

Introduction of NORPLANT® implants in a predominantly rural community in Sri Lanka and its subsequent withdrawal

**W.A.P.Fonseka¹,
H.I.C .Seneviratne²,V.Karunaratne³**

Journal of the College of Community
Physicians of Sri Lanka 1998; 3:18-26

Abstract

Objectives: To study the characteristics of acceptors of the NORPLANT® sub-dermal contraceptive implants and acceptability and complications of this relatively new method in a predominantly rural district in Sri Lanka.

Methodology: Acceptors of NORPLANT® implants in the Hingurakgoda health division from 1991 to 1996 were studied retrospectively using an interviewer administered questionnaire. Public Health Midwives were used to collect data by tracing family planning clinic records and it was possible to obtain information on acceptors of NORPLANT® implants from 172 eligible clients.

Results: Forty percent of the clients were between 26-30 years of age. The majority (50.6%) had two children at the time of acceptance and mean parity was 2.13 (+0.9) years. Approximately fifty percent of the clients had an educational level above grade 8. Fifty nine percent of the acceptors of NORPLANT® were using a modern family planning method before, while thirty three percent was not using any method. The mean age of the last child was 6.7 (+3.9) years and in a majority (62.2%) the last child was

between 3-5 years. The majority (55.8%) of the clients liked the method for its convenience, five years protection with single insertion. Most common persistent side effects were menstrual disorders (48.1%). Premature discontinuation of the method was relatively high (56%) and it was mostly due to side effects. Irrespective of the relatively high incidence of side effects most (64%) clients showed a favourable opinion towards NORPLANT®.

Conclusion and recommendations:

NORPLANT® implants are an acceptable and effective long active contraceptive that could be introduced to rural communities in Sri Lanka. Proper counselling before acceptance and follow up would be of extreme importance in minimising the incidence of side effects and premature discontinuation of the method. In view of lack of facilities for sterilisation NORPLANT® implants could be considered as an alternative, provided appropriate clients are selected.

Introduction

Sri Lanka is reported to have a Total Fertility Rate (TFR) of 2.3 according to the 1993 Demographic Health Survey(1). High literacy rate (specially among females), increasing employment opportunities for females, continuous efforts to promote family planning through government and non government channels are some of the major contributory factors for the reduction of fertility(2,3). It is observed that 66.2% of currently married women practice some form of contraception, of them 44% are on modern methods. During the last three decades several new methods and modern techniques have been introduced into the National Family Planning Programme. With the successful completion of the third phase clinical trials in Chile and several other countries in mid and late seventies, NORPLANT® became widely accepted in many developing and developed countries (4,5). The Family Planning Association of Sri Lanka (FPASL) introduced NORPLANT® in 1985(6). on an experimental basis as a part of a multi-centre

¹ Specialist in Community Medicine, Family Health Bureau, Ministry of Health, Sri Lanka.

² Medical officer, National Institute of Health Science, Ministry of Health, Sri Lanka.

³ Director, Family Health Bureau, Ministry of Health, Sri Lanka.

clinical trial. Subsequent to the encouraging preliminary results shown by the study on NORPLANT[®] undertaken by the FPASL, supported by the findings of studies done in other parts of the world, government decided to include NORPLANT[®] in the National Family Planning Programme in 1990(6,8). The most popular family planning method during this time was sterilisation (48.3% both male and female) amongst the current users⁶. Sterilisation was the most popular method amongst new acceptors of family planning as well, contributing to 30.3% of the total acceptance(7). By the late eighties sterilisation rates decreased drastically due to youth unrest in the south and ethnic conflicts in the northern parts of the country. NORPLANT[®] thus became a good alternative choice for clients who desired to limit the number of children.

At the outset facilities for NORPLANT[®] implantation was only available in the two large cities of the island. This was mainly due to two reasons, firstly medical officers trained on the implantation were not available in adequate numbers. Secondly, the supply of implants and equipment necessary to provide services in other parts of the country were limited.

