

Use of Norplant in Pakistan: Two Years Experience

Pages with reference to book, From 3 To 7

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Abstract

The acceptability and efficacy of norplant (levonorgestrel sub-dermal implants) was assessed over a period of two years among 445 married women aged 19 to 45 years. Twenty women were lost to follow-up while the remaining 425 were regularly followed-up. At the end of two years, 388 women were still continuing with norplant (91.2%). During this period, there was only one pregnancy (0.26%). There was no significant change in mean systolic or diastolic blood pressure. However, there was a significant increase ($P < 0.001$) in mean weight and decrease ($P < 0.001$) in the mean duration of menstrual cycle. Thirty-seven women (8.7%) got the implant removed. The major reason for removal (67.6%) was menstrual disturbances. Nine acceptors (18.59%) developed side effects, which were related to the type of symptoms often associated with steroid contraception. These findings are similar to those reported from other countries. The high efficacy (99.74%) and acceptability (continuation rate of 91.29%) as well as long acting (5 years) nature of norplant suggest that this method of contraception can safely be promoted in Pakistan (JPMA 44:3, 1994).

Introduction

According to the Pakistan Demographic and Health Survey (1990- 91) ¹, 17.6% married, fecund women wanted to postpone their pregnancies and 36.4% wanted no more births. This is in addition to those 21.4% births, which during the last 5 years, were either unwanted (13%) or mistimed (8%). Thus 75.8% of the women in reproductive age were in need of family planning services. Conventional and semi-terminal methods of family planning are usually well accepted but due to the socio-cultural pattern of extended family system, regular use of these methods is difficult for people living in rural and semi urban areas. The procurement of contraceptives is difficult due to lack of knowledge about location of service outlets and the medical facilities. There is always hesitation in the acceptance of surgical contraception due to its being irreversible, the risk of injuries to vital organs and subsequent morbidity and mortality. Family planners have always been in search of a method, which the desirous couples could adopt as an outdoor procedure and should be safe, effective, inexpensive and reversible. Norplant subdermal implant system which is a long acting, reversible, low dose progestagen, developed by the International Committee for Contraception Research (ICCR) of the Population Council as a simple out-door procedure, seems to be the most promising choice. It consists of six flexible closed capsules made of silastic (dimethylsiloxane/methylvinylsiloxane copolymer). Norplant is not made of new ingredients; what is new about the method is how it delivers the contraceptive drug into the body. Each of the six capsules is 34 millimeters long, has a diameter of 2.4 millimeters and contains 36 milligrams of levonorgestrel in dry, crystalline form. The capsules are sealed at each end with silastic (polydimethylsiloxane) medical grade adhesive² (Figure 1).

