Safety, Efficacy and Acceptabilty of Norplant[R] Implants in Jos, Northern Nigeria

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Abstract

Context: Norplant[R] is a long acting reversible progestogen method suitable for women of all ages. It is however not without side effects that may affect its continuous usage. Documentation of such changes is important for counselling acceptors to achieve user's satisfaction.

Objective: To evaluate the safety, efficacy and acceptability of Norplant[R] amongst its acceptors.

Study Design, Setting and Subjects: This study was part of ongoing prospective longitudinal studies that involved 23 women who had complete records at three years out of the 37 healthy non breast feeding informed volunteers recruited from our family planning clinic in August 1997. Data on socio-demographic characteristics, menstrual pattern, packed cell volume, weights, blood pressure, side effects and user's satisfaction were analysed.

Results: The mean age and parity of the acceptors were 31.7 ± 3.4 years and 4.7 ± 1.0 respectively. Even though the mean weight at 12months (63.2 ± 11.7kg was not statistically different (p 0.5) from the mean weight at pre-insertion (62.5 ± 11.2kg), there were statistical significant increases in weights at 2years (66.9 ± 12.1kg; p= 0.001) and at 3years (65.9 ± 11.6kg; p 0.01). Apart from the slight statistically significant increase (p 0.02) in systolic blood pressure at 2years, the blood pressure changes at 1year and 3years did not show significant changes. Main side effects were menstrual abnormalities, weight changes, headache, abdominal pain and dizziness. The packed cell volume significantly increased. Continuation rate was 100% and there was no pregnancy recorded. Users were satisfied with the method because of its convenience, low risk of pregnancy and long duration of action.

Conclusion: Norplant[R] subdermal implant was an effective safe and acceptable method of contraception amongst the acceptors, despite its minimal side effects.

Key Words: Norplant[R] Implants, Safety, Efficacy and Acceptability [Trop J Obstet Gynaecol, 2004;21:95-99]
Norplant[R] ***is a registered trademark of The Population Council for levonorgestrel subdermal implants***

Introduction

In developing countries each year, an estimated 585,000 women die from complications of pregnancy, childbirth and unsafe abortion i.e. about one every minute[1]. It is estimated that between 10% and 20% of these pregnancies were unwanted at the time of conception. Thus, up to 100,000 maternal deaths could be avoided if women who did not want children used effective contraception. When maternal morbidity is also taken into account, it is estimated that preventing unwanted pregnancies would avert a total of 4.6million disability-adjusted life years. Even though Nigeria's population constitutes 2% of the world's population, it accounts for 10% of the world maternal deaths, About 60,000 Nigerian women die each year[2].

The fertility level in Nigeria remains high at a national average of about 5.2 children per woman. There is a low contraceptive prevalence rate of 9% and a large pool with unmet needs[3]. Norplant implant is a long term reversible progestogen, which has gained worldwide acceptance with over 11million women around the world using the method[4,5]. It is safe and effective[6]. The implants are likely to suit women of all ages, who have completed their desired family size, but decline sterilization and women who need child spacing for several years and those who want the effectiveness of hormonal contraception, without the side effects of oestrogen[7, 8]. Its availability, accessibility will make it one of the method mix, women could choose from, to reduce some of the causes of maternal morbidity and mortality.

Like every other family planning methods, Norplant implant has its drawbacks such as bleeding problems, cost, discomfort of minor surgery required to insert and remove. Menstrual problems range from amenorrhoea to frequent, irregular heavy bleeding or spotting [9, 10]. Such aberrations have led to discontinuation of method in the 12months of use[11, 12]. Inspite of the aberrations in menstrual pattern, increased haemoglobin had been documented in the literature[9, 10, 13]. Other side effects reported in the literature include headache, weight changes, dizziness, nervousness, nausea, dermatitis, acne, change of appetite, mastalgia, hirsutism or alopecia[15, 16, 17]. Women's attitude towards these side effects varied from tolerance to acceptability in those who experienced them[8]. This study evaluated the safety, effectiveness and acceptability of Norplant[R] amongst the acceptors.

