BLEEDING PATTERNS AND ACCEPTABILITY AMONG NORPLANT® USERS IN SINGAPORE

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ABSTRACT

NORPLANT® contraceptive implants are silastic implants containing levonorgestrel. This study describes our experience with 100 acceptors of NORPLANT® implants in Singapore. No pregnancies occurred during the first year of use. The majority found the method's ease of use to be the most attractive feature. Disruption of menstrual rhythm appeared to be the least liked feature. However the incidence of these menstrual irregularities appeared to diminish with time. Implant users have tolerated this early disruption of their menstrual rhythm well and the continuation rate at the end of the year was 97%. Thus it appears that Norplant® is a safe, effective and acceptable method of contraception.

Key words: Levonorgestrel containing contraceptive subdermal implants

SING MED J. 1989; No 30: 145 — 147

INTRODUCTION

NORPLANT® contraceptive subdermal implants offer potential family planning clients a safe, effective, long-acting, reversal hormonal contraceptive. NORPLANT® implants have previously been shown to be a highly effective method of contraception in several countries and in different populations (1-5).

The primary side effect associated with this contraceptive method is disruption of the women's menstrual cycles. Since these disruptions could play an important role in patient acceptance and compliance (6), evaluation of acceptors' menstrual pattern is important. Earlier studies indicated that both increased as well as reduced menstrual bleeding occurred at the same frequency in the first year of use and that these menstrual changes tend to stabilise after one year. Despite these changes in menstrual patterns, satisfaction with the method has been high as measured by continuation rates and by acceptor interviews.

Norplant® is currently undergoing clinical trials at the Fertility Control Clinic, National University Hospital, Singapore. This paper presents the results of the first year of use of NORPLANT® with particular attention paid to acceptability of the method and menstrual pattern analysis.

METHODOLOGY

Enrolment and follow-up

Enrolment of the cases began in May 1985 and 100 cases were recruited by November 1985. This report is based on data from clinic visits through November 1986.

In recruiting acceptors, the principal criteria used by the Population Council's International Committee for Contraception Research were followed. Acceptors in the study met the following criteria — they had to be between 18 and 40 years of age, sexually active but not currently pregnant, not breastfeeding, not using injectable contraceptives in the six months prior to admission and who had none of the standard contraindications to the use of hormonal contraceptives. They had to be easily followed-up on a regular basis and also had no other contraceptive use during the study.

Women who met all the above criteria were fully informed about the purpose of the study and the risks and benefits associated with the use of this contraceptive method. Each acceptor was also given a complete physical examination, including a gynaecological examination. Written informed consent was obtained prior to insertion of the implants.

Follow-up of all acceptors was scheduled at 1, 3, 6 and 12 months after admission to the study, although the women were encouraged to return to the clinic for any problems that occurred at any time. Follow-up of all women is ongoing at six monthly intervals until removal of the implants or five years.

Menstrual bleeding data collection and analysis

Each woman participating in the study was asked to keep a daily record of her menstrual bleeding events coding '0' for no bleeding, '1' for spotting or light bleeding (but no sanitary protection needed) and '2' for heavy bleeding (sanitary protection needed). Data analysis of the daily bleeding calenders is based upon completed 90 day interval, or reference periods according to the methodology developed by Rodriguez et al (7). In this analysis, a bleeding run is defined as a series of bleeding or spotting days beginning with a first day of bleeding per vaginam.

RESULTS

Socio-demographic characteristics

The mean age of the entire group was 29.5 years and the average length of education was 7.8 years. The average parity was 2.1 livebirths. Sixty-nine percent of the women said that they did not want any more children.

Contraceptive use among acceptors was quite high.

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Barrier methods (almost exclusively condoms) were the primary method used by 52% of the acceptors. The IUD and oral contraceptives were used by a similar percentage of women (12% and 11% respectively). Only 16% of the women reported that they had used no method in the month prior to admission.

Table 1.
SELECTED SOCIO-DEMOGRAPHIC CHARACTERISTICS NORPLANT® PRE-INTRODUCTORY CLINICAL TRIAL — SINGAPORE

	No.	%
Age (years)		
< 20	1	1.0
20 — 24	18	18.0
25 — 29	40	40.0
30 — 34	28	28.0
35 — 39	13	13.0
Mean	29.5	
Education (years)		
0	2	2.0
1 — 6	36	36.0
7 — 13	60	60.0
13+	2	2.0
Mean	7.8	
Parity		
1	18	18.0
2	55	55.0
3	23	23.5
4	4	4.0
Mean	2.1	
Contraceptive method in month prior to admission		
None	16	16.0
IUD	12	12.0
Orals	11	11.0
Barriers/spermicides	52	52.0
Withdrawal/rhythm	8	8.0
Folk medicine	1	1.0
Women wanting no more children	69	69.0

Termination and continuation

The one year cumulative lifetable rates showed that no pregnancies occurred during the first year of use (Table 2). The one-year follow-up rates was 100%. A total of three removals were reported, two due to menstrual disturbances, and one due to planned pregnancy. No removal of complications were reported for any of the three removals.

Table 2.
ONE-YEAR CUMULATIVE LIFE-TABLE RATES (PER 100 WOMEN) NORPLANT® PRE-INTRODUCTORY CLINICAL TRIAL — SINGAPORE

Event	Rate*
Pregnancy	0.0
Removal for:	
Menstrual problems	2.0 (2)
Desired pregnancy	1.0 (1)
Continuation	97.0
Woman-months	1180.0

*Number of events reported in parentheses

Weight and blood pressure changes

Average weight remained essentially unchanged after 12 months of use. There was a 7 mmHg decrease in systolic blood pressure, while there was no change in diastolic blood pressure.