In 1991, NORPLANT[®] implants were introduced in two of the health divisions, each comprising 60-70,000 population, in the Polonnaruwa district as a pilot project(8). The district has a predominantly (85-90%) rural population(9). NORPLANT[®] implants became rapidly popular in the Polonnaruwa district and the demand increased over a few years. After five years, the supply of implants ceased and the project had to be stopped abruptly. The NORPLANT[®] implants became non-available in the government sector by 1996(10,11).

This paper presents findings of a study done to examine the acceptability, complications of the new contraceptive method NORPLANT[®] and the characteristics of the

acceptors in a predominantly rural district of Sri Lanka.

Methods

The study was done in one of the two health divisions, namely Hingurakgoda divisional health area, in the district in 1997. All clients who accepted the method, minimum one year before the data collection, during 1991 to 1996 were included. The addresses of all these acceptors were traced from the clinic records and the villages were identified. The Public Health Midwives (PHMM) who are responsible for the provision of primary health care in these identified villages were used as interviewers for the data collection. They were trained by the investigators on the administration of the questionnaire, which was pre-tested in the adjoining area.

Public Health Midwives did the data collection. Verbal consent was obtained by the PHMM before including clients in the study. A multitude of problems were faced by the PHMM in trying to trace clients and it was possible to include 172 clients in the final sample. Some clients were found to be originally from other areas, while in some others the addresses were either incomplete or incorrect. PHMM also found that some clients had left the country for jobs in the Middle East. The reasons indicated above had no direct connection to acceptance or failure of the method, the effect of non-response on the results may be considered minimal.

Results

The majority of clients (40.1%) in the sample were between 26-30 years (Table 1). The mean age of NORPLANT[®] acceptor was 28.9 (+4.91) years, while husbands of the clients were older. The mean age of the husbands (33.7 +5.47 years) was about five years higher than that of the clients. Almost half (50.6%) of the clients had two children, while the mean parity was 2.13 (+0.97). The majority of NORPLANT[®] acceptors

Table 1: Characteristics of the NORPLANT® acceptors and their spouses in the sample (n=172)

	Client		Spouse	
	No.	%	No.	%
Age (in years)				
20-25	48	27.9	10	5.8
26-30	69	40.1	39	22.7
31-35	36	20.9	63	36.6
36-40	15	8.7	45	26.2
>40	04	2.3	15	8.7
Mean (+SD)	28.9(+4.92)		33.7(+5.47)	
Parity				
1	46	26.7		
2	87	50.6		
3	28	16.3		
4	7	4.1		
>4	4	2.3		
Mean (+SD)	2.13(+0.97)			
Educational level (Grade)				
Nil	04	2.3	02	1.2
1-5	45	26.2	29	16.9
6-8	53	30.8	47	27.3
9-10	64	37.2	85	49.4
>10	06	3.5	09	5.2
Median	8		9	
Employment Status				
Employed	04	2.3	168	97.7
Not employed	158	91.9	14	8.1
Family planning methods used preceding acceptance of NORPLANT®				
Nonusers	58	33.7		
DMPA	49	28.5		
Oral Pill	53	30.8		
IUD	10	5.8		
Traditional				
Methods	02	1.2		
DMPA: Depo Medroxy Progestagen Acetate				
IUD: Intra-Uterine Device				

(40.7%) had an educational level above grade 8. Husbands of the clients however, had a higher educational level (Table 1). The Polonnaruwa district being one of the major paddy growing areas in the country most of the clients (91.9%) were categorised as not employed. However, most married women in this area are actively involved in paddy cultivation with their husbands. Mean age of the last child of the client at the time of

acceptance of NORPLANT® was 6.71 years (+3.9). The age of the last child in 62.2% of clients was 3-5 years, while 10% had children above the age of eight years. Table 2 shows the family planning methods, if any, used by the clients preceding implantation of NORPLANT®. One third of the clients had not used a family planning method prior accepting to NORPLANT®. Among the users the most popular method

was the oral contraceptive pill (OCP, 30.6%), followed by the injectable, Depo Medroxy Progesterone Acetate (28.5%). Only a small proportion (5.8%) has used the intra-uterine contraceptive device (IUCD).

