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Original Research Article

Weight gain and menstrual abnormalities between users of Depo-provera and Noristerat

Yusuf Abisowo Oshodi*, Joy Oyinyechi Agbara, Olamide O. Ade-fashola, Fatimat Motunrayo Akinlusi, Haleemah Folashade Olalere, Taiwo O. Kuye

Department of Obstetrics and Gynecology, Lagos State University Teaching Hospital, Ikeja, Lagos, Nigeria

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***Correspondence:**
Dr. Yusuf Abisowo Oshodi,
E-mail: yusufoshodi@gmail.com

ABSTRACT

Background: Progesterone only injectable contraceptive provides long acting contraception against unwanted pregnancy. Alterations in menstrual pattern are a well known side effect of this effective contraceptive method. Objective of this study was to compare the weight gain and pattern of menstrual abnormalities in users of Depot Medroxyprogesterone Acetate (DMPA) and Norethisterone Enanthate (Noristerat) in LASUTH.
Methods: Retrospective comparative study conducted over a 3year period (January 2013 to December 2015) and involving 237 subjects who used injectable hormonal contraceptive (either DMPA or Noristerat). Case records of all the subjects were retrieved and information obtained on socio-demographic data, parity, previous contraceptive method and reason for discontinuation within one year of usage. Other information including subjects' weight, menstrual cycle length and pattern, and side effects were collected at 3, 6 and 12 months for DMPA group and 2, 4 and 12 months interval for Noristerat group. Data obtained were analyzed using statistical packages for social sciences (version 19).
Results: The combined mean age was 34.15±1.36 years. The mean weight at commencement was 68.16kg for DMPA and 66.61kg for Noristerat users while after a year, it significantly increased to 71.27kg for DMPA and 69.07kg for Noristerat users ($P<0.05$). No change in menstrual pattern was noted in 10% of DMPA and 7% of Noristerat users while 60% of DMPA and 57% of Noristerat had amenorrhoea by the end one year period. Five percent each of DMPA and Noristerat users perceived weight gain as problem significant enough to discontinue both methods respectively. Overall, 24% of DMPA and 19.1% of Noristerat users discontinued use after one year.
Conclusions: There were significant weight gain between users of DMPA and Noristerat which was not considered a problem. Amenorrhoea was the commonest menstrual abnormality responsible for discontinuation of either method.

Keywords: Depo-provera, Menstrual abnormalities, Noristerat, Weight gain

INTRODUCTION

Unintended pregnancies pose significant Public Health risks. One consequence of unwanted pregnancy is induced abortion.[1] And, because abortion though legal in Nigeria but the law restrictive, many of such procedures are conducted under unsafe conditions and this carries a substantial risk of maternal morbidity and mortality. It is estimated that about 25% of women who had induced abortion in Nigeria experience serious complications.[1]

After the birth of the first child, 80% of educated couples used spacing methods, whereas even after the birth of the third child, more than 50% of uneducated women did not.[2] Hence education plays a key role in contraceptive

acceptance and its use. Religious beliefs and cultural practices such as the desire for a male child are some of the factors responsible for poor use or non-usage of contraceptives in developing countries.[3]

Failure to utilize modern contraceptives leads to over population and increased demand on limited resources leading to wide scale poverty and deprivation.[3] With the low ranking of most African countries on the human development index, there is no doubt that the smaller the family size, the better the upbringing and development of children.[7] Among the various contraceptive methods available, hormonal agents are the most popular and most effective non-surgical method of contraception worldwide.[4] The most popular of these methods are the combined oral contraceptive pills, although in Nigeria and Africa as a whole, the injectable hormonal contraceptives are gaining acceptance among clients seeking longer contraception.[4] The injectable progesterone only contraceptive offer the advantage of not requiring storage and enabling women to maintain secrecy about their use of contraception, because members of their families may oppose the concept of birth control.[5]

Both progestogens are extremely effective in preventing pregnancy with a pregnancy rate close to zero.[9] Injectable contraceptives are associated with multiple side effects with secondary amenorrhea being the most common menstrual abnormality; others include polymenorrhea and weight gain.[5] However, the USFDA has discouraged their use for more than two consecutive years as evidence shows that prolonged use reduces bone mineral density; however, this loss generally seems to be temporary and reversible.[6]

In view of the foregoing, this study seeks to compare the pattern of menstrual abnormalities and weight gain in users of DMPA and Noristerat among the users in our tertiary institution.

