

**REVIEW OF CONTRACEPTION WITH NORETHISTERONE ENANTHATE
(NORISTERAT) AT RIVERS STATE UNIVERSITY TEACHING HOSPITAL,
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Article Received on 28/10/2020

Article Revised on 18/11/2020

Article Accepted on 08/12/2020

ABSTRACT

Background: Noristerat is an effective, safe and reversible progesterone-only contraceptive. Although it has these good qualities, the side effects and complications may lead to its discontinuation. **Objective:** To determine the prevalence rate, side effects, discontinuation and indications for discontinuation of noristerat at Rivers State University Teaching Hospital (RSUTH), Port Harcourt. **Methods:** This was a retrospective study of 874 clients attending family planning clinic at the RSUTH from 1st January, 2015 – 31st December, 2019. Their records were retrieved from the clinic and reviewed. Data was extracted, coded and analyzed using the statistical package for social sciences (SPSS) IBM version 25.0 (Armonk, NY). **Result:** Out of 874 acceptors of contraceptives within the study period, 37 accepted noristerat giving a prevalence rate of 4.2%. The mean age was 31.1 ± 5.23 years. Age range was 23-48 years and the modal parity was para 4. Majority of the clients were married, 34 (91.9%), multiparous, 24 (64.9%) and had tertiary level of education, 28 (75.7%). The discontinuation rate was 29.7%. The commonest reasons for discontinuation as well as side effects of noristerat were menorrhagia, irregular vaginal bleeding and weight gain with each accounting for 3 (27.3%) respectively. There was no accidental pregnancy. **Conclusion:** The prevalence and discontinuation rates of noristerat were low. Menorrhagia, irregular vaginal bleeding and weight gain were the commonest side effects and reasons for discontinuation.

KEYWORDS: Noristerat, side effects, discontinuation rate, acceptors, RSUTH.**INTRODUCTION**

Hormonal contraceptives are the most popular and most effective non surgical method of contraception worldwide.^[1] Norethisterone Enanthate (Noristerat, NET-EN) is an injectable progesterone -only contraceptive given intramuscularly at a dose of 200mg, two monthly in the first 5 days of a normal menstrual cycle, but can also be given at any time in the menstrual cycle after ruling out pregnancy. It is an oil suspension that is effective and convenient with a pregnancy rate close to zero when used correctly.^[2-4] Noristerat acts by preventing ovulation, inhibition of sperm penetration by causing changes in the cervical mucus and causing thinning and atrophy of the endometrium, thereby preventing implantation of a fertilized ovum.^[5]

The use of noristerat is not without side effects and complications which may be unacceptable to the clients resulting in high discontinuation rates seen in some studies.^[6,7] Noristerat is associated with loss of bone mineral density and increased risk of bone fracture which reverses after stopping its use. This is why United States Food and Drug Administration (USFDA) has discouraged its use for more than two consecutive

years.^[2,4,8] Main side effects are menstrual disorders including secondary amenorrhoea, irregular vaginal bleeding, menorrhagia and weight changes. Others are reduced libido, abdominal pain, headaches, chest pain and accidental pregnancies.^[3,6,7,9,10] Despite these side effects of noristerat, clients still choose and use them, hence the need for this study to determine the side effects, discontinuation rate and indications for discontinuation of noristerat at Rivers State University Teaching Hospital (RSUTH), Port Harcourt and compare the findings with other results of similar study.

MATERIALS AND METHODS

This is a retrospective study carried out at the family planning clinic of the Rivers State University Teaching Hospital (RSUTH) Port Harcourt, the capital of Rivers State in southern Nigeria. The clinic gets its clients from within Port-Harcourt and the neighbouring towns and villages.

Its own records section is different from the hospital records and this makes it easy to retrieve the clients' case notes. The clinic is headed by a consultant

Gynaecologist, with the support of trained family planning nurses and resident doctors.

At presentation, the clients were welcomed by trained family planning nurses and physicians who also counseled them. They were allowed to make informed choice based on their needs and available contraceptives suitable for them. Thereafter medical history and clinical examination were done. Urine analysis and pregnancy test were also done for the clients and informed consent obtained. The nurses injected 200mg of noristerat into the deltoid or gluteal muscle within 7 days of normal menstrual period after excluding pregnancy. It was also given six weeks post partum in lactating mothers. Follow up visits were at the first four weeks and thereafter two monthly. The clients were encouraged to come to the clinic if there were complications and these were recorded in the clients' cards. At each follow up visit, the clients were weighed, blood pressure checked and complications managed appropriately. Clients who did not follow up for two or more consecutive scheduled visits were regarded as lost to follow up.

The record cards of all the clients that accepted Noristerat between 1st January, 2015 and 31st December, 2019 were retrieved and studied. The information extracted from the cards included the socio-demographic characteristics of the clients, previous contraceptive methods used and their sources, side effects and complications of the current contraceptive method, discontinuation and the reasons for discontinuation of noristerat. The data was analyzed with the statistical package for social sciences (SPSS) IBM version 25.0 (Armonk, NY) using frequency counts and percentages and presented as tables and charts.