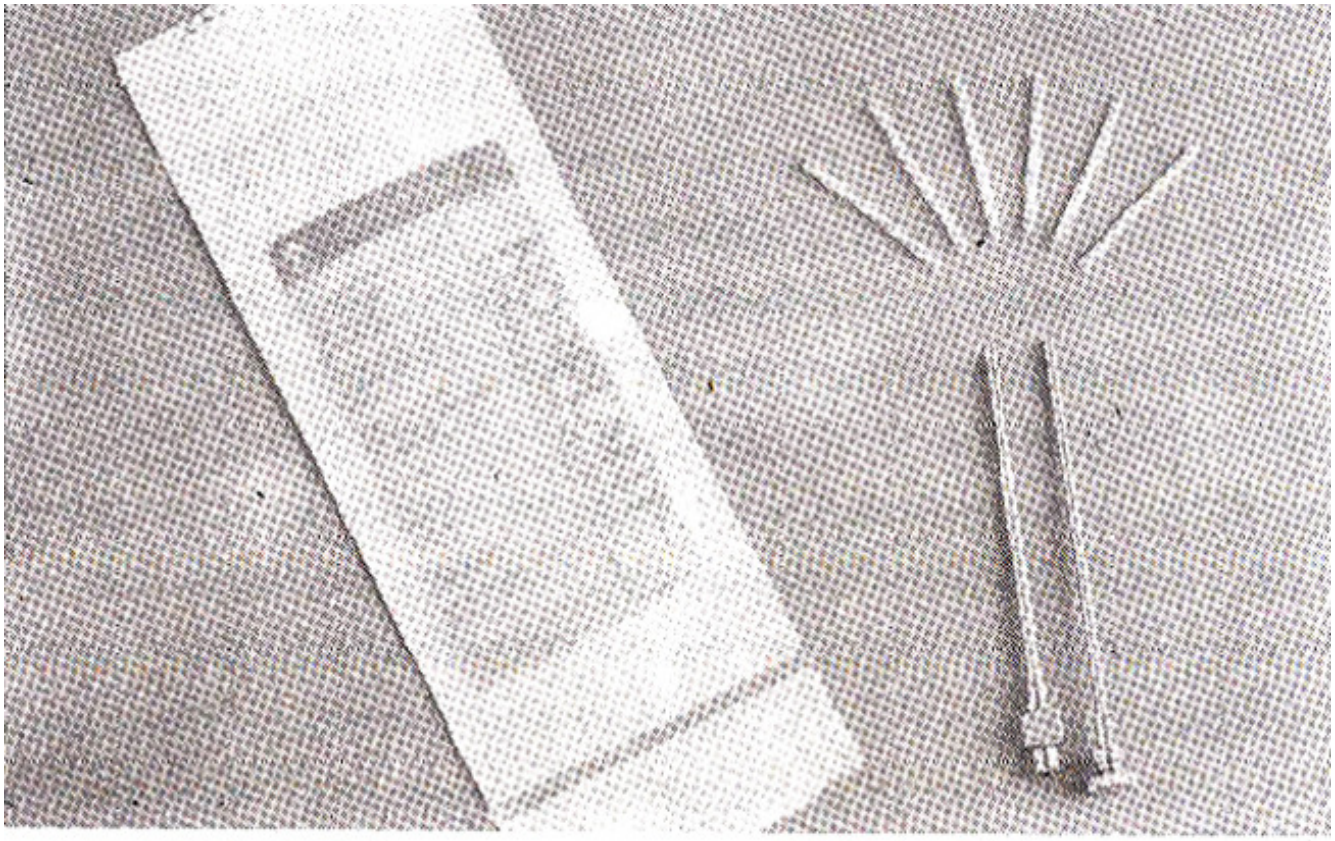


Figure 1. Norplant package.

Levonorgestrel (d(-)-13-beta-ethyl-17~alpha-ethinyl-17-beta- hydroxygon-4-en-3-one), the sole active ingredient, conforms to D-natural steroids. It is the progestational ingredient in many oral contraceptives and is not subject to ‘first-pass’ effect and is virtually 100% bioavailable^{3,4}. Levonorgestrel is an effective progestational agent, but the exact mechanisms by which levonorgestrel prevents conception at the low doses imparted by the norplant method are not completely defined. The contraceptive action of norplant is probably a combination of at least two effects: suppression of ovulation and thickening of the cervical mucus⁵. To insert an implant, the provider anaesthetizes an area of the skin on the inside of the woman’s upper arm. The provider then makes a 2 mm incision, either with a special trocar, if it is sharp, or with a scalpel and uses the trocar to insert the capsules just under the skin. The trocar is marked to indicate how far it should be placed under the skin to insert each capsule. The provider places the capsules in a fan shape, radiating out from the incision. Using a paper or plastic template to mark the pattern of the implants on the woman’s skin helps to ensure correct placement of the anaesthetic and the implants (Figures 2-5).