Table 2: Age of the last child at time of acceptance of NORPLANT® (n=172)

Age of last child	No.	%
<1	02	1.2
1-2	10	5.8
3-5	107	62.2
6-8	34	19.8
9-12	13	7.6
>12	06	3.5
Mean (+SD)	6.71(+3.9)	

As shown in the table 3 more than two-third (72.7%) of the clients received the information about the availability of NORPLANT® from the Public Health Midwife (PHM) of the area. Approximately 12% got the information from a friend who was already using the method. The reasons for selecting the method in 55.8% of clients it was due to the comparative convenience of the method (Table 3). This may most probably be attributed to the nature of administration of the contraceptive, where the client is free of the need to remember taking the drug, as in the oral pill and the injectables. Another 31.4% said that they selected NORPLANT® because it provided five years of protection with one set of implants. This may have been perceived as an advantage compared to other hormonal contraceptives. Of the total sample 88 clients indicated two reasons for the choice of the method. The majority (56.8%) of them gave five years of protection as the reason.

One hundred sixty (93%) clients said that they discussed about the acceptance of NORPLANT® with their husbands. Table 4 shows the general opinion of the husbands on NORPLANT®. A majority (85.0%) of them approved the method for their spouse.

Only a small proportion either disliked (8.7%) or showed indifference (6.3%) on the method.

Table 3: Source of information on NORPLANT® and reasons for the selection of the method (n=172)

Source of information	No.	%
PHM of the area	125	72.7
Friend using NORPLANT®	20	11.6
Family planning clinic	13	7.5
Medical Officer of Health	08	4.7
Other sources	08	3.5

Reasons for selection of the method

Comparatively convenient method	96	55.8
Five years of protection	54	31.4
Recommended by a user	03	1.8
Husband approved the method	09	5.2
Dissatisfied with other methods	04	2.3
Other reasons	06	3.5

PHM: Public Health Midwife

Side effects due to NORPLANT® were considered under two categories. Firstly, those due to the procedure of implantation itself, which generally occur within one week were categorised as immediate or early side effects. The side effects that persist or recurrent, which are generally due to the hormonal effect, were categorised as late side effects. Table 5 shows the distribution these side effects. Forty-four of the clients did not indicate early or immediate side effects. A considerable proportion (40.3%) complained of pain at the site of insertion. Other early side effects were present in negligible proportion, while 12.3% had complaints that could not be attributed to the insertion of implants.

Table 4: Husbands view on accepting NORPLANT® by the spouse

	No.	%
Husbands view		
Approved the method	136	85.0
Did not like the method	14	8.7
Indifferent to the method	10	6.3
Total	160	100

Table 5: Incidence of immediate and late side effects after the implantation of NORPLANT®

Side effect	No.	%
Immediate most important side effect		
No side effects	76	44.4
Pain at the site	69	40.4
Bleeding from the site	02	1.2
Fever	03	1.8
non specific side effects	21	12.3
Total	171	100 *
Late (most notable) side effect		
No side effects	55	32.4
Heavy menstrual bleeding	28	16.5
Irregular menstruation	24	14.1
Amenorrhea	30	17.6
Headache	07	4.1
Change in weight	07	4.1
Lethargy or laziness	02	1.3
Pain in the arm	17	10.0
Total	172	100

* One missing value (non response)

With regard to 'late' (or persisting) side effects, the majority was related to menstrual disorders. Heavy menstrual bleeding (16.5%), irregular bleeding (14.1%) and amenorrhea (17.6%) were the menstrual disorders indicated by clients. Approximately one third (32.4%) of the clients did not have 'late' side effects. As a cumulative percentage these side effects accounted for 48.1% of the complaints.

Incidence of other late side effects such as headache, weight loses or gain and lethargy were minimal. However, it is interesting to note that 10% of the clients complained of pain in the arm with NORPLANT® implants.