RESULTS

There were 874 contraceptive acceptors during the study period, out of which 37 women accepted Noristerat giving an acceptance rate of 4.2%. It is the 6th most accepted contraceptive after implanon, intrauterine contraceptive device (IUCD), jadelle, depo provera and oral contraceptive pills (OCPs). The ages of the clients ranged from 23 to 48 years. Majority of the clients 26

(70.3%) were between 25-34 years and the modal age group was 25-29 years. The mean age was 31.1 ± 5.2 years. Most of the clients were multiparous women, 24 (64.9%) and all were Christians. The parity range was 0 to 6 and modal parity was para 4.

Four nulliparae and grandmultiparae (10.8%) accepted and used NET-EN respectively. All the women had formal education out of which 28 (75.7%) had tertiary level of education, while 8 (21.6%) and 1 (2.7%) had secondary and primary levels of education respectively. Majority of the clients were married 34 (91.9%) while 3 (8.1%) were single. The socio-demographic characteristics of the NET-ET acceptors are shown in table 1.

Figure 1 shows the sources of previous contraceptives used by the clients. Nineteen (51.4%) clients got their previous contraceptives from government hospitals, 10 (27%) got theirs from private hospitals and 8 (21.6%) did not use any form of contraceptives prior to the use of noristerat. Majority of the clients, 20 (54.1%) previously used injectable contraceptives, 8 (21.6%) did not use any form of contraceptives, 5 (13.5%) previously used barrier method and 2 (5.4%) each used oral contraceptive pills (OCPs) and calendar method respectively. This is shown in table 2.

Side effects associated with the use of noristerat which also contributed to the reasons for discontinuation of this contraceptive method are shown in table 3. Twenty six (70.3%) clients did not have any complaints and did not discontinue the use of noristerat. Out of the 11 clients that discontinued noristerat, 3 (27.3%) clients each had menorrhagia, irregular vaginal bleeding and weight gain respectively. One (9.1%) client had secondary amenorrhoea and another one (9.1%) desired to get pregnant. Figure 2 shows the discontinuation rate of noristerat. Eleven clients discontinued the use of noristerat due to side effects of the drug and desire to become pregnant, giving a discontinuation rate of 29.7%. Throughout the study period there was no accidental pregnancy recorded.

Table 1: Socio-demographic characteristics of the clients.

Variable	No.	Percentage (%)
AGE		
20-24	2	5.4
25-29	14	37.9
30-34	12	32.4
35-39	7	18.9
40-44	1	2.7
45-49	1	2.7
EDUCATIONAL STATUS		
Primary	1	2.7
Secondary	8	21.6
Tertiary	28	75.7
RELIGION		
Christianity	37	100

PARITY		
Nullipara	4	10.8
Primipara	5	13.5
Multipara	24	64.9
Grand multipara	4	10.8
MARITAL STATUS		
Single	3	8.1
married	34	91.9

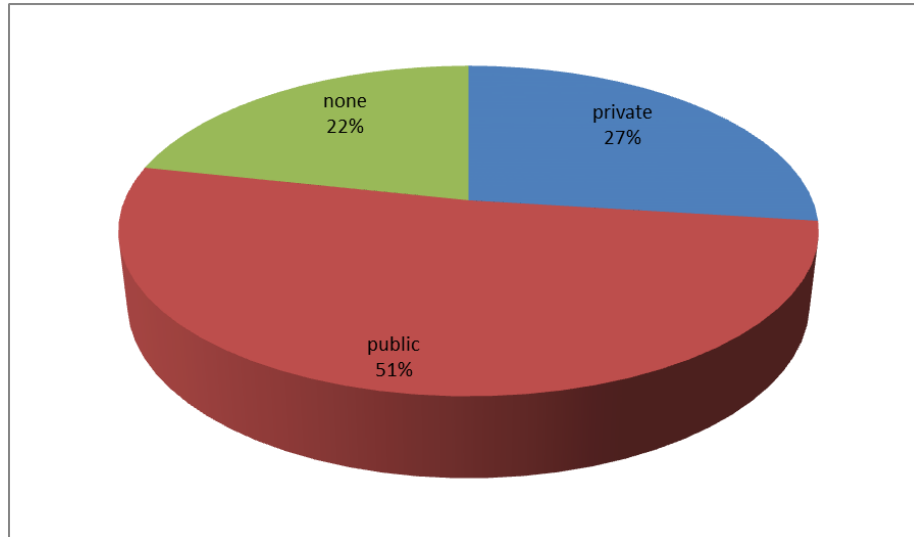


Figure 1: Sources of previous contraceptives used by clients.

Table 2: Previously used contraceptives by the clients.

Methods	Frequency	Percentage
Calendar	2	5.4
OCPs	2	5.4
Barrier	5	13.5
No method	8	21.6
Injectable	20	54.1

Table 3: Side effects and reasons for discontinuation of noristerat (n=11).

