum pregnancy test prior to insertion was negative. The other two were genuine method failures There was a client that had sepsis following insertion and expelled the implant. Surprisingly in another client the implant gradually migrated towards the axilla. (Table2).

Table 2

Side effects experienced by clients using implants

SIDE EFFECTS	Frequency	Percentage
Irregular vaginal bleeding	856	71.0
Amenorrhoea	180	14.9
Headache	59	4.9
Pain at insertion site	55	4.6
Itching at insertion site	34	2.8
Hypomenorrhoea	12	1.0
Pregnancy with implant in situ	2	0.2
Expulsion of implant	1	0.1
Migration of implant	1	0.1
Total	**1205**	**100**

A total of 1783(49%) clients discontinued the implants. The reasons for discontinuation are depicted in figure 1. The desire to conceive was the principal reason in 70% of clients. While 14.6% switched to other methods and 7.8% discontinued on account ofsideeffects.

Figure 1: Reasons for discontinuation of implants

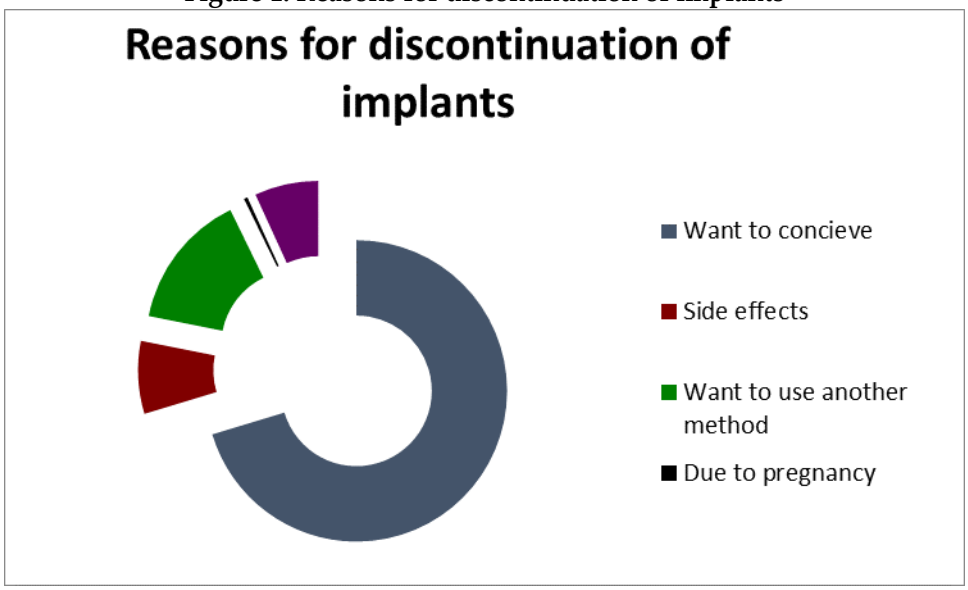

Table 3

Effect of Socio-demographic Characteristics on discontinuation of Sub dermal Implants

AGE	Continue	Discontinue	Statistic
<=19	144	141	X^2= 23.599
20-29	1012	1101	df=3
30-39	615	483	p-value= 0.000
>40	86	58	
TRIBE			
Hausa/Fulani	1581	1496	X^2= 1.105
Yoruba	76	78	df=3
Igbo	63	64	p-value= 0.776
Others	137	145	
PARITY			
Primipara	525	609	X^2= 15.69
Multipara	721	612	df=3
Grand multipara	507	465	p-value= 0.001
Great grand multipara	104	97	
EDUCATIONAL STATUS			
No Formal education	300	273	X^2= 0.488
Formal Education	1557	1510	p-value=0.485
OCCUPATION			
Housewife	1431	1360	X^2= 9.81
Civil servant	249	241	df=3
Businesswomen	30	12	p-value= 0.02
Student	147	170	

Further analysis to find out the association between sociodemographic variables and discontinuation rates was performed. This reveled that there was a statistically significant association between the age (X^2= 23.599, df=3, p-value= 0.000) , parity (X^2= 15.69, df=3, p value=0.001) and the discontinuation rates. The younger the age of the patient and the lower her parity the higher the rates of discontinuation.