Of the total of 172 clients who responded to the questionnaire the majority (68.6%) had used NORPLANT® for three to five years, at the time of data collection (Table 6). Due to

Table 6: Period of use, and the reasons for desire to remove or removal of NORPLANT®

	No.	%
Period of use (in completed years)		
Less than one year	13	7.6
One to three years	35	20.3
Three to five years	118	68.6
More than five years	06	3.5
Total	172	100
Reasons for desire to remove implants		
Heavy menstrual bleeding	32	44.4
Irregular menstruation	09	12.5
Amenorrhea	08	11.2
Change in weight	09	12.5
Headache	09	12.5
Non specific side effects	01	1.5
Total	67	00
Reasons for removal of implants		
Completion of five years	35	33.3
Menstrual disorders	34	32.4
Due to other side effects	24	22.9
Wanted to have a child	10	9.5
Other personal reasons *	02	1.9
Total	105	100

* In one of the clients implants were removed due to pregnancy

the retrospective nature of the study design there were clients with varying length of use in the sample. However, the period specified for the selection of clients in the study was determined so as to include clients with a minimum of one-year exposure.

Clients were asked whether they desired to discontinue the method prematurely at any time. They were also asked whether they actually discontinued the method by removal of implants. Of the total 67 (39%) clients said that they desired to discontinue the method prematurely, and the reasons given are shown in the Table 6. It is noteworthy that 68% of the clients desired a removal due to menstrual disorders.

Out of the clients who discontinued the method by removal of implants, only 33.3% had completed the effective period of five years (Table 6). Almost a similar proportion (32.4%) had a removal as a result of menstrual disorders, which included heavy menstrual bleeding, irregular bleeding and amenorrhea. Approximately one-fifth (22.9%) of the clients got the implants removed due to side effects such as change of weight, headache, lethargy etc.

It was observed that one client became pregnant within two months of the insertion of NORPLANT® implants. Further investigations revealed that she had a missed period at the time of insertion. This client had been pregnant at the time of accepting NORPLANT®.

The general opinion of the client on NORPLANT® was assessed by asking the questions shown in table 7, as well as their independent opinion. Of the total sample 111 (64.6%) clients said that it was a good family planning method (Table 7). Only a small proportion (7.6%) indicated that it was an unsatisfactory method. The clients were asked whether they would recommend this method to a close friend or a relative. The majority of the clients (61.6%) responded that they would recommend the method. However, 28 (16.3%) clients said they would recommend it with a caution about the side effects, while 19.8% said they would not recommend it (Table 7).

Table 7: Clients general opinion towards the NORPLANT® (n=172)

	No	%
Clients general response		
A good method	111	64.6
A satisfactory method	18	10.5
Many side effects	14	8.1
An unsatisfactory method	13	7.6
No comment	16	9.3
Recommend this method to a friend or a relative		
recommend	106	61.6
not recommend	34	19.8
Recommend with a caution on side effects	28	16.3
No comment	04	2.3

Discussion

Characteristics of the NORPLANT® acceptors observed in the study with regard to the age and educational level were very much similar to findings made by Basnayake et al. in 1985(6). Many other studies also have reported similar findings(12,13,14). Basnayake et al reported a mean parity of 1.8 (+0.9), with 68.9% of clients having at least two children, in comparison in the present study the mean parity was 2.13 (+0.97), while 77.3% had a minimum of two children (6). This difference could be attributed to the different level of fertility in urban and rural settings, as the study by Basnayake et. al was done in two of the major cities in the country. Studies done in other parts of Asia showed varying levels of parity. In Thailand 65% of the clients had 1-2 children (mean parity: 2.3)(6). A study done in Indonesia reported 28.8% (mean parity in this study was not indicated)(14). In contrast a study done in Egypt reported a very high mean parity of 5.9 with only 20% of the clients having two children (12). The social, cultural and religious background of the country, as well as the health policy are some of the major determinants of the average family size. Therefore, making

comparison of these findings between countries is of limited value.

About 10% of the clients had a last child above eight years of age, with a mean age of 6.7 (+3.9) years. This is suggestive of the fact that, a fair proportion of clients may have selected NORPLANT® as an alternative to sterilisation. This is more likely since the facilities for sterilisation in the Polonnaruwa District are very limited(7,8). It was found that 66.3% clients under investigation had used some form of family planning method before, which compared well with the findings (34%) of Basnayake et al(6). Satayapan et al, in Thailand found that only 13% had used a method before, while in Indonesia and in Egypt the proportion of non-users were found to be 37% and 19% respectively(13,14,15). The majority (46%) of the clients in Thailand selected NORPLANT® since they disliked the other methods, while 38% selected it due to positive motivation (influenced by the single insertion of implants)(13). However, 16% of the clients selected the method based on the recommendation by health personnel. In the present study majority (55.8%) decided to select NORPLANT® as it was comparatively a more convenient method in relation to other methods; only single insertion was involved. About one third (31.4%) liked the method because it provided five years of protection. The majority (85%) of the husbands of clients who discussed about the method in the study approved it for their spouse.

