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Five-year evaluation of safety, efficacy and acceptability of Norplant implants in Nepal

M. CHETRI (1), A. BHATTA (2), R.N. AMATYA (3)*, H. LAMA (1), T.R. DUNSON (3), S. SPIVEY (3), J.H. McMAHAN (3) and S. BALOGH (3)

(1) Family Planning/Maternal and Child Health Project, Lalitpur Family Planning Clinic, Patan, Nepal
(2) Family Planning Association of Nepal, Kathmandu, Nepal
(3) Family Health International, Research Triangle Park, NC, USA
**Correspondence*

Abstract

This paper presents findings based on a five-year, noncomparative study of Norplant contraceptive subdermal implants in Nepal. The study was designed to evaluate the contraceptive safety, efficacy, and overall acceptability of Norplant. Four hundred and seven women enrolled in the clinical trial, which began in 1985, at two study sites, located in Patan and Kathmandu. Follow-up visits were scheduled at 1, 3 and 6 months after Norplant insertion and every six months thereafter until removal or at the end of five years. Although five pregnancies were reported during the study, only two women (one from each center) were diagnosed as becoming pregnant while using Norplant. The pooled gross cumulative life-table pregnancy rate was 0.6 per 100 women at the end of five years. The pooled cumulative continuation rate was 62 per 100 women at the end of five years. The three most frequently reported reasons for discontinuation were menstrual problems, personal reasons, and medical reasons. Of the 125 women who completed a five-year user satisfaction questionnaire, the majority of the women (86%) planned to continue using contraception after study completion. Of these women, almost one half said they planned to use a second Norplant set. The findings suggest that the Norplant system is a safe, effective, and acceptable method of contraception among Nepalese women.

Introduction

Nepal, with a population of 22.6 million in 1995, is experiencing a gradual demographic transition from natural to regulated fertility and also a movement from

high to low fertility. The increased availability of family planning services, urbanization, improvement in educational status, movement of women into the labor force, and the support by the government and voluntary agencies of a national family planning program have helped to increase the use of modern contraceptive methods. Nepal's current level of modern contraceptive use (23%) is still low compared to many neighboring countries [1], and sterilization (male and female) makes up more than three-fourths of the modern contraception used. Introduction of an effective and acceptable reversible contraceptive method like Norplant could help to increase the contraceptive prevalence by providing more choices to Nepalese women.

The effectiveness of the Norplant contraceptive is comparable with sterilization and injectable contraceptives and is higher than that of oral contraceptives in general use. In clinical trials based on more than 50 000 woman-months of use, the effective lifetime of the Norplant capsule system has been determined to be five years. In the first two years of use, annual pregnancy rates have been reported at or below 0.5 per 100 women. The Norplant six-capsule system first received approval for marketing in Finland in 1983 and has since been approved for use in more than 30 countries, including the United States.

A pre-introductory multicenter clinical trial of Norplant in Nepal began in 1985 at two centers, Patan and Kathmandu, with the support of Family Health International (FHI). The principal objectives of this study were to evaluate the safety, efficacy, and overall acceptability of the implants. Other objectives were to introduce the Norplant implant system as a new contraceptive method in Nepal and use this opportunity to provide proper training to physicians in insertion and removal techniques, and in counseling clients. A final objective of the trial was to provide the opportunities for regulatory authorities and policy makers in Nepal to review the local clinical data and determine the appropriateness of the Norplant method for wider use.

Nepal was one of several Asian countries in which pre-introductory clinical trials of Norplant implants were conducted by FHI in collaboration with local investigators. Other countries included Bangladesh, Pakistan, the Philippines, Singapore, and Sri Lanka. This paper presents the results of this pre-introductory clinical trial in Nepal.

Methods

The participating institutions were Lalitpur Family Planning Clinic in Patan (a model family planning clinic of the Family Planning/Maternal and Child Health Project) and the Family Planning Association of Nepal (FPAN) clinic in Kathmandu. The study was conducted according to a standard protocol which was approved by FHI's Protection of Human Subjects Committee (PHSC). His Majesty's Government of Nepal, the Nepal Medical Review Board, and Ministry of Health gave approval to conduct the Norplant implant trials in November, 1984. Since use of the method requires a minor surgical procedure, training that included the proper placement and removal of the implants, client selection criteria, acceptor counseling, adverse events reporting, and follow-up procedures was provided to four investiga-

tors at an international training center, Raden Saleh Clinic in Jakarta, Indonesia, in January 1985.