DISCUSSION

The contraceptive implants available in the fertility research unit of UDUTH sokoto are Jadelle and Implanon. These implants were accepted by 63.2% of the clients during the 10-year period of study. They are therefore the most popular contraceptive method amongst the clients. This high uptake is much higher than what has been reported from Kano[4], Zaria[5], Jos[6], Uyo[7], Lagos[8] and Ilorin[9] all in Nigeria. This high uptake of the implants may be motivated by the convenience, effectiveness and safety. They are discreet and return to fertility is prompt. They do not require pelvic examinations and repeated hospital visits which is a major advantage. Implanon was available throughout the study period and it had dominated the contraceptive method mix throughout the period of study even after the introduction of Jadelle 2010. It was worthy of note that the implants were still the most popular method even in the earlier years of study when the contraceptive commodities were not free.

All the clients were married and most of them were very young of low parity and educated housewives who wanted to space their pregnancies. Infact up to 8% were teenagers. These clients are younger than those observed by others[6-9] They are also younger than the acceptors of modern

contraception observed in the same centre in earlier studies[10,11]. This may appear to be the beginning of a welcome development where the young adolescents are becoming more aware and accepting modern methods of contraception. Interestingly up to 15% of clients had no formal education but they still accepted the implants. This is in contrast to what obtained in some other studies[6,9].

There were no complications reported in the majority of clients (77%). However, in those that had the side effects the most common was irregular vaginal bleeding. This occurred in 71% of clients with side effects while amenorrhea only occurred in 15%. This is similar to what was reported from Jos[6] and Ilorin[9]. On the contrary amenorrhea was the most common in Abakaliki[12].Disruption of the menstrual cycle is the major drawback to the use of the implants. Despite the fact that the bleeding is usually not life threatening it is still a major cause for concern for most women as it causes discomfort and interferes with the sexual, social and religious activities. It may also lead to an increase in expenditure on sanitary protection. It's a significant cause for discontinuation in up to 8% of clients in this study.

Two pregnancies occurred during the study period that were genuine method failures. The first client had Jadelle for 17 months and became pregnant. She was a HIV positive patient on highly active antiretroviral therapy for more than 10 years. She weighed 66kg and was initially on Stavudine Lamivudine and Nevirapine, but her drugs were changed to Tenofovir Lamivudine and Efavirenz 5 months prior to the conception. The second patient had Implanon for 9 months she weighed 51.6kg. She was diagnosed with tuberculosis and placed on anti-Koch's drugs Rifampicin Isoniazid Pyrazinamide and Ethambutol. Such accidental pregnancies have also been reported in the USA [19]and in Jos[20] Nigeria. This is a rare occurrence as the pearl index for Jadelle and Implanon are 0.2 and 0 respectively. Drug interactions have been implicated as one of the mechanisms via which unintended pregnancies occur[1,2,3,13,14]. Particularly CYP450 hepatic enzyme inducers. The first client was on Efavirenz while the second was taking Isoniazid and Rifampicin. These medications probably accelerated the metabolism of oestrogen and progestins thereby reducing the available serum concentrations.

Migration of an Implanon rod towards the ipsi lateral axilla occurred in one patient. The implant was immediately removed. Migration of an implant occurs rarely but has been reported in the axilla[15], lungs[16] and even into the pulmonary artery[17].

The discontinuation rates in this study was 49%. This is higher than what had been reported in other parts of Nigeria [4-9]. However similar high discontinuation rates have been observed in Ethiopia[18], Cambodia[19] and Australia[20]. Further analysis revealed that age and parity had significant associations with the high discontinuation rates. Majority of the clients (84.1%) were young spacers who remove the implants have another child and return to insert another implant. The desire for more children was the main reason for discontinuation of the implants in 70% of the clients that removed them. Although 856 women experienced irregular vaginal bleeding only 96 of them removed the implants as a result of this. In Ethiopia however the main reason for discontinuation was principally due to menstrual disturbance. The implications of the findings of the study include a high acceptance of the contraceptive implants and a high side effect profile. Therefore, with more intensive health education and a reduction in side effect profile perhaps more clients are likely to maintain them for the long terms they were actually meant for and may eventually fertility rates may decline.

CONCLUSION

The implants are the most popular methods of modern contraception in the fertility research unit of UDUTH sokoto. Most clients were young spacers of low parity. A third of patients had side effects principal among which was irregular vaginal bleeding. Discontinuation rats were high and the desire to conceive was the main reason for this.

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