Materials and Methods

Thirty seven healthy Nigerian women who sought long

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term reversible contraception were recruited from the family planning clinic of Jos University Teaching Hospital (JUTH) in August 1997. They were of proven fertility, non-breastfeeding and non-smoking volunteers. None of the women received injectable contraception within 6months preceding the enrolment into the study. None of them was on haematinics. All the acceptors were given calendars to keep a daily record of menstrual bleeding events[9, 10]. At yearly follow up visits records of weight, blood pressure side effects were recorded. The clients also filled user's satisfaction questionnaire, which provided information on women's opinions and impressions about the method. Each acceptor served as her own control. Twenty-three subjects who had complete records at the end of 3years were analysed. Statistical analysis was with paired t-test. The level of significant was set at <5%.

Results

The age range of the acceptor was 25-38years with a mean ± SD of 31.7 ± 3.4years. Majority of the women were between the ages 30-34years (Table1). The parity ranged between 3-6 with a mean of 4.7±1.0 (Table 1).

Table 1. Age and Parity Distribution of Norplant[R] Acceptors

Age	Number	Percentage %
20-24	-	0
25-29	5	21.7
30-34	12	52.2
35-39	6	26.1
≥40	-	0
Total	23	100
Parity	Number	Percentage %
1-2	-	0
3-4	9	39.1
≥5	14	60.9
Total	23	100

All the women had formal education. There were significant increases (p 0.001 and p 0.01) in the mean weight at 2years and at 3years respectively compared with the pre-insertion mean weight (Tables 2 and 3).

Table 2.
Mean weight (mean ±SD kgm) and Mean Blood Pressure (Mean ±Sd mmHg)of Norplant[R] Acceptors over Three Years

	Pre-insertion	12months	24months	36months
Weight	62.5±11.2	63.2±11.7	66.9±12.1	65.9±11.6
P-value	-	0.5	0.001	0.01
Blood pressure	107.4/72± 8.6/7.5	108.7/73± 8.6/7.5	114.8/76.5± 8.6/7.5	110.1/76± 8.6/7.5
P-value	-	0.5/0.5	0.02/0.1	0.5/0.1

Table 3.
Weight changes of the Acceptors over Three years

Weight changes	One year No.	%	Two years No.	%	Three years No.	%
Weight increase	12	52.2	18	78.3	17	73.9
Weight loss	9	39.1	5	21.7	6	26.1
No change in weight	2	8.7	0	0	0	0
Total	23	100 %	23	100%	23	100%

Apart from the slightly significant increase in systolic blood pressure at 2years compared with the pre-insertion value; there was no other statistically significant change in the systolic and diastolic blood pressures at 1year and 3years (Table 2). Irregular menstrual patterns over the four reference period was experienced by 82.6%, 60.9% and 47.8% of the clients at 1year, 2years and 3years respectively [9,10]. In spite of these, the packed cell volume statistically increased over the 3years period [9,10]. Other side effects reported were headache, abdominal pain, and dizziness. These were mainly reported in the first 12months of use (Tables 4).

Table 4. Side effects experienced by Norplant[R] Acceptors over Three years

Side effects	Number	Percentage %
Headache	9	39.1
Abdominal pain	4	17.0
Dizziness	4	17.0
Decreased libido	3	13.0
Nausea/Vomiting	3	13. 0
Nervousness	2	8.7
Mastalgia	2	8.7

The clients' user's responses (Table 5) indicated that Norplant is a method associated with a high degree of client satisfaction. When the clients were asked about the features of Norplant[R] that they liked, the given responses were convenience, low risk of pregnancy and long duration of action. The feature least liked was the bleeding irregularity.

Table 5. User Satisfaction

Features	Number	Percentage %
1. Liked Features:		
a. Convenience	23	100
b. Low risk of pregnancy	23	100
c. Long duration of action	23	100
2. Least liked Feature:		
a. Bleeding irregularities	15	65.2
3 Discomfort during insertion		
4 No negative feelings about the method	21	91.3
5 Recommendation of the method to a friend	22	5.7
6 Usage of a second set of implant for contraception	21	91.3
7 Satisfaction about the choice of method	23	100
8 Received enough information about implant for decision making	23	100

Discussion

The mean weight of the Norplant® acceptors increased over the 3 years of use. The blood pressure showed slight increases, which were within normal range. Irregular bleeding patterns were reported, despite which packed cell volume increased. Other side effects included headache, abdominal pains and dizziness. No pregnancy was reported and the continuation rate was 100%. The users were satisfied with the method for its convenience, effectiveness and long duration of action. This study was part of an on-going longitudinal prospective study. The clients were their own control. The sample size was however small. Fourteen acceptors were dropped because they did not have complete records for analysis.