The study began in February 1985. Initially both centers were to recruit 200 women for the study. However, because recruitment at the Kathmandu center was very slow, 100 cases from its assigned caseload were re-allocated to the Patan center midway through the study, resulting in a target caseload of 100 at the Kathmandu center and 300 at the Patan center.

Standardized case report forms (CRFs) designed by FHI were used to record information about each acceptor at admission and at regularly scheduled follow-up visits. Recruitment for the study was completed at both centers in March 1986 and all 5-year follow-up visits were completed by April 1991.

In recruiting acceptors, the following selection criteria were followed: subjects had to be between 18 and 40 years of age, sexually active, previously pregnant, neither fully breastfeeding nor breastfeeding with supplementation unless at least six months postpartum, not using injectable contraceptives in the six months prior to admission, within the first seven days of the client's menstrual cycle at the time of insertion, and readily available and willing to return to the clinic for regular scheduled follow-up visits. Women with a history of liver disease, jaundice, sickle-cell anemia, or herpes gestationis were excluded from consideration. Prior to each insertion of the implants, physical and pelvic examinations were performed on each woman. Any evidence of thromboembolic disease, hypertension, pelvic inflammatory disease, undiagnosed vaginal bleeding, cancer, or pregnancy was also a condition for exclusion from the study.

Women who met all the criteria for inclusion in the study were fully informed about the purpose of the study and the risks and benefits associated with the use of this contraceptive method. Each woman who volunteered to participate in the study was required to give informed consent by signing a Volunteer Agreement.

Women were told that they could request removal of the implants at any time during the study. Follow-up visits of all acceptors were scheduled at 1, 3, and 6 months after Norplant insertion, and every six months thereafter, until removal at five years. However, women were encouraged to return to the clinic for any problems that occurred at any time, regardless of when the next follow-up visit was scheduled.

Information on selected sociodemographic characteristics, reproductive and contraceptive histories, and pre-existing medical conditions were obtained at the time of admission to the study. Events related to Norplant insertion were recorded on admission forms, and the occurrence of subsequent pertinent events such as accidental pregnancy, expulsion, removal, complications, and complaints were recorded on CRFs at the follow-up visits.

Women were discontinued from the study if the Norplant implants were removed. Reasons for removal included: accidental pregnancy, menstrual problems, other medical reasons, planning pregnancy, and other personal reasons. For women who became pregnant during the study, the estimated conception date was used as the date of discontinuation. For women who had their implants removed for any other reasons, the date of discontinuation was the removal date of the implants. The censoring date for the women who were lost-to-follow-up was the date of their last

follow-up visit.

Analyses were performed by center, as well as pooled. The life-table method was used to calculate all discontinuation rates [2]. Baseline characteristics, mean changes in blood pressure and weight, and changes in menstrual characteristics were reported. An assessment of user satisifaction was made among women completing all five years of use. The significance level was set at $p \leqslant 0.05$ for all statistical testing.

Overall, 407 women participated in the study. Of the 407 admissions, 13 cases were protocol violations; that is, they did not meet all of the selection criteria. Nine of the protocol violations were for abnormal pelvic findings at admission, one was for age (45 years) and three were for having Norplant insertions more than seven days after menses' onset (two of these three were later found to be pregnant). Because the nature of the violations was minor, all 13 women with protocol violations were included in the analysis. Only one acceptor from each of the two centers did not return for any follow-up visits.

Results

Sociodemographic characteristics

Table 1 presents participants' baseline characteristics by center and total. Overall, a typical woman in the trial was 29 years old with about 2 years of education, and 3 live births. Nearly half of the women (45.4%) had not used contraception in the month prior to study admission, and most (nearly 80%) did not want any additional children. On average, women at the Kathmandu center were slightly younger than women at the Patan center, had a lower number of live births, were more likely to have used a contraceptive method in the previous month prior to study admission, and were more likely to want additional children.

