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Original Research Article

Complications of nexplanon contraceptive implants and reasons for discontinuation, in Yenagoa, Nigeria

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ABSTRACT

Background: Though nexplanon is a safe and effective contraceptive implant, the complications are often troublesome to warrant removal. This study intends to determine the complications of nexplanon contraceptive implant, and the reasons for removal.

Methods: It was a retrospective cross-sectional study of 258 women, who used nexplanon contraceptive implants for a while and discontinued. Data collected was: bio-data, the duration of contraceptive use, rank of the inserter (nurse or resident doctor), rank of the remover, the complications experienced, and the reasons for implant removal.

Results: The mean duration of nexplanon use was 30.95±14.34 months, majority (96.1%) were inserted, and (82.2%) removed by trained nurses. Insertion by resident doctor significantly resulted in more complications than by trained nurses, odds ratio=5.10 [1.06, 24.51], p=0.02. The complication rate was 50%, and vaginal bleeding (25.2%) was the most common. Others are: headache (8.9%), pain at the injection site (3.9%), Weight gain (3.1%), amenorrhoea (1.6%), mood swing (1.6%), and breast pain (1.2%). Regarding contraceptive failure, the pearl index was low (0.06). Women who inserted once significantly had more complications than those who inserted twice, odds ratio=0.46 [0.22, 0.77], p=0.03. Women who used it for a period of ≤36 months significantly had more complications than those who used it for a longer period, odds ratio=0.53 [0.30, 0.92], p=0.02. The commonest reasons for removal were: expired implant (41.9%), desire to get pregnant (31.8%), and heavy vaginal bleeding (21.3%). The removal rate (secondary to complications) was 26.4%.

Conclusions: Nexplanon is an effective contraceptive implant with a very low failure rate. Irregular vaginal bleeding is the commonest complication, and the most common reason for discontinuation.

Keywords: Nexplanon, Complications, Implant removal

INTRODUCTION

Since the phasing out of Norplant contraceptive implant in 2008, Implanon took the center stage as the contraceptive implant of choice, and it dominated the scene for many years. This is because it is very effective, and easier to insert and remove; it has a single rod compared to the 5 rods in Norplant.¹ With the introduction of nexplanon in 2010, Implanon is in the process of being phased out; it is

being replaced with nexplanon in many countries globally.^{1,2}

The advantages of nexplanon over Implanon are: it is radio-opaque, and it can easily be located with X-ray, computed tomography (CT) scan or magnetic resonance imaging (MRI).³ Secondly it has a preload applicator designed to minimize none implant insertion, and deep insertion placement complications commonly encountered with Implanon.^{3,4}

Nexplanon is made of a single rod, flexible ethylene vinyl acetate polymer matrix. It contains 68 mg of etonogestrel, a synthetic progestogen derivative from 19-nortestosterone.⁵ It is inserted subdermally on the medial side of the left non dominant hand, and the polymer matrix design ensures controlled and sustained release for a period of 3 years.¹

Pharmacologically, nexplanon was designed to release about 60-70 ug of etonogestrel daily during the first week of insertion, but subsequently stabilizes at a rate of 30-40 ug/day over a period of two years.^{2,6}

Regarding the mechanism of action, released etonogestrel binds to progesterone receptors in the ovaries, leading to suppression of ovulation by inhibiting luteinizing hormone release.⁷ Other contraceptive mechanisms are: thickening of the cervical mucus to inhibit movement of sperm to the ovaries, and thickening of the cervical mucus, to inhibit implantation.^{1,8}

With respect to complications of nexplanon insertion and removal procedure, a large prospective cohort study, the nexplanon observational risk assessment (NORA) in USA, involving 7364 insertion procedures, reported the incidence of incorrect insertion as 12.6 per 1000 insertions (95% CI, 10.2–15.5).⁹ Incorrect insertion was diagnosed when there was unrecognized non-insertion, and partial or deep insertion into the muscle tissue.⁹ It was also observed that out of 5159 removal procedures, formation of fibrotic tissue around the implant was the most common complication.⁹

Complications commonly experienced at the site of insertion includes: irritation, pain, redness and swelling.^{1,10} Asystematic review of trials on insertion complications revealed the rates as pain (1.9%), swelling (0.5%), and redness (0.3%).¹ Another study on nexplanon reported an incidence of redness and swelling at the insertion site as 4.7%.¹⁰