METHODS

This was a retrospective study carried out in the Family Planning Clinic of Lagos State University Teaching Hospital (LASUTH), Ikeja, Lagos over a 3-year period (January 2013 to December 2015) following approval from our institution's Health Research and Ethics Committee. Two hundred and thirty-seven subjects were involved in the study comprising 135 in the DMPA group and 102 in the Noristerat. Case records of all the subjects were retrieved and information was obtained within one year of usage.

Information obtained includes socio-demographic data (Age, marital status, occupation, educational levels and religion) and parity, previous contraceptive methods and reasons for discontinuation. Data on subject's weights, menstrual cycle length and patterns of irregularity were also retrieved from the records as documented during the first 2 months, , the next 4 months following, up to 1 year of regular usage for Noristerat group and for the first 3 months, the following 6months and also up to 1 year of regular usage for the DMPA group.

Statistical analysis

The data obtained were analysed using SPSS version 20 (Chicago Illinois). Variables were represented using mean, standard deviation and cross tabulations were also performed. Comparative analysis of weight gain and menstrual abnormalities was done using student's paired t-tests and independent t test. P value <0.05 was considered statistically significant. Level of confidence interval was set at 95%.

RESULTS

One thousand, one hundred clients used the modern contraceptive methods within the 3-year study period. Intra-uterine contraceptive device was the commonest method used by 668 clients accounting for 60.72%. Three hundred and ninety four subjects accounting for 35.82% used hormonal contraceptives. This comprises 237 (21.55%) injectables (DMPA and Noristerat), 92 (8.36%) for combined oral contraceptive pills, 43 (3.91%) for progesterone only pills and 36 (3.27%) for Implanon users. Twenty two (2%) subjects used male condom and only 2 (0.18%) subjects had tubal sterilization (Table 1). The socio-demographic data revealed mean and age range of 34.15±1.36 (20-47) years. Sixty five percent of the subject had tertiary education compared to 21% that had secondary, 11% primary and 5.5% without any formal education.

Table 1: Contraceptive uptake and types.

Contraceptive method used	Number of patients	Percentage of use
IUCD	668	60.72%
Injectables (progesterone only)	237	21.55%
Combined oral contraceptives	92	8.36%
Progesterone only pills	43	3.91%
Implanon	36	3.27%
Condom	22	2%
Tubal sterilisation	2	0.18%

There was statistically significant difference in the two group considering the educational level (P=0.04). Majority of the clients were Christian (76%) while 19% were Muslim. Majority of respondents were Para 3-4 in both groups but comparative analysis did not reveal any significant difference in both groups (P=0.71) (Table 2).

Table 3 shows average weight gain from commencement up till the end of the one year. In the Noristerat group, mean weight at the first visit was 66.61kg (which was the starting weight) but this increased to 67.2kg at 2 months, 68.03kg at 4 months, and 69.07kg at 12 months. The difference in mean weight at the end of 12 months was statistically significant (p value=0.00).

Table 2: Socio-demographic distribution.

Characteristics	Noristerat Freq (%)	Depoprovera Freq (%)	Differences Absolute P values
Age (in years)			
20-24	7 (6.9)	12 (8.9)	
25-29	10 (9.8)	18 (13.3)	
30-34	38 (37.3)	42 (31.1)	0.12
35-39	21 (20.6)	44 (32.6)	
>40	26 (25.5)	19 (14.1)	
	102 (43)	135 (57)	
Religion			
Christianity	78 (76.5)	102 (75.6)	
Islam	21 (20.6)	25 (18.5)	0.58
Others	3 (2.9)	8 (5.9)	
	102 (43)	135 (57)	
Educational level			
None	5 (4.9)	8 (5.9)	
Primary	4 (3.9)	22 (16.3)	0.04
Secondary	25 (24.5)	25 (18.5)	
Tertiary	68 (66.7)	80 (59.3)	
	102 (43)	135 (57)	
Parity			
1-2	16 (15.7)	27 (20.0)	
3-4	74 (72.6)	94 (69.6)	0.71
>=5	12 (11.8)	14 (10.4)	
	102 (43)	135 (57)	

All the women in this study were married.