Implant placement, insertion time, and insertion site complications

All but 6 of the 407 acceptors had implants placed in the inner portion of the upper left arm; the other 6 insertions were in the inner portion of the right arm. The average insertion time was 5.6 min with a range of 5–14 min. Less than 10% of the women reported insertion site problems – mostly itchiness, swelling, pain, or infection (data not shown); however, only one case of infection at the insertion site was considered serious and the implants were removed.

Clinical measures

Although mean changes in body weight and systolic blood pressure between admission and the 5-year follow-up visits were found to be statistically significant ($p \leqslant 0.05$) by paired comparison *t*-test, these changes were not considered clinically

Table 1. Sociodemographic characteristics

Characteristics	*Patan (n = 307)*	*Kathmandu (n = 100)*	*Total (n = 407)*
Age (years)			
Mean ± SD[a]	29.7 ± 5.32	27.8 ± 5.59	29.2 ± 5.44
Median	30.0	26.0	29.0
Education (years)			
Mean ± SD[a]	2.0 ± 3.90	2.2 ± 4.16	2.1 ± 3.96
Median	0.0	0.0	0.0
Number of live births			
Mean ± SD[a]	3.4 ± 1.58	2.6 ± 1.28	3.2 ± 1.54
Median	3.0	2.0	3.0
Contraceptive methods in month prior to admission			
None (%)	42.4	55.0	45.4
Oral contraceptives (%)	46.6	36.0	44.0
Other (%)	11.0	9.0	10.6
Women not wanting additional children (%)	80.1	75.0	78.9

[a]SD refers to the standard deviation

Table 2. Mean weight and blood pressure at admission and mean changes between admission and yearly follow-up visits for the pooled centers[a]

	Average at admission	*Mean changes from admission*		
		Year 1	*Year 3*	*Year 5*
	(n = 407)	(n = 305)	(n = 241)	(n = 188)
Weight (kg)	47.8	0.6[b]	1.4[b]	2.8[b]
Blood pressure (mmHg)	(n = 407)	(n = 306)	(n = 243)	(n = 188)
Systolic	114.4	−1.3	1.1	3.4[b]
Diastolic	73.8	0.6	−0.1	0.4

[a]Values indicate the mean change from admission to the yearly follow-up visits

[b]Indicates mean changes that are statistically significant ($p < 0.05$) in a paired t-test comparison

significant. On average, the weight of a woman increased from 47.8 kg at admission by 2.8 kg at year 5; systolic blood pressure increased from 114.4 mmHg at admission by 3.4 mmHg at year 5; and diastolic blood pressure increased from 73.8 mmHg at admission by 0.4 mmHg at year 5 (Table 2).

Efficacy

Five pregnancies, four at the Patan center and one at the Kathmandu center, were reported during the five-year study period. Of these five pregnancies, three were considered to have been conceived prior to insertion and were not included in the life-table analysis. The two pregnancies that were directly attributable to method failure occurred at about 1 and 37 months after insertion and both pregnancies ended in a live birth. The pooled life-table rate for unintended pregnancy at the end of year 5 was 0.6 per 100 women, with 0.5 per 100 women at the Patan center and 1.0 per 100 women at the Kathmandu center; the rate was not significantly different among the two centers (log rank test, $p > 0.05$) (Table 3).

Table 3. Gross cumulative life table discontinuation rates and standard errors (per 100 women) by reason for removal for the pooled centers[a]

Reason for removal	*Year 1* *Rate[b] ± SE[c]*	*Year 3* *Rate[b] ± SE[c]*	*Year 5* *Rate[b] ± SE[c]*
Menstrual problems	5.7 ± 1.19	15.4 ± 1.90	18.4 ± 2.11
Personal reasons	1.1 ± 0.53	4.2 ± 1.09	7.3 ± 1.53
Medical reasons	1.8 ± 0.68	4.6 ± 1.14	7.0 ± 1.47
Desired pregnancy	0.5 ± 0.38	3.5 ± 1.03	5.8 ± 1.38
Side-effects	0.5 ± 0.36	2.3 ± 0.82	5.6 ± 1.39
Pregnancy	0.2 ± 0.25	0.2 ± 0.25	0.6 ± 0.45
Expulsion[d]	0.5 ± 0.35	0.5 ± 0.35	0.5 ± 0.35
Death	0.0 ± 0.00	0.3 ± 0.33	0.3 ± 0.33
Total discontinuation	10.1 ± 1.51	27.9 ± 2.27	38.4 ± 2.52
Total continuation	89.9	72.1	61.6
Total woman-years	381.2	994.5	1443.0