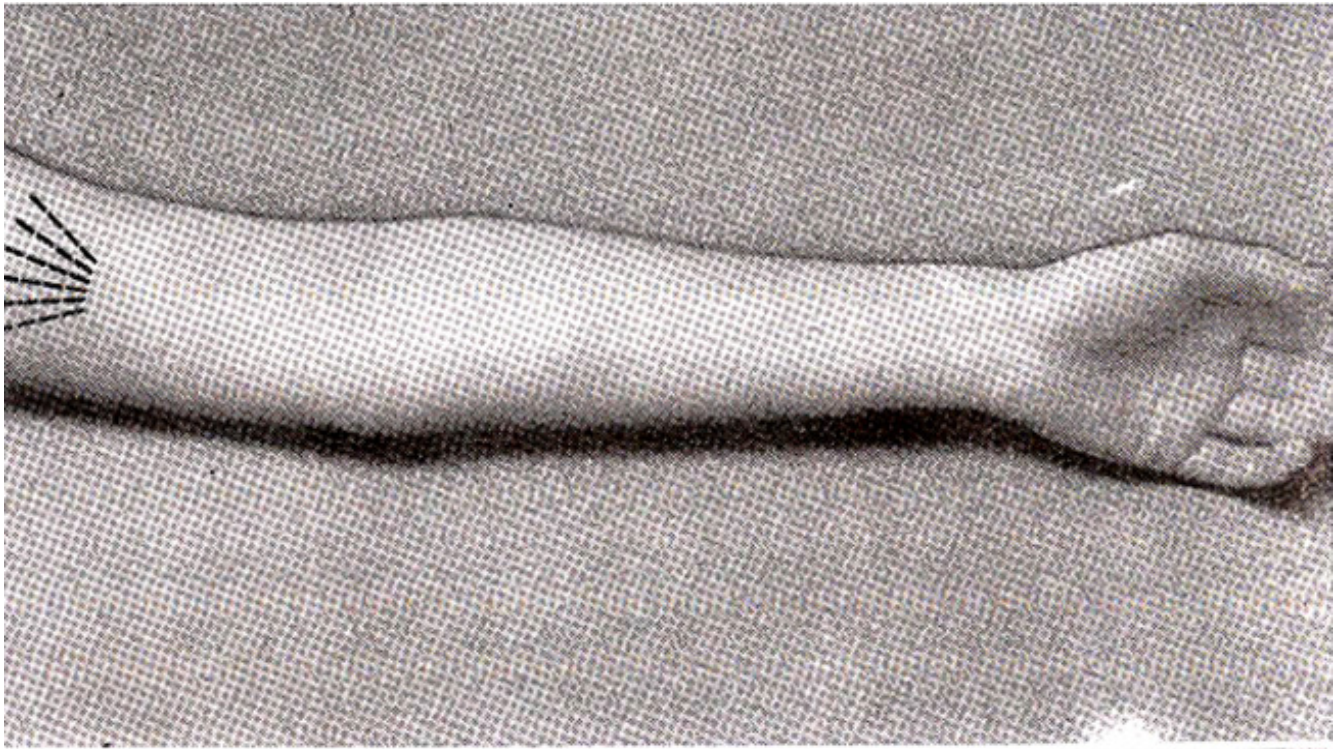


Figure 2. Insertion site.