Table 3: Weight gain and injectable contraceptives.

	Weight (kg) Mean	Mean difference	P value
(A) Depo-provera			
First visit	68.16±9.84	0	
Second visit	68.85±9.69	0.69±1.62	0.000
Third visit	69.75±9.90	0.9±1.29	0.000
A year	71.27±10.09	1.52±1.26	0.000
Noristerat			
First visit	66.61±9.02	0	
Second visit	67.2±8.69	0.59±1.90	0.000
Third visit	68.03±8.42	0.83±1.62	0.000
A year	69.07±8.39	1.04±1.36	0.000
(B) Term	**Type of IC**		
A year	Noristerat	71.27±10.09	0.067
	Depo-provera	69.07±8.39	

In the DMPA group, mean weight at the first visit was 68.16kg (which was the starting weight), and it increased to 68.85kg, 69.75kgand 71.27kg at 3 months, 6 months and 12 months respectively. This observed difference in

mean weight also reached statistical significance (P value=0.00). However, comparing the mean weight gain between users of DMPA and Noristerat at the 1st, 2nd, 3rd, and after a year visit, using an independent t-test, there were no statistical significant difference between them as P-value = 0.067 at each of the visits.

Table 4 shows menstrual patterns in both categories of women from commencement to the end of 12 months. In the Noristerat group, 21.05% experienced no change in their menstrual cycles at 2 months, but this proportion dropped to 2.44% at 12 months. In the DMPA group 7.75% of the patient experienced no change in their menstrual cycle at 3 months. This proportion however reduced to 0.87% at 12 months. Prolonged spotting and intermenstrual bleeding was common in both groups. Amenorrhea was the most common side-effect, accounting for 60% and 57.32% at the end of 12 months in the DMPA and Noristerat groups respectively. While there was statistically significant difference in both groups during the first follow-up visit, there was no statistically difference in the second and last visit one year later.

Table 4: Menstrual patterns experienced by users of injectable contraceptives.

Menstrual pattern (first follow-up visit)	Noristerat	%	Depoprovera	%	P value
No change	20	21	10	8	0.01
Increased flow	25	26	24	19	
Reduced flow	35	37	55	43	
Amenorrhoea	15	16	40	31	
Total	95		129		
Menstrual pattern (second follow-up visit)					
No change	5	6	2	2	0.3
Increased flow	13	14	11	9	
Reduced flow	42	47	62	50	
Amenorrhoea	30	33	48	39	
Total	90		123		
Menstrual pattern (a year follow-up visit)					
No change	2	2	1	1	0.89
Increased flow	8	10	9	8	
Reduced flow	25	30	36	31	
Amenorrhoea	47	57	69	60	
Total	82		115		

Table 5: Discontinuation rate.

Discontinuation rates	Depoprovera		Noristerat		P-value
	Count	%	Count	%	
At first follow-up visit	6	4%	7	6.86%	0.21
At second follow-up visit	12	9%	5	4.90%	
At 1 year	20	15%	8	7.84%	
Continued	97	72%	82	80.39%	
Total	**135**	**100%**	**102**	**100%**	

Table 6: Reasons for discontinuation.

Reasons for discontinuation	Depoprovera		Noristerat		P-value
	Count	%	Count	%	
Amenorrhoea	26	68%	12	60%	0.67
Prolonged spotting PV	6	16%	4	20%	
Irregular/ intermenstrual bleeding	4	11%	3	15%	
Weight gain	2	5%	1	5%	
Total	**38**	**100%**	**20**	**100%**	

Thirty-eight subjects (28%) in the DMPA group discontinued the method compared to 20 (19.61%) Noristerat users after one year (p=0.21) Table 5. Comparison of discontinuation rate between users of DMPA (68%) and for Noristerat (60%) did not reveal any statistically significant difference (p=0.67). Prolonged spotting was the second reason given by both groups accounting for 16% and 20% respectively. This was closely followed by irregular/intermenstrual bleeding observed in 11% of DMPA and 15% of Noristerat users respectively (Table 6).