[a]Three women from Patan who were reported pregnant prior to admission are not included

[b]The life-table rates are cumulative

[c]SE refers to the standard error

[d]Three additional women (1 from Patan and 2 from Kathmandu) were reported to have implant expulsion, but were continued after reinsertion

Table 4. Percentage of women with changes in dysmenorrhea between admission and yearly follow-up visits for pooled centers[a]

	Percentage with changes		
	Year 1 (n = 284)	*Year 3 (n = 232)*	*Year 5 (n = 182)*
None[b]	49.3	52.6	53.3
Improved	44.7	37.5	46.2
Unchanged	3.9	5.2	0.5
Worsened	2.1	4.7	0.0

[a]Includes only women reporting onset of dysmenorrhea at admission and yearly follow-up visits

[b]The term 'none' includes women who did not report dysmenorrhea at admission and yearly follow-up visits

Discontinuation and removal rate

Of the 407 women enrolled in the study, 149 women had early removal, 67 were lost-to-follow-up, and 191 women completed the study, totalling about 1443 woman-years. The leading cause of early removal during the study was menstrual problems, followed by other personal reasons, and medical reasons. The life-table total discontinuation rate was 38.4 per 100 women at 60 months for both centers (Table 3).

Menstrual problems

At the end of year 1, about 2% of the women reported their degree of dysmenorrhea had worsened; about 45% reported it had improved, and about 4% reported it had not changed (Table 4). At year 5, no women reported worsening in the degree of dysmenorrhea.

Less than 1% of the women reported a worsening in the degree of intermenstrual bleeding at their first follow-up visit. However, none who returned for their third year and fifth year follow-up visits reported a worsening of intermenstrual bleeding. In fact, at years 1, 3, and 5, around 5–6% of the women reported an improvement in intermenstrual bleeding since admission (Table 5).

At year 1, about 10% of the Norplant acceptors in the study reported at least one amenorrheic episode (defined as no menses for at least three months during the interval since the last follow-up visit). This proportion decreased to about 5% at year 5 (data not shown).

Table 5. Percentage of women with changes in intermenstrual bleeding between admission and yearly follow-up visits for pooled centers[a]

	Percentage with changes		
	Year 1 (n = 284)	*Year 3 (n = 231)*	*Year 5 (n = 182)*
None[b]	76.4	90.5	94.0
Improved	5.6	4.8	6.0
Unchanged	17.2	4.8	0.0
Worsened	0.7	0.0	0.0

[a]Includes only women reporting intermenstrual bleeding at admission and yearly follow-up visits

[b]The term 'none' includes women who did not report intermenstrual bleeding at admission and yearly follow-up visits

Medical problems

Twelve women were reported to have significant medical problems (as defined by the investigator) during the study. One death was reported due to heart failure, but this was determined to be unrelated to the use of Norplant implants. Other women exhibited a variety of transient medical problems such as typhoid fever, hepatitis, breast lumps, infection at the implant site, and arthritis. None of these problems, except the infection at the implant site discussed earlier, was considered to be related to the use of the implants. Minor medical complaints reported most often included dizziness, vertigo, giddiness, body ache and pain, headache, abdominal and pelvic pain, and change in appetite (data not shown).

Removal time and complications

The mean removal time was 9.4 min, ranging from 5 to 15 min. Four removal complications were reported. These complications included broken implants during the removal, deeply embedded implants, or infection at the implant site, but none of these complications was considered serious (data not shown).

User satisfaction

A questionnaire on user satisfaction was administered to women who returned for Norplant removal at the end of five years. Of the 191 Norplant acceptors completing five years of use, 125 (65.1%) completed the user satisfaction questionnaire. None

Table 6. Assessment of user satisfaction among women completing five years of use for the pooled centers[a]

Question/response	*%*
How would you describe your overall experience with the implants?	
Very favorable	38.4
Somewhat favorable	61.6
What have you liked most about the implants?	
Last for five years	79.8
Nothing	10.5
Ease of use	6.4
Low risk of pregnancy	1.6
Few side-effects	1.6
What have you liked least about the implants?	
Menstrual changes	44.8
Nothing	41.6
Insertion procedure	6.4
Appearance	4.8
Other	1.6
Feel	0.8

[a]Number of subjects responding to these questions was only 125

described the experience as unfavorable (Table 6). All respondents reported that they had received adequate information about duration of protection from pregnancy, return to fertility, insertion and removal procedures, and side-effects (data not shown).