The study had shown that the mean age and parity of the Norplant® acceptors were similar to those found in other studies[18,19,20,21]. Some other studies however documented lower age and parity distributions[22, 23, 24]. One of the major drawbacks of Norplant® is the disruption of bleeding patterns. Our previous studies[9, 10] had documented the reduced irregular bleeding patterns amongst the acceptors over the 36months of use. Over 60% of the clients considered bleeding irregularities as the least liked feature. However no client discontinued the use of the method because of effective counseling[9,10, 25] and the use of pelvic ultrasonography in clients with prolonged amenorrhoea for reassurance. In clinical studies 40-60% of users discontinued the use of Norplant® in the first year of use[26,27]. The irregular menstrual pattern did not have any untoward effects on the clients as their packed cell volume increased over the study period[9,10]. The increased packed cell volume is an advantage that may prevent anaemia in the developing countries. This finding is similar to other studies[13,24,28].

Most of the women in the study had weight gain. Other studies had also documented weight gain during Norplant® use[12,29], while some other studies reported either no change in weight[27] or both weight gain and weight loss amongst their acceptors[30]. Levonorgestrel is a derivative of 19 nortestosterone whose action is androgenic and anti-oestrogenic. The weight gain observed may have been a consequence of the anabolic effect of the progestogen in the body.

Experience from some other studies either showed no change in blood pressure[27] or minor changes within normal range[31,32]. The latter observation was found in this study. Sodium and water retention could occur as a result of progestogen contraceptive method. This may account for the slight but normal increase of blood pressure observed. Headache is experienced by 10-30% of implant users. Comparative studies of Norplant® and non-hormonal methods of contraception have found two to three fold higher rates of headache among Norplant® users[6,14,15,16]. The present study also confirms this. Other side effects experienced by the clients were abdominal pain, dizziness, decreased libido, nausea and vomiting, nervousness and mastalgia. They were mainly reported in the first 12months of use. These effects have also been reported in the literature[15,16]. and are method related.

There was no complication of implant insertion. This was because infection prevention practices such as pre-insertion skin preparation, use of aseptic technique and correct placement of the implants by trained medical staff were utilized. There was also no clinical evidence of enlarged ovaries especially amongst the clients who had abdominal pains. Enlarged ovarian follicles sometimes have been reported in women using continuous low dose progestogens. These are thought to be caused by delayed regression (atresia) of follicles. In some women, these persistent follicles may grow beyond the size they normally would reach, causing pelvic or lower abdominal discomfort. They regress on their own in vast majority of women. Treatment is not required unless they twist or rupture[17].

The effectiveness was 100% during the study period as none of the acceptors was pregnant. In clinical studies, the average annual pregnancy rate over a 5-year period was less than 1%[15]. Other side effects reported in the literature such as acne, hair loss, hirsutism, dermatitis were not experienced by the clients in this study. There was no severe adverse effects. Implant users seldom have serious adverse events. In large prospective studies 2-6% users have reported such event. In pooled analysis, the rate of hospitalization for cardiovascular

disease, diabetes mellitus, gall bladder disease and pelvic inflammatory disease was 20.7/1000 which was less than for the general population[6].

The continuation rate was 100%. Experience from the literature[4,20,23,33,34,35] had demonstrated that Norplant[R] implant is safe, effective and acceptable. This study has also confirmed this observation.

In conclusion, this study has shown that Norplant[R] is efficacious and free from major side effects and acceptable to Nigerian women. The findings in the study should be used in counseling clients to ensure adequate decision making and client satisfaction of the method. Future research in the area of randomized study that will involve more acceptors and in other teaching hospitals in the country are needed to confirm the results of this study.

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