

A review of clinical experience with progesterone-only injectable contraceptives at OAUTHC, Ile-Ife

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ABSTRACT

Background: Progestogen-only injectable contraceptives (POICs) remain the most popular contraceptive method in Nigeria. Considering how widely used POICs are worldwide, there is little published evidence of their safety and effectiveness. There is also a paucity of research to determine associations between the influence of age and parity and the preferred choice of POICs in women.

Aim: This study was to determine the use prevalence and the influence of age and parity on the preferred choice of POIC, and also the reasons for discontinuation among users of POICs at the family planning clinics of OAUTHC, Ile-Ife.

Materials and Methods: A retrospective record of 324 women who chose POICs out of a total of 1,029 clients seen at the family planning units of the hospital was collected for the period between January and December 2015. Information relevant to this study objectives was extracted using a purpose-designed proforma. Data were analyzed with SPSS version 16, and results were presented as frequencies and percentages. Pearson Chi-square test was used as test of significance where applicable and a *P* value < 0.05 was considered statistically significant.

Results: The prevalence of POIC during the study period was 31.49%. Depo-Provera (depot medroxyprogesterone acetate [DMPA]) was the most popular injectable preferred by the women. Age and parity had significant effects on the preferred injectable contraception with *P* values of 0.032 (CI 0.088-0.099) and 0.002 (CI 0.009-0.013), respectively, as younger clients with lower parity preferred Noristerat while preference for DMPA increased with age and parity. Majority (67%) did not experience any side effect; secondary amenorrhoea was the most common side effect experienced by 27% of the clients. Only 34% continued with the method for the duration of study while 66% discontinued for different reasons.

Conclusion: POICs are very effective and safe long-acting reversible method of contraception. While DMPA may be the more popular overall choice, norethisterone enanthate (NET-EN) is preferable in younger women of low parity.


Key words: Depoprovera; Ile-Ife; Noristerat.

Introduction

Decision making concerning fertility control is, for many people, a deeply personal and sensitive issue, often involving religious or philosophical convictions.^[1] Family planning refers to a conscious effort by a couple to limit or space the number of children they want to have through the use

of contraceptive methods.^[2] Nigeria constitutes 2% of the world population but accounts for 10% of global maternal

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deaths, about 60,000 maternal deaths occur annually in Nigeria.^[3] Knowledge of contraception is widespread in Nigeria; 85% of women and 95% of men report knowing about a contraceptive method,^[2] but the contraceptive prevalence rate is low. Fifteen percent of currently married women use a contraceptive method, an increase of only 2 percentage points from the 2003 Nigeria Demographic and Health Survey (NDHS). Ten percent of currently married women report using a modern method. Injectables remain the most popular contraceptive method among them.^[2]

The high level of awareness about contraception but very low level of use has been established in studies in Nigeria.^[4-7] The 2013 NDHS results indicate that the total fertility rate (TFR) is 5.5 births per woman. Overall, Nigerian women have about one child more than the number they want. This high fertility rate accounts for Nigeria's high maternal, infant, and neonatal mortalities.^[8]

Steroid sex hormones may be injected intramuscularly to provide a depot, which, depending on the drug, dosage, and formulation, may provide contraception for 1 month, 6 months, or even 1 year. A pure progestin may be used, or the injection may consist of a combination of a progestin with an estrogen. Most of these regimens prevent ovulation by suppression of anterior pituitary function.^[1] There are two commonly used injectable progestogen-only contraceptives that have been available in many countries in the world since 1983.^[9] These are depot medroxyprogesterone acetate (DMPA) and norethisterone enanthate (NET-EN).

The pharmacological composition of DMPA is medroxyprogesterone acetate, a semi-synthetic derivative of progesterone that features the same pharmacological profile but is remarkably more potent. DMPA inhibits gonadotropin-releasing hormone pulsatility and gonadotropin secretion, and the luteinizing hormone (LH) is much more suppressed than the follicle-stimulating hormone (FSH), thereby effectively preventing ovulation. This results in the estradiol levels being low in long-term users.^[10] NET-EN is administered at the dose of 200 mg every 60 days, and inhibits fertility through a mixed, two-phase mechanism: during the first portion of the drug's half-life span, the contraceptive effect is exerted at the hypothalamic level, whereas later on when ovulation is restored, the action is likely to be peripheral on the cervical mucus and/or the endometrium.^[9,11]

Ideally, both progestogen-only injectable contraceptives (POICs) should be started within 5 days of the menstrual cycle, to rule out pregnancy. Injection in the first 7 days of menses results in immediate ovulation suppression. However,