With respect to the failure rate, etonogestrel containing contraceptive implants have been reported as the most effective contraceptives, with very low pearl index.^{11,12} A study reported the failure rate as 0.34 pregnancies per 100 women per year.¹¹ However, some other studies reported zero pregnancy rates, with zero pearl index.^{12,13}

With respect to the failure rate, Nexplanon has been reported as the most effective contraceptive methods, with a Pearl index of 0.02 (95% CI, 0.00–0.06).¹¹ A study reported the failure rate as 0.34 pregnancies per 100 women per year.¹² Another study reported the failure rate of etonogestrel implants as zero, (Pearl index, 0; 95% CI 0.0–0.2).¹³

Hormone related complications of etonogestrel contraceptive implants are common and irregular vaginal bleeding was reported as the most common.¹⁴ However, some women rather develop amenorrhea as a

complication.¹¹ Other reported side effects are: weight gain, headache, breast tenderness, acne, and loss of libido.^{12,14}

As a result of the side effects of etonogestrel implants, a study rated the dissatisfaction rate (66%), and discontinuation rates (27%) as high.¹¹ Some of the common side effects leading to implant removal were reported as: irregular vaginal bleeding (11%), weight gain (2%), and mood changes (2%), others are headache (2%), acne (1%), and depression (1%).¹¹

The complications of nexplanon has been widely studied and published globally, but no study has been done in Yenagoa, Bayelsa State in Nigeria. The outcome of this study is expected to augment our contraceptive counseling, and patient management protocols.

Aim and objectives

This study intends to determine the complications of nexplanon implant, and the reasons for removal or discontinuation in Yenagoa, using NDUTH as a case study. It would also determine the socio-demographic characteristics of the women.

METHODS

Study site

This study was carried out at the family planning unit, department of obstetrics and gynaecology at NDUTH. The hospital is located in Yenagoa, Bayelsa State in Southern Nigeria. As a teaching hospital, NDUTH serves as a referral center for the primary, secondary and tertiary health institutions in the Bayelsa state. The hospital also receives patients from communities in the neighboring states, such as Rivers, Delta and parts of Abia State.

Study design

It was a retrospective cross-sectional observational study of 258 women who received nexplanon contraceptive implants, and discontinued after a while. It was carried out for a period of 6 years, from January 2018 to December 2023.

Inclusion criteria

Included in this study were women who accepted to use nexplanon contraceptive implant after counseling, used it for a while, and decided to discontinue. The implants were then removed.

Exclusion criteria

Excluded from this study were women still on nexplanon contraceptive, and those who used other implants available in NDUTH. Also excluded were women who inserted nexplanon elsewhere, and were removed in NDUTH.

Data collection

During the study period a total of 583 women inserted nexplanon contraceptive, out of these 258 women who met the inclusion criteria were identified.

The case notes of these women were retrieved from the hospital record, and information extracted was socio-demographic characteristics of the women, the duration of contraceptive use (in months), the rank of the inserter (nurse or resident doctor), the rank of the remover, the complications experienced, and the reasons for implant removal.

Data analysis

Data was coded into (IBM) statistical package for the social sciences (SPSS) Statistical Package for Windows (version 25), and Epi Info Statistical Software (version 7) and analyzed. Results were presented in tables as rates, proportions, and mean with standard deviation. Test of significance was by odds ratio, and differences in mean was compared with independent student's t-test. Using confidence interval of 95%, statistical significance was set as p values of ≤ 0.05 .

RESULTS

During the study period, a total of 583 women used nexplanon contraceptive in NDUTH. Out of these, 258 women had their nexplanon removed (for various reason), giving a removal rate of 44.3%. This includes women without nexplanon complications, such as expired implant, and desire for more children.

The mean maternal age was 27.17 ± 6.40 years, the median parity was para 3, and most of the women 156 (60.5%) were married. They were predominantly from Ijaw tribe 187 (72.5%); Bayelsa State where the study was conducted is in the heart of Ijaw land. Most of the women (32.6%) were traders, majority (50.4%) attained tertiary level of education.

Following nexplanon insertion, the mean duration of contraceptive use was 30.95 ± 14.34 months. A great majority (96.1%) was inserted by trained nurses, and only a handful (3.9%) was by resident doctors. With respect to the number of times implants was inserted, most of the women (82.6%) inserted just once, and most were removed by nurses (82.2%).

