ANALYSIS OF WEIGHT, PACKED CELL VOLUME CHANGES AND MENSTRUAL PATTERN IN NORPLANT IMPLANT ACCEPTORS IN ILORIN, NIGERIA

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ABSTRACT

Context: Norplant[R] is the registered trade mark of the population council for contraceptive subdermal

implants.
Norplant[R] implant contraceptive consists of six capsules containing progestin levonorgestrel. Each capsule is 3.4cm long and 2.4mm in diameter and contains 36mg of levonorgestrel crystals packed into a silastic capsule.

Objective: The aim of this study was to evaluate the effect of Norplant[R] implant use on weight, packed cell volume and describe the menstrual pattern observed during the period of use.

Subjects and Methods: This was a prospective study that involved 59 clients who had complete records at one year out of 71 informed volunteers recruited from the family planning unit of the University of Ilorin Teaching Hospital Ilorin from 1st March, 2002 to 31st December, 2003. Data on their weights packed cell volume and menstrual events were analysed at 3, 6, and 12 months of study.

Results: The mean age(years) and parity of new Norplant[R] implant acceptors during the period of study were 36. 1 5.6 and 3.9 1.5 respectively. The mean weight (kg) at pre-insertions was 66.5 [10.7] and 67.8 [10.7] and 68.9 [10.5] at 3, 6 and 12 months of Norplant[R] implant use. The analysis of variance did not show statistical significant difference (P < 0.551) in the mean weight measured at pre-insertion 66.5 compared to the weight at 3, 6 and 12 months of Norplant [R] use.The mean packed cell volume estimation (%) at pre insertion was 36.6 3.7 and had a statistical significant (p 0.003) rise to mean values of 37.3 3.4, 38.2 3.4 and 38.8 2.4 at 3, 6 and 12 months of Norplant[R] use. The mean packed cell volume estimation (%) at pre insertion was 36.6 3.7 and had a statistical significant (P 0.003) rise to mean values of 37.3 [3.4], 38.2 [3.4] and 38.8[2.4] at 3,6 and 12 months of Norplant use respectively.Amenorrhea was the commonest observed menstrual change during the period of study. All acceptors were recruited with normal menstrual flow and at the end of the twelve months study period only 3 (5.1%) were still experiencing normal menstrual flow and 40 (67.8%) were amenorrheic.

Conclusion: Norplant[R] Implant use was beneficial in maintaining weight and improving the packed cell volume of users. The menstrual change observed was tolerable.

INTRODUCTION

Experience with Norplant[R] implant system is about 20 years old in Nigeria. The introduction of this long acting, reversible hormonal contraceptive that required no ongoing user effort and provided up to seven years of contraceptive protection at levels of efficacy comparable to female sterilization has broadered the choice of methods for users[2-5.] Implants systems are the only reversible method that requires minor surgery for insertion and removal.

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Abnormal menstrual bleeding constitute the single most important factor contributing to discontinuation of Norplant[R] use world wide [1-4]
Changes in the pattern of menstrual bleeding are almost universal in women using progestogens only methods of contraceptions and despite the observed menstrual changes studies from Nigeria had not shown any adverse effect on the haemoglobin statues of users[4-6] and rather they were found beneficial to patients with sickle cell disease[7]. Though a huge population of Norplant [R] users experience menstrual complaints other non-menstrual complaints do occur

and are serious enough to warrant request for termnation Termination of use,[8-11] Weight change constitutes an important non menstrual side effect, though it was not significant in adolescent users and it may therefore be an advantage for the adolescent group [12, 13.] Metabolic studies in Norplant [(R)] implant acceptors have also not implicated derailment of glucose or fat metabolism [14].

The present study was undertaken to document the menstrual pattern, Packed cell volume and weight changes for Norplant[R] implant acceptors in our Center to enhance our knowledge and form an objective basis in counseling prospective clients for Norplant[R] implant use.