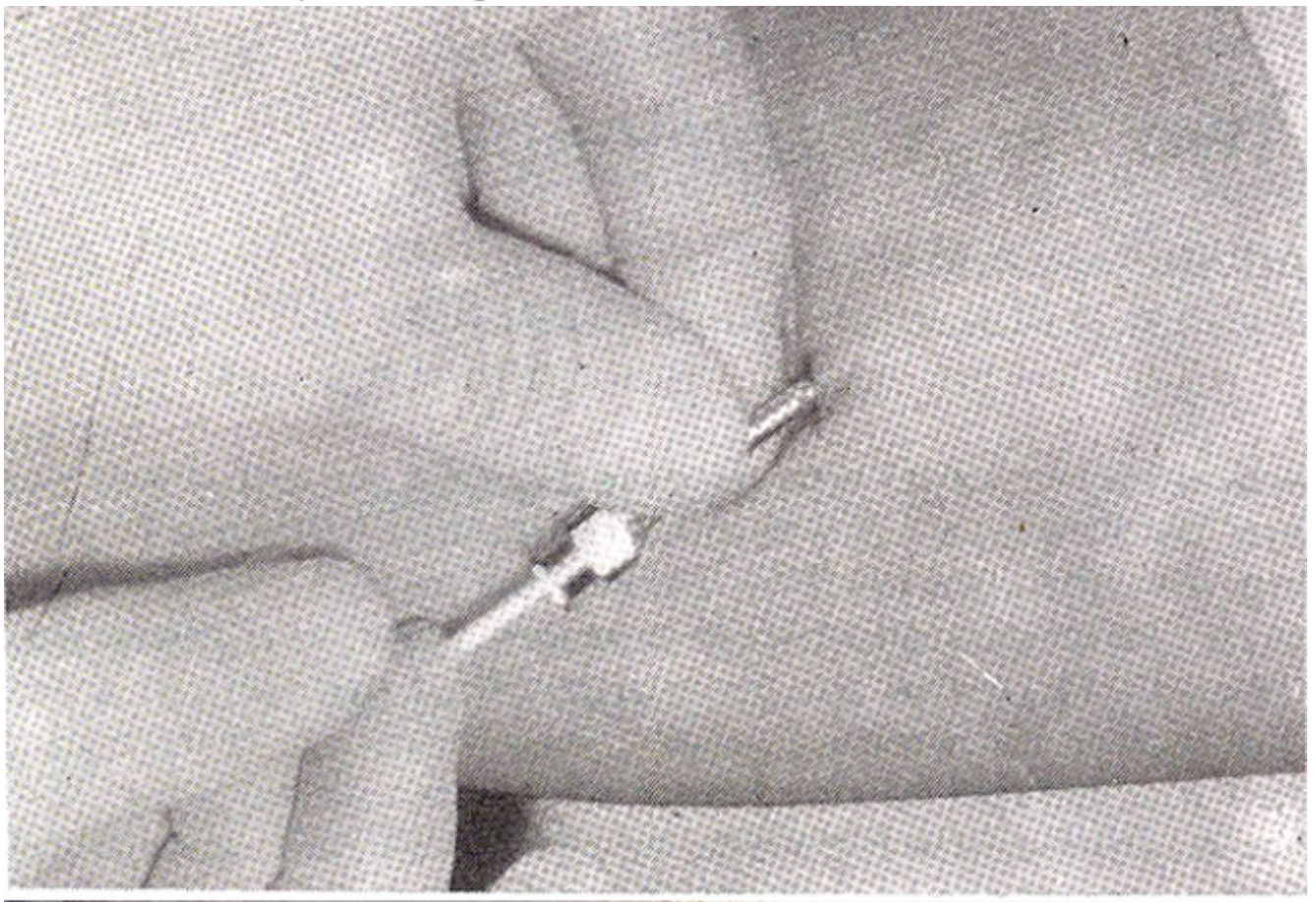


Figure 3. Loading the implant into trocar.