POICs can be commenced at any stage of the menstrual cycle, providing that the woman is not pregnant. The quick start method means that she does not have to wait for her next menses to begin. The 14-day rule should be observed, which means that she must abstain from, or have protected sexual intercourse, for 14 days after the administration of the injection if started in mid-cycle.^[12]

Progestogen-only injectables are very effective methods of fertility control with published failure rates of 0.3% in the first year of use.^[13] After the injections are discontinued, there may be considerable delay in reestablishment of regular ovulation and corresponding true menstrual bleeding. However, fertility rates are essentially normal at about 18 months after discontinuation.^[1]

An advantage of the drug is that its use is independent of coitus or a daily activity such as pill taken.^[1] Therefore being discreet, it enables the women to maintain secrecy about their use of contraception,^[14] especially in some African settings where the use of contraception is discouraged due to cultural or religious reasons. POICs also offer the advantage of not requiring special storage (making them suitable for use in tropical countries like Nigeria).^[14] Lactating mothers can successfully breast feed their babies as the POICs do not adversely affect milk composition, quality, or quantity.^[15] Reported noncontraceptive benefits of POICs include reduction in frequency of sickle cell crises, reduction of menstrual cycle disorders, less dysmenorrhoea, less symptoms of premenstrual tension, and reduction in seizure frequency in women with epilepsy.^[16]

Bone mineral density may be reduced among those who receive injections of medroxyprogesterone. Changes in bone density appear similar to those seen during lactation. Subgroups of long-term users of Depo-Provera may experience a decrease in spinal bone density that appears to be reversible following discontinuation.^[1] Changes in the menstrual cycle are inevitable with injectable contraceptives, and are commonly referred to as "menstrual chaos." Changes in menstrual patterns may result in amenorrhea and breakthrough bleeding.

Withdrawal bleeding may be heavy, irregular, or absent, and there may be spotting. Amenorrhea is a predictable side effect of DMPA and NET-EN owing to the inhibition of both ovulation and follicular development.^[10] Amenorrhea may be generally more acceptable to women than prolonged or frequent bleeding.^[17] Side effects other than irregular bleeding that may be encountered include a delay in ovulation when discontinued; thus when a delay in return to fertility, mildly androgenic effects may increase existing depression,

acne, and hair loss.^[10] Others are weight gain, headache, nervousness, abdominal discomfort, dizziness, and fatigue.^[11]

Justification

Nigeria has one of the highest maternal mortality ratios in sub-Saharan Africa, and ranks as the country with the second highest number of maternal deaths in the world.^[18] Use of long-acting reversible methods is proposed as a strategy to reverse undesirable maternal health consequences in developing countries.^[19,20]

Considering how widely used DMPA is worldwide, there is little published evidence of its safety and effectiveness.^[21] There is also paucity of research to determine associations between the influence of age and parity and the preferred choice of POICs in women.

Aim

This study aims to determine the use prevalence, the influence of age and parity on the preferred choice of POIC, side effects, and discontinuation rate as well as the reasons for discontinuation among users of POICs at the family planning clinics of our hospitals.

Materials and Methods

Study location

This study reviewed the clinical experience with POICs chosen by women accessing family planning services in a Nigerian teaching hospital family planning unit. The health facility consists of two hospitals and two primary health care centers. These hospital units serve not only the health administrative zone in which they are located but also receive clients from other parts of Osun State and some parts of Oyo, Ondo, and Ekiti States which are neighboring states.

Study design

A descriptive study.

Data collection method

A retrospective record of 324 women who chose POICs at the family planning units of the hospital out of a total of 1,029 clients seen was collected for the period between January and December 2015. After due counseling by family planning nurses and physicians, a full medical history was taken and clinical examination as well as pregnancy test were performed to exclude known contraindications to POIC and pregnancy.

DMPA marketed as Depo-Provera® and NET-EN marketed as Noristerat® are the two POICs available in Nigeria. A dose of 200 mg NET-EN or 150 mg DMPA was injected into the gluteal/deltoid muscle within the first 7 days of a normal

menstrual period where menstrual dates were known. It was also given after abortion and 6 weeks after delivery in breastfeeding mothers who were yet to resume menstruation. Repeat injections and observations were done after every 60 days for those receiving NET-EN and every 90 days for clients on DMPA. At each visit, all the complaints volunteered by the patient were documented. The weight, blood pressure, and result of urinalysis were recorded. A patient was considered lost to follow up if she defaulted more than twice from scheduled injections.