MATERIALS AND METHODS

This was a prospective study of new acceptors of Norplant[R] implant system in the Family Planning Unit of the University of Ilorin Teaching Hospital, Ilorin from 1st March 2002 to 31st December, 2003.

Seventy one (71) healthy, non breast feeding women aged 22-42 years with regular predictable menstrual pattern were recruited for the study. None had history of chronic medical disorders and general and pelvic examinations revealed no abnormalities.

Each new acceptor was properly counseled for this new choice and an informed consent was obtained. Pre-insertion evaluation included general health evaluation, detailed menstrual history including the last menstrual period to exclude pregnancy, previous contraception use, packed cell volume estimation was made by the micro-hematocrit method and weight measurement in kilograms. A specially designed daily bleeding card on which a distinction code was made between spotting and bleeding card on which a distinction code was made between spotting and bleeding was issued after thorough explanation was made on its use to record menstrual events throughout the year. A three monthly appointment was given after Norplant[R] implant insertion up to a period of one year. On each clinic visit, the general health review was performed. Whole blood was taken for packed cell volume estimation by micro-hematororit method and the weight was obtained by using standard weighing scale after due zero balancing. The weight was obtained in kilograms and recorded. The bleeding card was reviewed for menstrual abnormalities over the period since last visit.A total of fifty nine (59) clients who completed the study having attended the follow up clinic visits at months, 6 months and 12orplant[R] implant insertion ant 12 months after

Norplant[R] implant insertion and they form the subject of the present study. The remaining twelve (12) informed acceptors were lost to follow up and hence had incomplete records and were not considered further.

Data were analysed using the SPSS statistical package version 6. Analysis of variance (A NOVA) was used to test for statistical significance p< 0.05.

RESULTS

There were a total of one thousand five hundred and forty-eight (1548) new acceptors of all Family Planning methods during the study period. Seventyone (71) accepted Norplant[R] implant with an incidence of four point six percent (4.6%). The mean age and parity of Norplant[R] implants acceptors were 36.1 [5.6] and 3. 9 [1.5] respectively. Thirty seven point two percent (37.2%) of new Norplant[R] acceptors had not used any form of modern Family Planning method. Table 1.

The mean weight (kg) at pre-insertion was 66.[510].7 66.5 [10.7] and 68.9[10.5]at 3 months. 6 months and 12 months following visits.

The f-distribution of these weight measurement was 0.7 P value 0.5. This did not show significant statistical difference. Table 2.

The mean packed cell volume (%) new Norplant [R] implant acceptor at insertion was 36.6 3.7. Mean values of 37.3 [3.3], 38.2 [3.4] and 38.8 [2.9] were obtained for 3 months 6 months and 12 months followings visits respectively.

The f-distribution of these mean values of packed cell volume was 4.7 P value 0.003.Highly statiscally significant. Table 2.

Menstrual Bleeding Pattern

At pre-insertion period all the acceptors recorded normal menstrual flow with predictable dates and this was recorded as 100%. The proportion of those observing normal menstrual flow fell to 8.5%, 3.4% and 5.1% at 3months, 6 months and 12 months follow up visits respectively.Amenorrhea (Absence of menstrual flow) became the prominent menstrual pattern at 3 months follow up with thirty six (61%) clients recording this event Seventeen (28.8%) recorded spotting and only one (1.7%) recorded prolonged bleeding.At 12 months period of use three (5.1%) clients use still experiencing normal menstrual flow and forty (67.8%) recorded amennorhea. Two (3.4%) clients recorded prolonged bleeding which did not necessitate request for removal.