DISCUSSION

Progesterone only injectable contraceptive is a widely used method of contraception among the women attending our family planning clinic, and it is the second commonly accepted method only next to intrauterine contraceptive device. The prevalence of 21.55% is comparable to 22.1% reported from Osogbo, 21.9% in Ilorin, and 23.3% in Port harcourt but higher than the 7.9% and 14.2% reported from Ibadan and Jos respectively.[7-11] However, this study prevalence was lower than 26%, 50% and 71.8% reported from Isagamu, Zaria and Abia in respectively in different geopolitical zones in Nigeria.[12-14] In general, there seems to be regional variation in the use progesterone only contraceptives which may be as a result of cultural and religious beliefs and individual client perception of the contraceptive method.[9]

All the women in this study were married. This is similar to findings Oye-Adeniran et al, where their subjects were sexually active, fecund and married.[15] The largest proportion of the women in this study (83.5%) had secondary and tertiary education, only 5.5% had no form of education. This high percentage was expected as studies have shown that formal education significantly increases the utilization of contraceptive methods.[2]

This study also showed that for women in both groups (DMPA and Noristerat), there was an observed increased in the mean weight over 12 months which was statistically significant. The DMPA group gained 3.1kg (4.5%) compared to 2.4kg (3.7%) in the Noristerat group. This is similar to the findings by Moore et al, Mia et al and Berenson et al.[16-18] Hormonal contraceptives (injectables) have been found to increase intake of food by stimulating the appetite and decreasing energy expenditure. DMPA and Noristerat despite normal diet, has also been found to cause slight water retention hence contributing to increase in weight gain.[19] However, age, caloric intake, race, exercise among other factors can contribute to the different changes in weight observed amongst the subjects. Lifestyle changes are often contributory or causative.[19] However, the number of patients considering weight gain to be a major problem was low (5% for Depo-Provera and 5% for Noristerat). This may be explained by the fact that many Nigerian women usually perceive weight gain as a sign of good health and vitality leading to high socio-economic status of the woman.[19] However, this might be hazardous to patients who are overweight ab-initio as any weight gain might tilt them towards obesity and its accompanying morbidities. Therefore, overweight subjects are preferably excluded from the use of hormonal contraceptives.

The incidence of menstrual abnormalities increased steadily from the second and third months of use to the end of 12 months in both groups of women. Amenorrhea accounted for most of the menstrual abnormalities in both groups, with an incidence of 60% in the Depo-Provera group, and 57% in the Noristerat group. This is similar to the findings of Kaunnitz, and Polanecsky et al, whose studies showed that at least 50% of DMPA users will be amenorrhoeic by 12 months of use, but contrasted with the study of Chowdhury23 who reported a mere 12.7% incidence of amenorrhea in patients who used Noristerat for 12 months.[20-22]

The discontinuation rates at 6 months and 1 year were 13% and 28% respectively in the DMPA group. This translates to continuation rates of 87% and 72% which are quite high when compared to a similar study by Polaneczky et al, where continuation rates were 65% and 42% at 6 months and 1 year respectively.[22] In the Noristerat group, continuation rates were 93.00% at 2 months and 80% at 1 year. This is similar to findings of Chowdhury et al with continuation rate of 75% at 12 months.[23] Among reasons for discontinuation not related to desire for pregnancy, amenorrhea tops the list followed by prolonged spotting and irregular/intermenstrual bleeding. The reason for this may not be unconnected to importance women attached to the menstrual bleeding, lack of which could be referred to culturally as early symptoms of impending infertility. Many of the patients when asked about the menstrual irregularities experienced, complained about their perception of having reached menopause and this was not acceptable to them.[14] There was no report of accidental pregnancy during follow-up among the subjects. This supports previous reports of the effectiveness of the contraceptive method and its association with low failure rate.[8,19]

This study has limitations in its retrospective design. However, the significant weight gain in users of injectable contraceptives was tolerable as very few of the users perceive this as a problem. Amenorrhea, prolonged spotting and irregular/intermenstrual bleeding are common side effects, experienced by the users. Optimal counseling at onset of usage and re-enforcement during follow-up is essential to encourage use and perhaps reduce discontinuation rates among users of injectable contraceptives in long term.

CONCLUSION

There were significant weight gains between users of DMPA and Noristerat which was not considered a

problem. Amenorrhoea was the commonest menstrual abnormality responsible for discontinuation of either method.

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