A total of 324 clients had POICs within the period under study out of which 18 had incomplete records and were therefore excluded from the study leaving a total of 306 files which were complete. Information about age, marital status, highest level of education, parity, previously used contraceptive methods, preferred injectable contraception, side effects experienced by the POIC acceptors, discontinuation, and reasons for discontinuation were extracted from the hospital records using a purpose-designed proforma.

Data analysis

Analysis was done with respect to use prevalence, profile of the acceptors, and discontinuation rate over the period of study. The influence of age and parity was considered on the choice of preferred injectable contraceptive. Data were cleaned and analyzed with Statistic Package for Social Sciences version 16; results were presented as frequencies and percentages. Pearson Chi-square test was used as test of significance where applicable and a *P* value < 0.05 was considered statistically significant.

Limitations of the study

The retrospective nature of this study prevented direct access to the clients and thereby increased the incidence of incomplete records. Also being a hospital-based study, it cannot give a true picture of the use prevalence of POICs for this environment because of other sources of obtaining the injectable contraceptive such as primary health care centers and patent medicine vendors. This review, however, was able to address the study objectives and provided information that can be used for further studies, training of contraceptive providers, program planning, and policy formulation.

Results

A total of 1,029 clients were seen at the two family planning units of the hospital between January to December 2015; 324 of these clients accepted POICs after due counseling. The use prevalence of POICs during the study period was 31.49%. Eighteen of the clients had incomplete records and were therefore excluded from the study leaving a total of

306 files which are complete. The POICs acceptors were between the ages of 20 and 45 years with mean \pm standard deviation (SD) of 32.68 ± 4.76 years as shown in Figure 1.

Table 1 revealed that majority (60%) of the acceptors were educated up to secondary school level. Parity of the acceptors in Table 2 ranged from 1 to 7 with a mean \pm SD of 3.37 ± 1.34 . Table 3 showed that fresh acceptors accounted for 35% of the POICs clients, about 25% of the acceptors migrated from natural family planning to modern contraception, while the remaining 40% switched from other modern methods. Depo-Provera (DMPA) was the most popular injectable preferred by 63% of the women while 37% opted for Noristerat (NET-EN) as depicted in Figure 2.

Age and parity had significant effects on the preferred injectable contraception with *P* values of 0.032 (CI 0.088-0.099) and 0.002 (CI 0.009-0.013), respectively, as younger clients with lower parity preferred Noristerat (NET-EN) while preference for Depo-Provera (DMPA) increased with age and parity as shown in Tables 4 and 5. Table 6 revealed that majority (67%) did not experience any side effect; 27% experienced secondary amenorrhea which was the commonest side effect. The discontinuation rate in Figure 3 revealed that only 34% continued with the method for the duration of study while

66% discontinued for different reasons. Table 7 showed that the reasons given for discontinuation were mainly menstrual abnormalities in 49% of the women and inability to keep up with the appointments in 43%. There was no accidental pregnancy recorded during the study period.

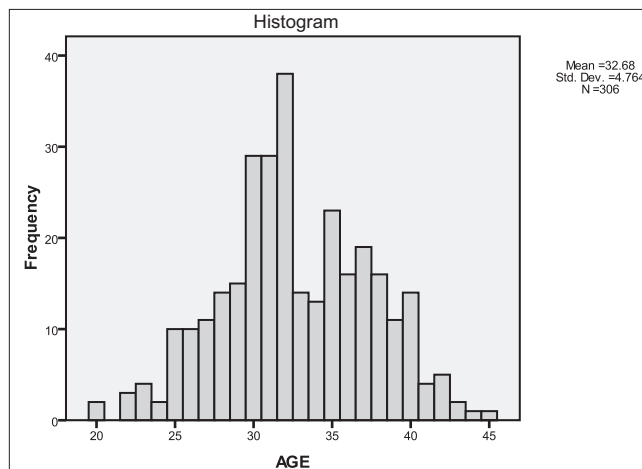


Figure 1: Age distribution of POICs acceptors

Table 1: Highest level of education of POICs acceptors

Level	Frequency	Percentage
None	12	3.9
Primary	84	27.5
Secondary	182	59.7
Tertiary	28	8.9
Total	306	100

Table 2: Distribution of POICs acceptors by parity

Parity	Frequency	Percentage
1-3	158	51.64
4-6	136	44.44
7-9	12	3.92
Total	306	100
Mean \pm SD		3.37 \pm 1.34