For about 80% of the respondents, the most liked aspect of the implants was that they lasted for five years (Table 6). Bleeding irregularities were the least liked aspect (45% of the respondents). Eleven women (8.8%) said they had considered removal earlier due to their irregular menses, but none had followed through with a request for removal for this reason (Table 7). When asked if they ever considered removal because of increased blood flow or duration, seven women (5.6%) said they had considered it but did not request removal for this reason.

About 72% of the acceptors at both the centers felt that the date on their clinic card was the most important removal reminder. The proportion of women planning to continue using contraception after the completion of this study varied between the centers, with 93% in Patan and 31% in Kathmandu. Of these women, about 48% at the Patan center and 75% at the Kathmandu center said they would like to use another Norplant set (data not shown).

Table 7. Reasons given for considering removal during five-year duration of Norplant implant use for the pooled centers[a,b]

Reason	*%*
Spotting or irregular menses	8.8
Increased bleeding flow or duration	5.6
Decreased bleeding flow or duration	1.6
Other side-effects	6.4

[a]Number of subjects responding to these questions was only 125

[b]Of the users who responded that they considered removal during the five-year duration of Norplant implant use, none actually requested removal

Discussion

The findings presented in this five-year clinical trial suggest that the Norplant contraceptive implants are safe, effective, and acceptable among Nepalese women. Only two unintended pregnancies occurred during the five-year study, yielding a five-year pregnancy rate of 0.6 per 100 women. This finding is consistent with results reported in other studies, in which five-year pregnancy rates have ranged from 0.0 to 2.0 per 100 women, and the overall five-year continuation rate of 61.6 per 100 women is also comparable to the rates reported in other international studies [3–6]. The continuation rate at the Kathmandu center (44.5 per 100 women) was significantly lower than the continuation rate at the Patan center (63.0 per 100 women). This difference in the rates between the two centers could be due to the different attributes of Norplant acceptors noted above. It may also be due to different provider practices in initial and/or subsequent counseling of clients about the usual side-effects of the method, or to differences in the way requests for removal were handled by staff at the two centers. Studies in other countries have shown a wide disparity in the content and quality of provider responses to requests for removal. Both sympathetic and unsympathetic counseling can extend continuation rates. Also, some providers have more success than others with side-effect management [7].

There has been some concern expressed in public that women using Norplant have gained a lot of weight in a short period. The data in this study do not show a large weight gain for Nepalese women. Moreover, no discontinuations due to weight gain were reported.

Disruption of the menstrual rhythm, particularly increased bleeding, is one of the major side-effects reported among Norplant users in this study and other studies [8–10]. Irregular menses is more common in the early years of use, resulting in more removals due to menstrual problems in these early years. In this study, the five-year gross cumulative discontinuation rate due to menstrual problems was 18.4 per 100

women, which is lower than the rate reported in a Bangladesh study [4] and slightly higher than that reported in a Sri Lanka study [5]. The discontinuation rates due to menstrual problems seem to vary widely among studies. It is believed that cultural variables strongly influence women's perceptions and attitudes about alterations in bleeding patterns and their willingness to tolerate these irregularities. Thorough counseling is recommended to reduce the apprehension that both women and husbands may have about menstrual irregularities and other side-effects [11].

The discontinuation rate due to side-effects other than menstrual disturbances was 5.6 per 100 women, which is comparable to that reported in other international studies [8]. Most side-effects in this study were not serious and are often associated with steroidal contraception (dizziness, vertigo, giddiness, headache, and back and neck pain).

The majority of women who completed five years of Norplant use described their overall experience with the implants as very favorable. The most liked aspect of the implants was their long duration of use, and the least liked aspect was the effect on the menstrual pattern, a finding similar to other studies [4,5,12]. A small percentage of women who had Norplant for five years said that they had considered removing the implants for menstrual disturbances. Since none of the users actually had them removed for this reason, they may have perceived the benefits of pregnancy prevention to be greater than the inconvenience of menstrual irregularities and, in some cases, the irregularities may have subsided to acceptable levels.