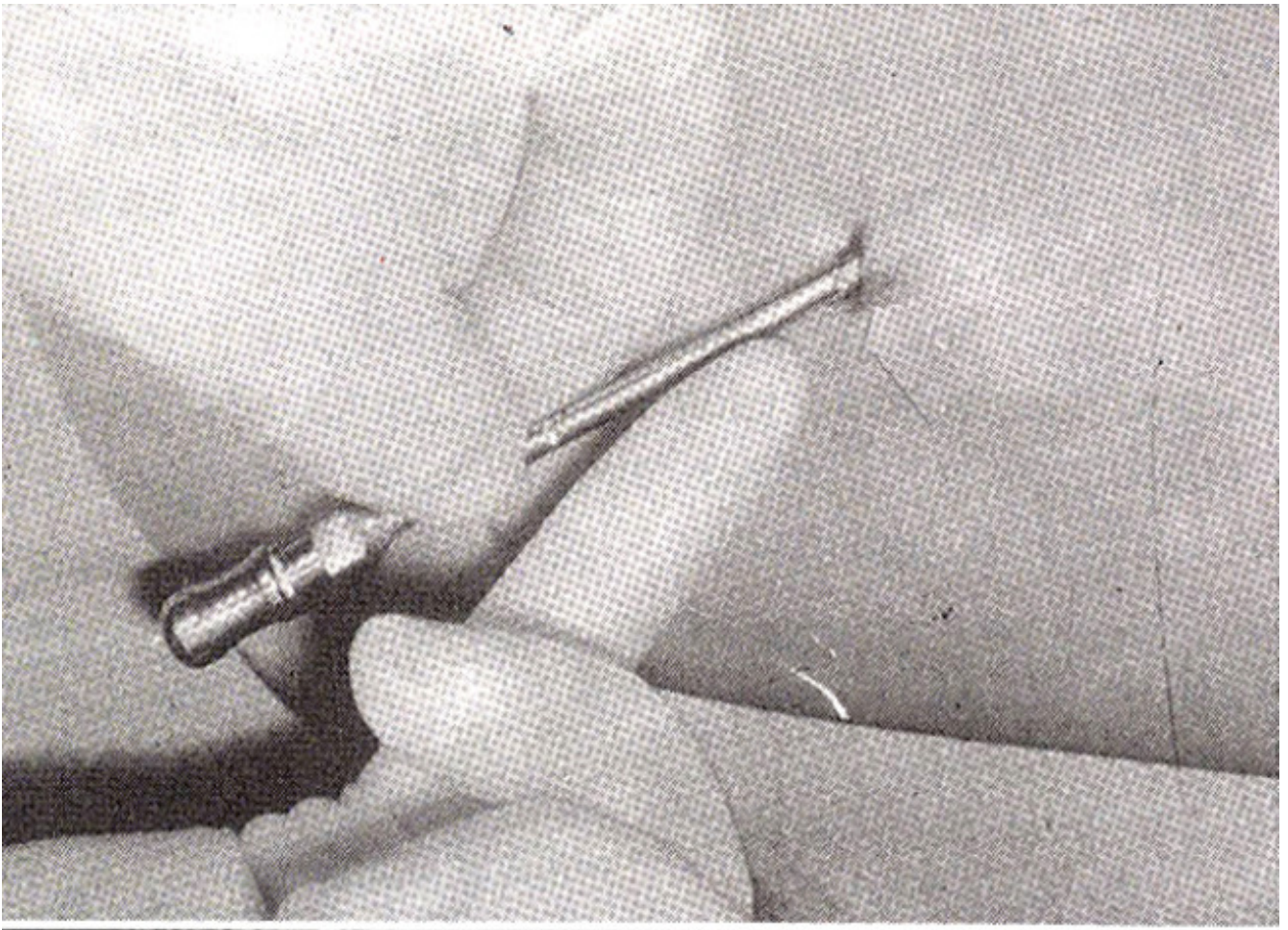


Figure 4. Pushing the implant with plunger.