Insertion site complications

A total of 20 insertion site complications were reported by the acceptors during the first year of use. Of these, 19 complications were due to local reaction (pain, itching, tenderness or redness at the implant site). In all these cases, the local reaction was transient and lasted only a few days after insertion. No expulsions or infections at the implant site were reported by any of the acceptors during the first year of use.

Post-insertion adverse experience

Dizzines/giddiness (14 cases) and weakness/fatigue (8 cases) were the most frequently reported adverse effects after local reaction at the implant site. There were no other significant adverse reactions.

Menstrual pattern change

The mean number of bleeding and spotting days per 90 day reference period decreased from 31.3 days in the first period to 21.6 days in the fourth period.

Table 3.
BLEEDING IRREGULARITIES, BY REFERENCE PERIOD, NORPLANT® PRE-INTRODUCTORY CLINICAL TRIAL — SINGAPORE

	Reference Period	Days after Insertion	No.	%
Frequent Bleeding (5+ runs)	1	1-90	3	3.0
	2	91-180	3	3.1
	3	181-270	5	5.3
	4	271-360	3	3.4
Prolonged Bleeding (8+ days in a run)	1	1-90	48	48.0
	2	91-180	41	41.8
	3	181-270	29	30.9
	4	271-360	18	30.5
Numerous Bleeding Days (21+ days)	1	1-90	18	18.0
	2	91-180	11	11.2
	3	181-270	6	6.4
	4	271-360	4	6.8
Numerous Bleeding and/or Spotting Days (31= days)	1	1-90	46	46.0
	2	91-180	31	31.6
	3	181-270	23	24.5
	4	271-360	12	20.3
Infrequent Bleeding (< 2 runs)	1	1-90	42	42.0
	2	91-180	44	44.9
	3	181-270	42	44.7
	4	271-360	31	52.5
Amenorrhoea (60+ days without bleeding or spotting)	1	1-90	13	13.0
	2	91-180	20	20.4
	3	181-270	19	20.2
	4	271-360	14	23.7
Few Bleeding Days (< 5 days)	1	1-90	39	39.0
	2	91-180	42	42.9
	3	181-270	42	44.7
	4	271-360	31	52.5

* Percentage of cases with data for the reference period that fall into specified category.

Frequent bleeding defined as 5 or more bleeding

runs increased slightly over the first three reference periods. Thereafter it decreased in the fourth reference period. The percentage of women reporting prolonged bleeding (8+ days in a run) decreased from 48.0% in the first reference to 30.5% in the fourth period. The percentage of women reporting numerous bleeding days (21+ days) decreased over the first three reference periods from 18.0% to 6.4%. Likewise the proportion of women reporting numerous bleeding and/or spotting days defined as a total of 31 or more bleeding or spotting days during a reference period, decreased by more than half (46.0% to 20.3%).

The percentage of women reporting infrequent bleeding (< 2 runs) and amenorrhoea (60+ days without bleeding or spotting) were 42.0% and 13.0% respectively in the first reference period. These percentages increased slightly in the second reference period, remaining essentially the same in the third and rose to 52.5% and 23.7% respectively, in the fourth reference period. The percentage of women reporting few bleeding days (< 5 days) per reference period increased during the first year from 39.0% to 52.5% in the first and last reference period, respectively. However, no acceptors discontinued implant use because of amenorrhoea or decreased bleeding.

User satisfaction

User satisfaction questionnaires designed to elicit acceptors' opinions and impression about the method, were administered at the 6-month follow-up visit. Of the 100 acceptors recruited in the study, 96 user satisfaction questionnaires were completed.

The responses given indicate that the NORPLANT® system is a method associated with a high degree of user satisfaction. When women were asked about the one feature of the implants that was most attractive to them, the most frequent response was the ease or convenience of use (79.1%).

As expected, the features least liked about the implant was its effect on the menstrual cycle and the resultant bleeding irregularities (54.2%). Other side effects and the insertion procedures were not perceived to be drawbacks to the method. Approximately 38% of the women had no negative feelings about the method.

When asked if they would recommend this method to a friend, 85.4% said they would and 55.2% of the women stated that they would use a second set of implants themselves if they still wanted to use birth control after this set was removed. Almost 96% of the women felt that they had received sufficient information about the method.

DISCUSSION

The findings presented in this one year experience with NORPLANT® suggest that the implant system is a highly effective, safe and acceptable method among Singapore women. In this study, the continuation rate was 97% after one year with no pregnancies. Non menstrual complaints were relatively infrequent among users of NORPLANT®.

As demonstrated in other international studies (3, 4, 5, 6, 8), disruption of menstrual rhythm, particularly increased bleeding in the early months of use, appears to be the method's main drawback. However, despite this, only two acceptors in this study discontinued implant use because of bleeding irregularities, indicating that most women are willing to tolerate slight menstrual changes during the first year of NORPLANT® use. Furthermore, the data presented show that the incidence of prolonged or excessive bleeding tends to diminish over time.

The key to the high continuation rates and high degree of satisfaction may have been the counselling these women received; 96% stated that they had received sufficient information about the method. The majority found their experience favourable enough to recommend NORPLANT® to others and many acceptors said that they would use a second set if they still wanted to use birth control after the first set was removed.

CONCLUSION

The initial findings on NORPLANT® are encouraging. Despite the changes in menstrual patterns, the method was highly acceptable to the women in the study and has the potential for wider use in the future.

ACKNOWLEDGEMENTS

We are grateful to the medical and nursing staff of Fertility Control Clinic, National University Hospital for the invaluable help. The study was supported by a grant from Family Health International, USA.

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