The complication rate was 50%, among the complications; irregular vaginal bleeding (25.2%) was the most common, which could be mild (spotting) or heavy bleeding. The nexplanon contraceptive failure rate (pregnancy rate) in NDUTH was 0.4%, with a pearl index of 0.06.

With respect to the reasons for nexplanon removal, expired implant (41.9%) was the commonest reason for removal, followed by desire to get pregnant (31.8%). Among the

complications experienced, profuse vaginal bleeding (21.3%) was the most common reason for removal.

Table 1: Socio-demographic characteristics of the women.

Socio-demographic factor	Frequency, n=258	Percentage
Maternal age (years)		
≤ 19	22	8.5
20-24	47	18.2
25-30	77	29.8
30-34	57	22.1
35 and above	55	21.3
Parity		
Nulliparous	27	10.5
Multiparous	183	70.9
Grand multiparous	48	18.6
Marital status		
Married	156	60.5
Single	102	39.5
Total	258	100.0
Tribe		
Ijaw	187	72.5
Igbo	33	12.8
Yoruba	8	3.1
Hausa/Fulani	1	0.4
Other tribes	29	11.2
Occupation		
House wife	37	14.3
Trader	84	32.6
Farmer	31	12.0
Civil servant	50	19.4
Student	42	16.3
Company staff	7	2.7
Artisan	7	2.7
Place of living		
Rural	214	82.9
Urban	44	17.1
Educational level		
Primary	26	10.1
Secondary	102	39.5
Tertiary	130	50.4

Out of 258 women who inserted nexplanon during the study period, 68 women had their implants removed because of nexplanon complications, giving a rate of 26.4%.

Regarding complications of nexplanon, women who used it for a period of ≤ 36 months significantly had more complications than those who used it for a longer period, odds ratio=0.53[0.30, 0.92], $p=0.02$.

Nexplanon insertion by resident doctor significantly resulted in more complications than insertion by trained nurses, odds ratio=5.10 [1.06, 24.51], $p=0.02$. There was

no difference in the rate of removal between doctors and nurses, $p=0.96$. With respect to the number of times the implant was changed (especially when it has expired),

women who inserted once significantly had more complications than those who inserted twice, odds ratio=0.46 [0.22, 0.77], $p=0.03$.

Table 2: Nexplanon insertion, complications and reasons for removal.

Variables	Frequency, n=258	Percentage
Duration of contraceptive use (in months)		
<12	23	8.9
12–24	65	25.2
25–36	97	37.6
37–48	48	18.6
49–60	25	9.6
>60	0	0.00
Rank of inserter		
Nurse	248	96.1
Doctor	10	3.9
Number of times nexplanon was inserted		
1	213	82.6
2	45	17.4
Rank of remover		
Nurse	212	82.2
Doctor	46	17.8
Complication experienced		
No complication experienced	129	50.0
Complication present	129	50.0
Specific complications N=129		
Vaginal bleeding	65	25.2
Headache	23	8.9
Pain of injection site	10	3.9
Weight gain	8	3.1
Hypertension	3	1.2
Nausea	5	1.9
Amenorrhea	4	1.6
Mood changes	4	1.6
Breast pain	3	1.2
Acne	3	1.2
Contraceptive failure	1	0.4
Reason for removal N=258		
Implant has expired	108	41.9
Desire to get pregnant	82	31.8
Heavy vaginal bleeding	55	21.3
Headache	7	2.7
Weight gain	3	1.1
Hypertension	2	0.8
Contraceptive failure	1	0.4

Table 3: Determinants of complications of nexplanon.

Variables	Complication of nexplanon (%)		Total (%) n=258	Odds ratio	Confidence interval	P value
	No complication n=141 (54.7%)	Complication present n=117 (45.3%)				
Maternal age (years)						
≤19	13 (5.0)	9 (3.5)	22 (8.5)	1.14	[0.44, 2.99]	0.78
20-24	26 (10.1)	21 (8.1)	47 (18.1)			

Continued.