In this study 44.4% of the clients did not have complaints related to the insertion of implants (early side effects). The most common persistent or recurrent side effects were related to menstrual disorders (48.1%), and most studies done in different parts of the world also observed menstrual disorders to be the commonest side effects with differing frequency. Basnayake et al observed that 23.8% had regular menstruation, while 58.7% and 17.5%

respectively had irregular bleeding and amenorrhea(6). Davie et al. found that 43% of the clients discontinued the method due to menstrual disorders(16).

Satayapn et al in Thailand, Haigen et al in the USA and Ruminjo et al in Kenya found 61%, 80% and 72% incidence of menstrual disorders, respectively(13,17,18). As a result of slow release of synthetic progestin, levonogestral, without the opposing action of exogenous oestrogen their use is expected cause disruption in the women's menstrual pattern. However, these disruptions need to be at a tolerable level for women to continue the contraceptive for a reasonable length of time. Proper counselling prior to the acceptance could be a vital ingredient in making clients to be prepared for possible side effects, thereby it could decrease the proportion of premature discontinuation.

Of the total 105 client who had their implants removed, only 33.3% had completed the effective period of five years. The first year continuation rate reported by Basnayake et al. was comparatively high (98%), though it is not possible to comment on the retention rate in the subsequent years(6). Experiences in Bangladesh (86.3%) and Kenya (91%) also showed high continuation rates in the first year of use(18,19). Davie et al. showed that the continuation rate dropped from 84% to 80% during twelve to eighteen months of use, while Ruminjo et al. indicated a drop from 91% to 80% from first to second year(16,17). According to observations made in Thailand (n=567) the continuation rate was 90%, 78%, 70%, 61% and 42% at end of first, second, third, fourth and fifth years respectively, after the insertion of implants(20).

Irrespective of the high incidence of menstrual disturbances, along with other side effects, many studies indicated fairly high client satisfaction with NORPLANT®. Approximately 64% of the clients in this study showed a favourable opinion and only

less than 20% had an unfavourable opinion towards the method (Table 7). Basnayake et al showed an even higher level (>90%) of client satisfaction, in the first year(6). A study done using the similar design in Indonesia (n=610), showed that 85% of the clients expressed a positive attitude towards NORPLANT[®](21). Two other studies done in USA showed comparatively lower (60% and 68%) levels of client satisfaction(17,22). Basnayake et al used a prospective study design and it was a part of a multi-centre clinical trial. Therefore, it is likely that the counselling of clients would have been comparatively better. The fact that the study was conducted in urban setting too may have had positive influence on the results.

In conclusion, this study indicates that NORPLANT[®] is an acceptable and very effective long active contraceptive, which could be introduced to rural communities in Sri Lanka. Its incidence of side effects however, needs to be taken into serious consideration before introducing a new method. Careful planning, meticulous monitoring and proper evaluation would be key issues in maintaining a sustainable programme. Availability of continuous and uninterrupted supply to maintain the programme is vital, especially when such new method is introduced. Abrupt cessation of supplies could negatively influence the credibility of the programme due to loss of confidence among clients. Adequate counselling by trained personnel before the acceptance of the method is of paramount importance to achieve maximum client satisfaction. This also becomes a crucial requirement to reduce premature discontinuation, whereby this method could be used cost effectively.

Acknowledgements

The authors would like to gratefully acknowledge the assistance rendered by all members of staff at the Hingurakgoda Divisional Health Directors office. We would like to extend our sincere gratitude to

Dr. S.C. Weerakkody of the Family Health Bureau who kindly consented to train medical officers on insertion of NORPLANT. Assistance provided by the "Hemas Pharmaceuticals" Company Ltd. by providing audiovisual aids and funds for conducting the training sessions are acknowledged.