Table 3: Previously used contraception by POICs acceptors

Methods	Frequency	Percentage
None	108 PREVIOUS	35.3
Natural methods	75	24.5
Pills	39	12.7
Condoms	53	17.3
IUCD	28	9.2
Emergency	2	0.7
Implants	1	0.3
Total	306	100

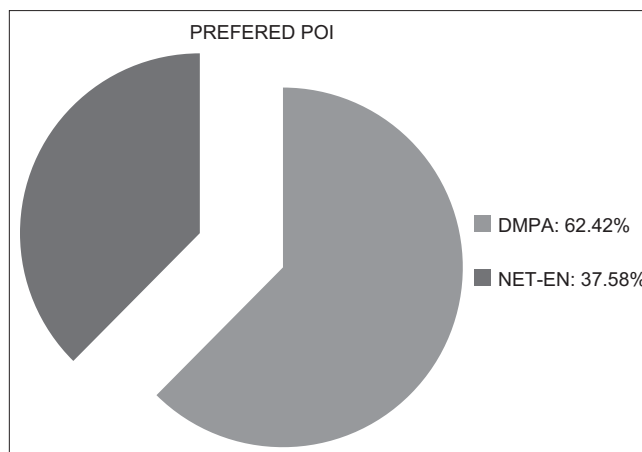


Figure 2: Preferred POI Contraceptive

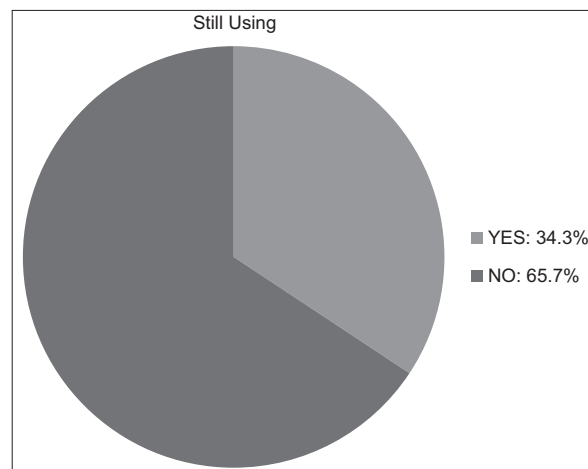


Figure 3: Discontinuation rate of POICs

Table 4: Influence of age on the preferred injectable

Age groups	DMPA	NET-EN	Total
20-24	3	9	12
25-29	27	39	66
30-34	67	53	120
35-39	64	18	82
40-44	20	5	25
45-50	0	1	1
Total	181	125	
<i>P</i> (95% CI)	0.032 (0.088-0.099)		

Table 5: Influence of parity of the preferred injectable

Parity groups	DMPA	NET-EN	Total
1-3	73	85	158
4-6	98	38	136
7-9	10	2	12
Total	181	125	306
<i>P</i> (95% CI)	0.002 (0.009-0.013)		

Table 6: Side-effects experienced by POICs acceptors

Side effects	Frequency	Percentage
None	205	67
Menorrhagia	1	0.3
Amenorrhoea	82	26.8
Breakthrough bleeding	1	0.3
Weight gain	16	5.2
Abnormal vaginal discharge	1	0.3
Total	306	100

Table 7: Reasons for discontinuation of POICs

Reasons	Frequency	Percentage
Ready for another baby	10	3.27
Menstrual abnormalities	149	48.69
Inability to keep appointments	133	43.46
No reason	14	4.58
Total	306	100

Discussion

The use prevalence of POICs during the study period was 31.49%. This is higher than the incidence of 12.6%, 22.1%, and 23.3% obtained from earlier studies at Ile-Ife,^[22] Oshogbo,^[23] and Calabar^[15] in Southwest and South South Nigeria, respectively. This rise may be attributable to the slight increase in the national contraceptive prevalence rate from 13% to 15% and increasing acceptability of injectable contraceptives having become the most popular contraceptive method.^[2] Religious and sociocultural influences on the choice of contraception can explain the higher values of 64.6% and 50.7% obtained from Kano^[24] and Zaria^[25] both in Northwest Nigeria.

The POI injectable acceptors were between the ages of 20 and 45 years with mean \pm SD of 32.68 \pm 4.76 years. This

is comparable with the age profile in similar studies by Adeyemi *et al.*^[23] and Njoku *et al.*^[15] About 63% of them were in the age group of 20 to 34 years; clients older than 35 years accounted for less than 37% of the study population. This was not unexpected because ages 20 to 35 years represent the peak reproductive period with high fecundability, then declining fertility in later years.