Variables	Complication of nexplanon (%)		Total (%) n=258	Odds ratio	Confidence interval	P value
	No complication n=141 (54.7%)	Complication present n=117 (45.3%)				
25-30	43 (16.7)	34 (13.2)	77 (27.8)			
30-34	30 (11.6)	27 (10.5)	57 (22.1)			
35 and above	29 (11.2)	26 (10.1)	55 (21.3)	0.92	[0.45, 1.88]	0.81
Parity						
Nulliparous	17 (6.6)	10 (3.9)	27 (10.5)	1.85	[0.80, 4.29]	0.14
Multiparous	98 (38.0)	85 (32.9)	183 (70.9)			
Grand multiparous	26 (10.1)	22 (8.5)	48 (18.6)	0.98	[0.52, 1.85]	0.93
Marital status						
Married	89 (34.5)	67 (26.0)	156 (60.5)	1.28	[0.77, 2.11]	0.33
Single	52 (20.2)	50 (19.4)	102 (39.5)			
Tribe						
Ijaw	102 (39.5)	85 (32.9)	187 (72.5)			
Igbo	16 (6.2)	17 (6.6)	33 (12.8)	1.27	[0.61, 2.67]	0.52
Yoruba	5 (1.9)	3 (1.2)	8 (3.1)	0.72	[0.17, 3.11]	0.65
Other tribes	18 (7.0)	12 (4.7)	30 (11.6)			
Occupation						
Unemployed	101 (39.1)	93 (36.0)	194 (75.2)	0.65	[0.37, 1.16]	0.14
Employed	40 (15.5)	24 (9.3)	64 (24.8)			
Place of residence						
Rural	116 (45.0)	98 (38.0)	214 (82.9)	0.90	[0.47, 1.73]	0.75
Urban	25 (9.7)	19 (7.4)	44 (17.1)			
Educational level						
Primary	12 (4.7)	145.4	26 (10.1)	0.76	[0.33, 1.75]	0.51
Secondary	60 (23.3)	42 (16.3)	102 (39.5)	0.60	[0.25, 1.43]	0.24
Tertiary	69 (26.7)	61 (23.6)	130 (50.1)			
Duration of contraceptive use (months)						
≤36	93 (36.0)	92 (36.7)	185 (71.7)	0.53	[0.30, 0.92]	0.02*
>36	48 (18.6)	12 (4.7)	73 (28.3)			
Rank of the inserter						
Nurse	139 (53.8)	109 (42.3)	248 (96.1)			
Doctor	2 (0.8)	8 (3.1)	10 (3/9)	5.10	[1.06, 24.51]	0.02*
Rank of the remover						
Nurse	116 (45.0)	106 (44.1)	222 (86.0)	1.01	[0.54, 1.93]	0.96
Doctor	25 (9.7)	11 (4.3)	36 (14.0)			
Number of times implant was inserted						
One time	115 (44.5)	98 (38.0)	213 (82.6)			
Two times	26 (10.1)	19 (7.4)	45 (17.4)	0.46	[0.22, 0.77]	0.03*

DISCUSSION

Since the introduction of nexplanon contraceptive implant in 2010, it has maintained preference over implanon, and it is rapidly replacing it in many countries globally, including Nigeria.^{3,15} As stated above, the advantage nexplanon has over implanon is its ability to be detected radiologically (radio-opaque), and the preloaded application designed to minimize insertion errors.³

However, nexplanon and implanon are pharmacologically the same drug; they contain the same synthetic progestogen 68 ug of etonogestrel (as active ingredient). They have the same mechanism of action, contraceptive

effectiveness, similar failure rates, same duration of usage (3 years), and similar side effects or complications.^{8,9} Physically, they are both single rod implants, and are relatively easy to insert and remove.¹⁵

This scope of this study is limited to the complications of etonogestrel, and does not include insertion errors, such as none release of implant, and deep insertion into muscle tissue. It does not also cover removal difficulties, and implant migration.

Regarding the complications of nexplanon, evidence from this study indicates that irregular vaginal bleeding was the most common in NDUTH, and our rate of 25.2% was similar to the 19.2% reported in Canada.⁶ However, it was

much lower than the 86.9% reported in Port Harcourt, and the 80% reported among adolescents using etonogestrel contraceptive implant.^{16,17}

The reason why some women on etonogestrel implant have abnormal vaginal bleeding, and why some bleed more than others is not well understood, however it is assumed to be multi-factorial. A study reported that women on etonogestrel contraceptive implants have increased endometrial vascular fragility, with dilatation and congestion of endometrial vessels, which could precipitate bleeding.^{18,19}