Table 1. **Previous Contraceptive use pattern in new Norplant[R] Implant Acceptors.**

Family planning method % Previously used	Number of clients	Per %
None	22	37.2
Condom	13	22.1
Withdrawal	3	5.1
IUCD	15	25.4
Oral combined ILLS	6	10.2
Total	**59**	**100**

Table 2: **Mean Values SD of Weight (Kg) and packed cell volume 9%0 of Norplant[R] implant Acceptors during the Study period.**

	Pre-insertion	3 Months		
Weight(kg)	66.5 ± 10.7	66.5± 10.6		
Packed cell Volume %	36.6 ±3.7	37.3 ± 3.3		
	6 month	12 Month	F	P
Weight	67.8±10.7	68.9±10.5	0.7	0.5
PCV	38.2±3.4	38.8±2.9	4.7	0.003

Table 3: **Observed menstrual pattern one year of Norplant[R] implant use**

Menstrual Pattern	Pre-Insertion	3 months	6months	12months
Normal	59(100%)	5(8.5%)	2(3.4%)	3(5.1%)
Amenorrhoea	-	36(61%)	38(64.4%)	40(67.5%)
Spotting	-	17(28.8%)	19(32.2%)	14(23.7%)
Prolonged	-	17(28.8%)	-	2(3.4%)

DISCUSSION

Norplant[R] Implant, an effective, reversible contraceptive method which has been in clinical use for about 20 years in Nigeria is still not a popular method of choice in this country. Probably as a result of poor knowledge of the method by health providers. New acceptors of Norplant[R] method were four point six percent of new acceptors of all Family Planning methods during the period under study at the Family Unit of the University of Ilorin Teaching Hospital, Ilorin. Low level of practice of contraception in this environment is clearly showed in this study as forty two point three percent of new Norpalnt[R] Implant acceptors were either never used any method or practicing withdrawal method despite its unreliability for protection against unwanted pregnancy.

This is a strong pointer to improve the awareness campaign of contraceptive use in this environment using every available forum.The mean age of acceptors in this study was 36.1 5.6 years and this is rather in the upper range of reproductive age. This is also the observation in other similar studies in Nigeria[4, 5, 6]. This observation may be due to the fact that most Family planning units are not youth friendly.

Women are known to be conscious of their weight for various reasons. Socials and other related reasons. It is not surprising that weight change can make a woman to change her mind about the use of a contraceptive method 14. The mean weight of Norpalnt[R] Implant acceptors at insertion was 66.5 10.7 and the mean values of weight (kg) at 3 months, 6 months and 12 months of Norpalnt[R] Implant use 66.5 10.6, 67.810.7 and 68.9 10.5 respectively.

The differences in the mean value were not statistically significant. Weight change was not a significant complaint in this study and this observation will be a positive reason why more women will want to enjoy the contraceptive benefit of Norpalnt[R] Implant. If proper counseling is done more women can be reasonably reassured of keeping their appearance while still enjoying the contraceptive benefit of the method. There is a significant rise of packed cell volume after one year of use of Norpalnt[R] implant contraceptive as demonstrated by this study. Similar observation of increased improvement in packed cell volume or haemoglobin concentration was made by other studies in Nigeria[4, 6, 7]. This observed rise in packed cell volume may not be unconnected with the prominent menstrual pattern observed in this study. Amenorrhea (absence of menses) is the commonest menstrual pattern observed in this study.

Improvement in the packed cell volume with use of Norpalnt[R] implant contraceptive is a great advantage to users in the developing world where anaemia is a significant health problem. Norpalnt[R] implant contraceptive can be encouraged in suitable patients who are prone to developing anaemia in pregnancy in the interval of pregnancies to ensure that adequate packed cell volume is achieved at the beginning of the next pregnancy.

Amenorrhea is the commonest menstrual change observed in this study and all the fifty nine clients who completed the study were still continuing to use the

Method. The change in the menstrual pattern observed did not deter continous use of the method probably because the clients were thoroughly counseled and understood the harmlessness of the change and the confidence that they can demand termination of use at anytime they report in the Family planning Clinic for such request builds further trust in the contraceptive method.

The findings in this study had further improved our understanding of the effects of Norplant [R] Implants and would make objective counseling of clients better to ensuring satisfactory use.

In conclusion, Norplant [R] Implant use was beneficial in maintaining weight and improving the packed cell volume of users. The menstrual change observed was tolerable.

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