Reasons and side effects	Frequency	Percentage
Weight gain	3	27.3
Menorrhagia	3	27.3
Irregular vaginal bleeding	3	27.3
Desire to get pregnant	1	9.1
Secondary amenorrhoea	1	9.1

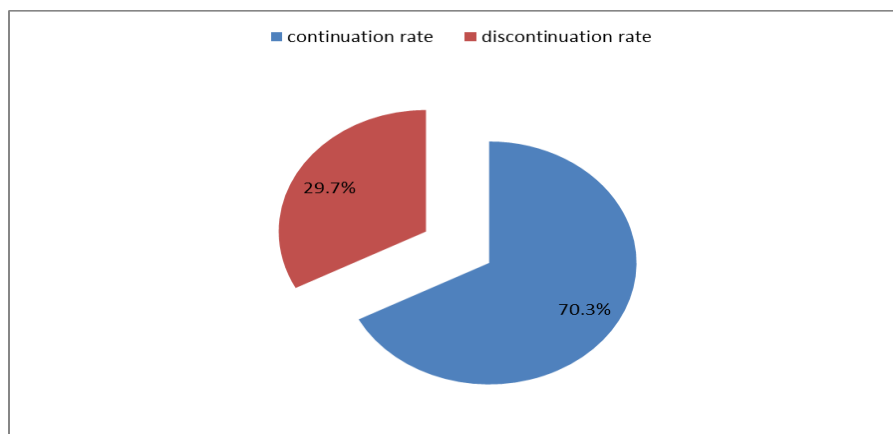


Figure 2: Continuation and discontinuation rates of noristerat.

DISCUSSION

The acceptance rate of noristerat throughout the study period was 4.2% which was slightly lower than a similar study done in south- south Nigeria.^[8] It is the sixth after intrauterine contraceptive device (IUCD), implanon, jadelle, Depo Provera and OCPs. In a previous study done in the same centre by Nonye-Enyidah *et al.*, it was the fifth frequently used contraceptive following IUCD, implanon, jadelle and depo provera with an uptake rate of 8.5%.^[3] This result probably means that the use of noristerat is on the decline or this is a smaller study compared to the previous study. This study also revealed the use of OCPs surpassing that of noristerat, this is so because the clients use OCPs to correct the menstrual disorders caused by noristerat. Religious beliefs and cultural practices such as desire to have a male child are some of the factors responsible for poor uptake of contraceptives in developing countries such as Nigeria.^[7] Also with the advent of newer contraceptives, the uptake of noristerat in our centre has drastically reduced over the years. This is due to the long term coverage of these contraceptives like IUCD and subdermal implants which can last for five years and more. This decline in the use of noristerat is similar to findings in other centres.^[6,11]

The mean age of the acceptors in this study was 31.1 years. This is similar to those from previous studies in southern Nigeria.^[9,11,12] Majority of the clients 26 (70.3%) were within the age range of 25 and 34 years which is in keeping with the findings from other centres.^[9,11,12] All the clients had formal education. Several studies have confirmed the fact that contraception is more readily accepted and used by educated counterparts. Therefore education plays a key role in contraceptive acceptance and use.^[4,12,13] All the women in this study were Christians. This is not surprising because majority of population in southern Nigeria are Christians.

Most of the clients that accepted noristerat were multipara which is in keeping with previous studies.^[9,13] This is because it is usually the multiparous women who seek contraception to limit the family size and space the childbirths.^[7,14]

Seventy percent of the clients had no complaints indicating a very good safety profile of noristerat. The commonest complications experienced by the clients were menstrual disorders and most of them had irregular vaginal bleeding, menorrhagia and weight gain. This is in keeping with results of several studies.^[2,11,15,16]

In this study menorrhagia, irregular vaginal bleeding and weight gain were the commonest reasons for discontinuation of noristerat. These menstrual disorders are due to the effect of the drug on ovarian function and secondary amenorrhoea results from ovarian suppression and endometrial atrophy.^[10,17] The discontinuation rate of noristerat was 29.7% which is lower than 32.7% of depo provera in the same study. This 29.7% is slightly higher

than 27.1% recorded by other studies.^[15,18] There was no report of accidental pregnancy during the use of noristerat indicating how effective this method of contraception is. This finding is also similar to other studies.^[11,12,19]

CONCLUSION

The acceptance rate of noristerat is low and there was a decline in its use. Menstrual disorders may occur as side effects of this contraceptive which could lead to its discontinuation. Noristerat has been found very effective in preventing accidental pregnancies. Sufficient counseling and adequate support during the use of noristerat will reduce the discontinuation rate of this very effective contraceptive.

Ethical approval

Ethical approval was given by the Hospital's Ethics committee.

Acknowledgement

We wish to express our gratitude to the staff of the family planning clinic for their kind support.

Competing interests

Authors have declared that no competing interests exist.

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