Contraceptive use is positively associated with women's level of education and contraceptive use increases with educational attainment.^[2] Majority (60%) of the acceptors in this study were educated up to secondary school level while less than 4% had no education at all. This is in keeping with findings from the national surveys that 37% of women who have more than a secondary education use a contraceptive method, as compared with only 3% of women with no education.^[2]

Parity of the acceptors in this study ranged from 1 to 7 with more than half (52%) between Para 1 and 3 while parity greater than 6 constituted only 4%. This may be due to the fact that clients with higher number of children were likely to be older and likely to have completed their family size, and may find longer acting contraceptives like Intrauterine Contraceptive Device (IUCD) and implants more suitable than injectables.

Fresh acceptors constituted 35% of the POI clients in this study while 43% switched from other modern methods such as condoms, pills, IUCD, emergency contraception, and implants to POI method. These values were slightly lower than 41.3% and 58.7% obtained for fresh acceptors and previous use of modern contraceptives obtained from a similar study.^[23] The difference may be due to variations in contraceptive counseling skills and individual client's perception of the different contraceptive methods.

The finding that 25% of the acceptors migrated from natural family planning methods like withdrawal and periodic abstinence to an effective modern method of contraception like POI is not surprising considering the high failure rates associated with such natural methods of family planning. In this study, the popularity of Depo-Provera (DMPA) which was preferred by 63% of the women versus 37% for Noristerat (NET-EN) is in keeping with findings from several studies on POI.^[15,23,26] This popularity may be due to the reduced frequency of clinical visits associated with DMPA compared with NET-EN.

The influence of age and parity on the preferred choice of POI is a unique aspect of this study which was not considered in previous studies on POI that were reviewed. Age and parity had significant effects on the preferred

injectable contraception as younger clients with lower parity preferred Noristerat (NET-EN) while preference for Depo-Provera (DMPA) increased with age and parity. This perhaps may be due to the fact that Noristerat (NET-EN) is suited to women who prefer the reduced likelihood of amenorrhea and require a shorter return time to fertility.^[10] This reflects the needs of younger women with lower parity.

The finding that majority (67%) of the clients in this study did not experience any side effect is a welcome development which will encourage such users. Secondary amenorrhea is the most common side effect experienced by 27% of the acceptors which is consistent with findings from several similar studies.^[15,23-27] The discontinuation rate from this study was 66%. Only 34% continued with the method for the duration of study while 66% discontinued for different reasons which is unacceptably high. Although this discontinuation rate is slightly lower than the finding from a similar study in Port-Harcourt which reported a 77% cumulative discontinuation rate,^[26] it is, however, much higher than 19% and 22% reported in studies from Calabar and Osogbo, respectively.^[15,23] Four noncomparative studies from the United States demonstrated discontinuation rates among DMPA users ranging from 41% to 77% at 1 year. Another study also showed cumulative discontinuation rates up to 79% among DMPA users at 5 years.^[28-31]

Reasons given for discontinuation were mainly menstrual abnormalities in 49% of the women and inability to keep up with the appointments in 43%. Regular menstruation is perceived as a sign of healthy reproductive function and general well-being. There are myths about the absence of menstruation leading to a buildup of bad blood in the body and making the woman ill. Also breakthrough/unpredictable bleeding can be inconvenient as well as a source of embarrassment. Therefore, irregular menses is a major cause of apprehension and anxiety in these women with little tolerance for the cause. These factors may be responsible for the high discontinuation rate which is in keeping with the reasons cited from several studies.^[10,15,23,26]

Appropriate counseling to disabuse the myths, repeated reassurance, and short-term use of combined oral pills to correct the abnormal bleeding patterns may help to reduce the rate of discontinuation in those experiencing these side effects. There was no accidental pregnancy recorded in the clients during the study period which confirmed the effectiveness of POI as evidenced by other similar studies.^[13,23]

Conclusions and Recommendations

POICs are very effective and safe long-acting reversible contraceptives. While DMPA may be the more popular overall

choice, NET-EN is preferable in younger women of lower parity. Majority of the women studied tolerated POICs well but the rate of discontinuation was rather high. Adequate counseling and information to prepare the minds of the clients about the menstrual disruption, constant reassurance, support, and measures to correct abnormal bleeding can help to reduce the discontinuation rate.

Information technology also has a role to play in the form of programmed short message service (sms) reminders that can be sent to the clients around the due date of their injections. This will help to reduce the incidence of clients failing to turn up for their appointments and enhance continuation.

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Conflicts of interest

There are no conflicts of interest.

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