The introduction of Norplant implants will give Nepalese women a safe and effective contraceptive alternative to sterilization and other less effective, temporary methods. This method will be particularly useful for women who are interested in long-term protection from pregnancy, but who are not ready for a permanent sterilization method [11]. Given the poor transportation facilities in Nepal, Norplant is a convenient method of contraception for many Nepalese women in rural areas who would otherwise travel many hours to have access to contraceptive methods. These women would probably prefer a method like Norplant that requires no compliance, as compared to barrier methods and other methods that require daily compliance and occasional re-supply.

Norplant is reported to be one of the most cost-effective contraceptive methods in the United States, in terms of the relative cost of pregnancy prevention and treatment of side-effects [13]. However, use of Norplant requires a considerable outlay of funds which is not affordable in the private sector for most Nepalese women. At present, Norplant is provided free of cost at government health centers where it is available, and if the government can continue to make it available through public sector facilities, it may serve as an excellent choice to many women who want a long-term, birth spacing method.

Conclusion

The Norplant implant system has great potential to expand the contraceptive options available for women in Nepal.

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Resumé

Le présent exposé reprend les résultats tirés d'une étude non comparative de cinq ans effectuée au Népal sur les implants contraceptifs sous-cutanés Norplant. Cette étude était conçue de manière à évaluer l'efficacité contraceptive et l'acceptabilité générale de ces implants. Quatre cent sept femmes ont été recrutées pour des essais cliniques, qui ont débuté en 1985 dans les deux localités de Patan et Katmandou. Les visites de suivi étaient prévues à 1, 3 et 6 mois après l'insertion des Norplant et ensuite à intervalles de 6 mois jusqu'au moment du retrait, ou au terme de cinq années. Bien que cinq grossesses aient été signalées dans le courant de l'étude, la grossesse en présence de Norplant n'a été diagnostiquée que chez deux femmes (une dans chaque centre). Au terme des cinq années, le taux brut cumulé global de grossesses s'est élevé, d'après la table de survie, à 0,6 pour 100 femmes. Le taux cumulé global de poursuite était de 62% à la fin des cinq ans. Les trois motifs d'abandon évoqués le plus souvent avaient trait à des problèmes de menstruation, des raisons personnelles et des raisons médicales. Sur les 125 femmes ayant rempli un questionnaire de satisfaction après cinq ans, la majorité (86%) avaient l'intention de continuer à recourir à la contraception une fois l'étude terminée. Parmi celles-ci, près de la moitié ont précisé leur intention d'utiliser une seconde série des mêmes implants. Ces résultats donnent à penser que le système Norplant est une méthode de contraception sans danger, efficace et acceptable pour les femmes népalaises.

Resumen

Este trabajo presenta resultados basados en un estudio no comparativo de cinco años de los implantes subdérmicos anticonceptivos Norplant en Nepal. El objetivo del estudio era evaluar la seguridad y eficacia anticonceptivas y la aceptabilidad general de Norplant. Cuatrocientas siete mujeres participaron en el ensayo clínico, iniciado en 1985, en dos lugares de estudio situados en Patan y Katmandú. Se programaron visitas de seguimiento a los 1, 3 y 6 meses después de la inserción de Norplant y cada seis meses posteriormente hasta el retiro o al final del período de cinco años. Si bien se notificaron cinco embarazos durante el estudio, sólo dos mujeres fueron diagnosticadas como una gravidez iniciada mientras utilizaban Norplant. La tasa de gravidez de tabla de vida acumulativa bruta combinada fue del 0,6% al final del período de cinco años. La tasa de continuación acumulativa combinada fue del 62% al concluir el período de cinco años. Los tres motivos más frecuentes del abandono fueron problemas menstruales, motivos personales y motivos médicos. De las 125 mujeres que llenaron un cuestionario de satisfacción de la usuaria al final de cinco años, la mayoría (86%) pensaba seguir recurriendo a la anticoncepción después de haber concluido el estudio. Casi la mitad de estas mujeres dijeron que pensaban utilizar una segunda serie de Norplant. Los resultados sugieren que el sistema Norplant es un método anticonceptivo seguro, eficaz y aceptable entre las nepalesas.