Another mechanism is increased expression of angioproteins, which leads to increased vascular permeability, and tendency to bleed.^{18,20} There is also the gene expression theory, a study reported that women with low chemokine C-X-C motif 1 (CXCL1), also known as growth regulatory oncogene alpha has 6.8 fold increased risk of vaginal bleeding when using etonogestrel implant, odds ratio=6.8 [2.21, 20.79], $p=0.001$.²⁰

Weight gain is a source of great concern to women, and before accepting a contraceptive method, issues related to weight gain must be addressed during counselling. This obsession is not limited to grown-up women; adolescents also experience it; a study reported a significant increase in weight gain among adolescents on etonogestrel contraceptive implant.¹⁷ However, another study reported that only overweight or obese adolescents are affected.²¹ Regarding increase in weight gain (in this study), our rate of 3.1% is appreciably low, compared to that of USA. In Michigan it was 9.0%, and in Nashville, it was reported that 6.3% of women on etonogestrel cited weight gain as the sole reason for discontinuation.^{17,22}

The reason why women on etonogestrel contraceptive have weight gain has been linked to hormonal changes (progestogen effect) on lipid metabolism, which results in increased fat storage (especially in the abdomen, hips and thighs).^{23,24} Etonogestrel contraceptive has also been reported to increase appetite and fluid retention, leading to weight gain.^{23,24} The reason why some women on etonogestrel gain weight, (and others don't) has been linked to variation in gene expression of ESR1; a genetic variants of estrogen receptor.²⁵

Some women do experience significant headache when using nexplanon.²⁶ According to the highlights of prescribing information for nexplanon, as much as 25% of patients develop headache, and this has been vindicated in this study; headache was the second most common complication (in NDUTH) after vaginal bleeding.¹⁵ Though our rate was much less, the information is of value when counseling patients in need of contraception, so that they will have an idea of what to expect.

Regarding contraceptive effectiveness, this study has reckoned with others on the effectiveness of nexplanon, as our failure rate was very low, with a pearl index of 0.06.

This did not deviate widely from results in other centres: In Port Harcourt, the Pearl index was 0.003, and in USA the nexplanon observational risk assessment (NORA) reported a pearl index of 0.02.^{9,16}

The reason why the pregnancy or contraceptive failure rates are so low with etonogestrel implants is because etonogestrel, a synthetic progestogen is designed to bind to progesterone receptors with high affinity.^{7,8} This leads to inhibition of luteinizing hormone secretion in the ovaries; as a result, ovulation is suppressed.⁸ Various studies have actually reported complete suppression of ovulation, with zero pregnancy rates. They include: a studies in Abuja in Nigeria, and by the Canadian Agency for Drugs and Technologies in Health (CADTH).^{6,27}

With respect to the reason for removal of nexplanon, the most common reason in this study was not from etonogestrel side effects (or complications), but expired implants. This is not in concordance with the trend in many centres in Nigeria, where the desire to get pregnant was the commonest reason. Some of these centres are: In Port Harcourt (48%), Abuja (31.35%), and in Sokoto, it was 49%.^{16,27,28} High desire to get pregnant increases family size.

In Nigeria, attempts have been made to explain the high level of desire to get pregnant and large family size. A study in Sokoto cited the reasons as: socio-economic status, culture, religion, basic human rights and government policies.²⁹ According to the Nigerian National Demographic Health Survey, 27% of our women want to have more children, and 20% want to have another child (soon) within the next 2 years.³⁰ As a result, our total fertility rate is very high (5.3 children per woman).

Regarding discontinuation of contraceptive implants (in this study) because of unbearable complications, severe irregular vaginal bleeding tops the list. The 18% rate in NDUTH did not vary widely with results from other centre; 19.3% in Canada, 18.4% in Abuja, Nigeria, and 17.2% from another study.^{6,27,31}

Following implant removal for bleeding, women who desire to continue with contraceptive implant are usually advised to have levonorgestrel intra-uterine system (Mirena).³² It is a long acting contraceptive implant, with the ability to effectively control bleeding.³²

Though many articles have written on the duration of implant use, there is dearth of information on the relationship between duration of use and complications. Our results suggest that use of nexplanon for a period of >36 months (>3 years) is associated with fewer complications.

There is no satisfactory explanation to this effect, but one can speculate that the human body adapts to etonogestrel over time. This, as a matter of fact calls for further studies.

CONCLUSION

Nexplanon is an effective contraceptive implant with a very low failure rate. Irregular vaginal bleeding is the commonest complication and the most common reason for discontinuation.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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