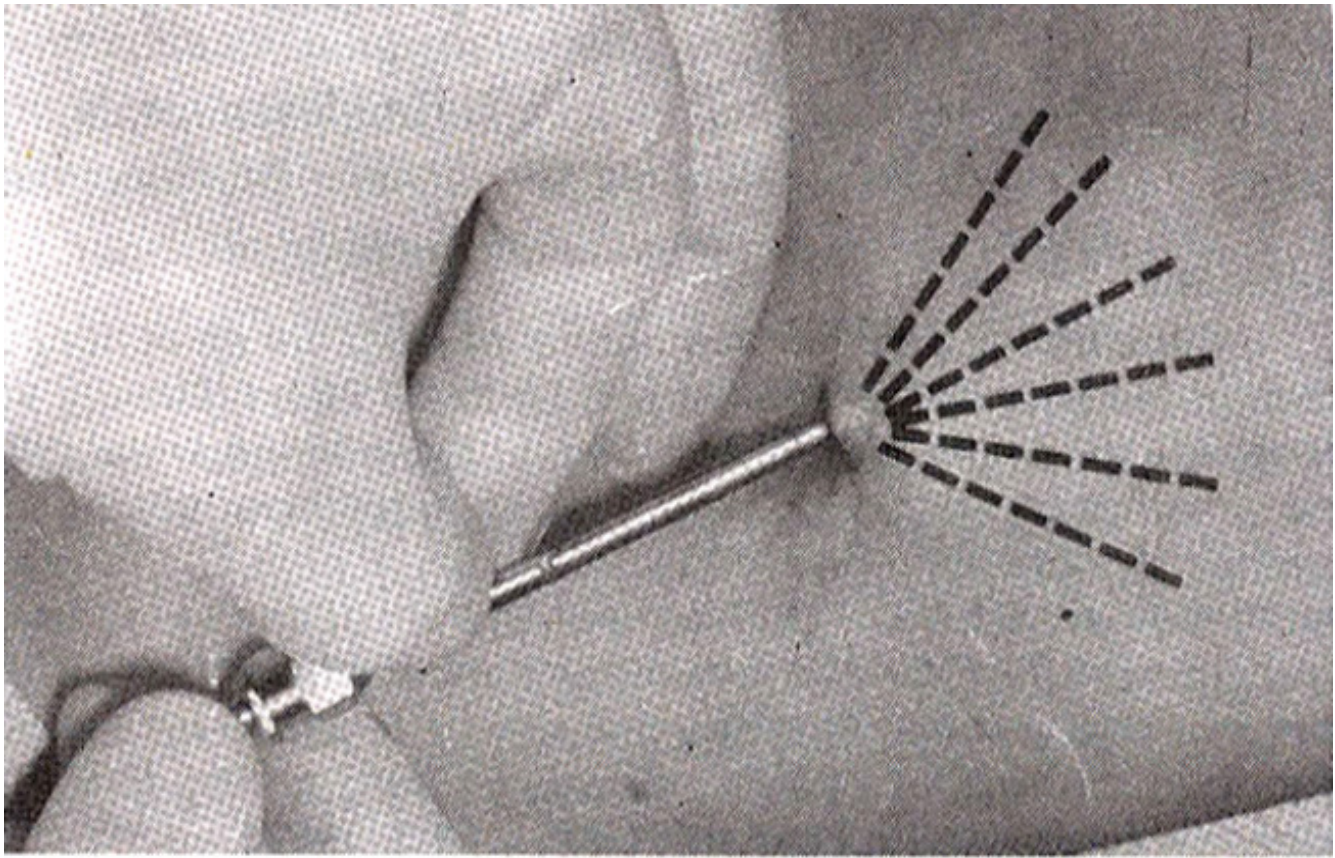


Figure 5. Six implants in position.

Placing the capsules just under the skin, not deeply, helps to assure that they can be removed easily later. When all six capsules are in place, the provider closes the incision with an adhesive bandage, no stitches are needed and places compresses and gauze over the entire area. Insertion usually takes 8 to 10 minutes. The study was conducted at four clinics situated in Karachi, Lahore, Faisalabad and Peshawar, under the supervision of eminent gynaecologists. The study was conducted with the approval of Government of Pakistan in accordance with the protocol laid down by Family Health International (FHI). A senior gynaecologist and one doctor from Indonesia got formal training in the application, removal and counselling of norplant implant. These doctors further trained other doctors and paramedics of the four centres, which were to be involved in the trial study. International Planned Parenthood Federation (IPPF) supplied norplant implants, which were used for the present study. To ensure maximum follow-up, women from urban and pen-urban areas within a radius of 30-40 km were registered. Women included in the study were: 1) aged between 20 and 45 years; 2) married with at least two living children; 3) having no pelvic and skin inflammatory disease and 4) with regular menstrual pattern. Every acceptors were provided with full information regarding the purpose of study and their rights and obligations during the participation. An informed consent was obtained prior to implant. The implant were inserted according to the procedure laid down by WHO⁶, described under introduction. By the end of enrollment period, 445 women opted for this study. Follow-up of all acceptors was scheduled at 1, 3, 6, 12, 18 and 24 months intervals after enrollment. The respondents enrolled in the study were stressed about the importance of their follow-up visits. Each participant was asked to keep a record of her menstrual events and report to the clinic as per schedule. Efforts were made to follow all enrolled acceptors.

Results

The socio-demographic characteristics of the acceptors are shown in Table I.

Table I. Distribution of socio-demographic characteristics of 445 norplant acceptors.

Characteristics	Percentage
Age groups	
20-24 years	10.34
25-29 years	27.42
30-34 years	34.83
35-39 years	21.57
40-44 years	2.25
Not recorded	3.59
No. of live births	
1-2	9.41
3-4	42.92
5-6	31.92
7-8	8.32
≥ 9	2.71
Not recorded	4.72
Education	
Illiterate	55.06
Primary	7.87
Middle	7.19
Matric	10.79
F.A./F.Sc.	6.07
B.A./B.Sc.	1.35
M.A./M.Sc.	0.22
Not recorded	11.45
No. of more children wanted	
None	65.39
1	15.74
2	8.54
3	0.45
4	0.22
≥ 5	9.44
Area of residence	
Lahore	37.30
Faisalabad	28.54
Peshawar	13.03
Karachi	21.13
Previous contraception	
None	46.74
IUD	9.66
Pills	8.54
Injectable	3.37
Condom	26.29
Withdrawal	0.89
Foam	0.22
Not recorded	3.82
Time since last pregnancy	
≤ 1 year	34.83
1-2 years	22.47
3-4 years	10.56
≥ 5 years	4.50
Not recorded	27.6

Out of 445 acceptors, 20 were lost to follow up (4.49%) because they shifted to other cities. Of the remaining 425 acceptors, 419 regularly visited the clinic, while six were visited at their homes. During 2 years of study period, 37 acceptors got the implants removed, so at the end of two years, there were

388 cases showing continuation rate of 91.2% after 2 years. The medical and anthropometric data of acceptors at the time of study and at follow up are given in Table II,

Table II. Distribution of medical and anthropometric data among acceptors and continuous users at 2 years follow-up.