References

1. Demographic Health Survey of Sri Lanka 1993, Department of Census and Statistics and Ministry of Health, 1995, 23-40, 90-98, 99-110
2. Population Division, Ministry of Health, Emerging Population Issues in Sri Lanka, Ministry of Health and Women's Affairs, 1993.
3. Sri Lanka National report on population, International Conference on Population and Development, 1994 Cairo in Egypt, Population Division, Ministry of Health and Social Services, 1994.
4. Sivin I, International experience with NORPLANT[®] and Norplant-2 contraceptive. *Studies in Family Planning*, 1988; 19(2)81-94
5. Segal SJ. The development of NORPLANT[®] implants. *Studies in Family Planning* 1983; 14(6/7):159-162
6. Basnayake S, Thapa S, Balogh SA, Evaluation of safety, efficacy and acceptability of NORPLANT[®] implants in Sri Lanka. *Studies in Family Planning* 1988; 19: 1:39-47
7. Annual Report of Family Health Bureau 1987, Family Health Bureau, Ministry of Health 1988 (15-36)
8. Annual Report of Family Health Bureau 1990, Family Health Bureau, Ministry of Health 1991 (15-36)

9. Department of Census and Statistics, Statistical Abstract of Democratic Socialist Republic of Sri Lanka 1991, Department of Census and Statistics, Sri Lanka 1991; iii: 51-75
10. Annual Report of Family Health Bureau 1995, Family Health Bureau, Ministry of Health 1996 (15-36)
11. Annual Health Bulletin 1995, Ministry of Health, Department of Government Printer, 1996 (5-14,43-75)
12. Shaaban MM, Salah MM, Zarzour A, Abdullah A, A prospective study of NORPLANT[®] implant and TCu 380Ag IUD in Assiut, Egypt. *Studies in Family Planning* 1983; 14(6/7):163-169
13. Satayapan S, Kanchanasinith K, Varakamin S, Perception and acceptability of NORPLANT[®] implants in Thailand. *Studies in Family Planning* 1983; 14(6/7): 170-176
14. Marangoni P, Cartagena S, Alverado J, Diaz J, Faundes A, NORPLANT[®] implants and TCu 200 IUD: A comparative study in Ecuador. *Studies in Family Planning* 1983; 14(6/7): 177-180
15. Lubis F, Prihartono S, Alverado, Agoestina T, Affandi B, Sutedi H, One year experience with NORPLANT[®] implants in Indonesia. *Studies in Family Planning* 1983; 14(6/7):181-191
16. Davie J, Hiremath K, Glasier A, The introduction of a new contraceptive: two years experience with NORPLANT[®]. *Health Bulletin*, 1996; 54(4):14-17
17. Haugen MM, Evans CB, Kim MH, Patient satisfaction with levonogestrel-releasing contraceptive implant. Reasons and pattern of removal. *Journal of Reproductive Medicine*, 1996; 41(11):849-854
18. Ruminjo JK, Achwal I, Ruminjo IN, Acceptability of NORPLANT[®] contraceptive sub-dermal implants in Kenya. *East African Medical Journal*, 1994; 71(9): 558-561
19. Akther H, Dunson TR, Amatya RN, Begum, Chowdry T, Dighe N, Krueger SL, Rahman S, A five year clinical evaluation of NORPLANT[®] sub-dermal contraceptive implants in Bangladesh acceptors. *Contraception*, 1993; 47(6) 569-582
20. Tseng LH, Lee TY, Yang YS, Ko TM, Chuang SM, NORPLANT[®] sub-dermal contraceptive system: experience in Taiwan. *Contraception* 1996; 53(3): 177-180
21. Neopramana NP, Rusbandi, Factors influencing attitudes about NORPLANT[®] contraceptive sub-dermal implant. *Contraception* 1993; 9(3):215-226
22. Eilers GM, Seanson TK, Womens satisfaction with NORPLANT[®] as compared with oral contraceptives. *Journal of Family Practice*, 1994; 38(6): 596-600