Characteristics	Initial	Follow-up
Systolic blood pressure		
≤ 90 mmHg	1.35	1.80
90-100 mmHg	9.89	10.31
100-110 mmHg	30.34	31.96
111-120 mmHg	23.14	24.74
121-130 mmHg	4.49	3.86
131-140 mmHg	0.22	0.77
≥ 140 mmHg	0.90	-
Not recorded	29.67	26.56
Diastolic blood pressure		
≤ 60 mmHg	4.04	4.12
61-70 mmHg	36.63	44.58
71-80 mmHg	24.95	22.68
81-90 mmHg	3.37	1.80
91-100 mmHg	0.22	0.26
Not recorded	29.67	26.56
Weight		
≤ 40 kg	1.80	2.58
40-49 kg	20.22	18.81
50-59 kg	25.84	26.29
60-69 kg	14.38	16.24
70-79 kg	4.72	5.41
80-89 kg	1.80	1.55
≥ 90 kg	0.89	1.29
Not recorded	30.36	27.83

Table III. Distribution of menstrual pattern among acceptors and continuous users at 2 years follow-up.

Characteristics	Initial	Follow-up
Length of last menstrual cycle		
< 10days	3.33	0.26
10-15 days	37.14	3.09
16-20 days	42.04	5.15
21-25 days	-	28.35
26-30 days	-	28.61
Irregular	0.22	10.06
Amenorrhoea	-	12.89
Not applicable	2.92	-
Not recorded	14.84	10.06
Duration of flow		
1-2 days	3.15	1.81
3-4 days	26.75	10.82
5-6 days	32.59	23.71
7-8 days	20.89	32.99
≥ 9 days	0.22	6.19
Amenorrhoea	-	12.89
Not applicable	2.92	-
Not recorded	13.48	11.59
Type of flow		
Scanty	15.06	18.30
Moderate	64.94	49.23
Excessive	3.60	7.99
Not applicable	2.92	12.89
Not recorded	13.48	11.59
Inter-menstrual bleeding		
Staining/spotting	0.90	45.88
Moderate	17.30	6.44
Severe	1.57	15.46
None	63.82	7.74
Not applicable	2.93	12.89
Not recorded	13.48	11.59

while Table III shows the menstrual pattern of acceptors at the time of admission to study and at 2 years follow-up. The mean age of acceptors was 30.7+4.76 years. The maximum number of women (34.8%) were aged 30-34 years followed by those between 25 to 29 years (27.24%). The mean number of live births was 48. The maximum proportion of acceptors (42.9%) had 3-4 children. The next largest group (31.9%) was of women who had 5-6 children. Majority of women (55%) were illiterate; 15% had less than 10 years of schooling, only 1.5% were graduate or postgraduate. About two third of acceptors (66.3%) do not want any additional children. However, only 50 did use any contraception to achieve this aim. More than half women (57.3%) accepted norplant within 2 years of last delivery. The mean weight of acceptors at the time of admission to the study was 53.36+10.95 kg and 46% weighed between 40 and 59 kg. The mean systolic blood pressure was 108.38+9.79 mmHg, while mean diastolic blood pressure was 68.27+10.79 mmHg (Table II). The duration of the last menstrual cycle among majority of acceptors (42%) was 26-30 days followed by 21-25 days in 37.1% acceptors. The mean duration of menstrual cycle was 25.1+3.5 days. Among 80.2% acceptors, the duration of

menstrual flow was between 3 and 8 days (Table III). A perusal of Table II and III reveals that there was no significant change in mean systolic blood pressure (107.8 ± 8.9 mmHg), or mean diastolic blood pressure (68.1 ± 2.2 mmHg). However, there was a significant increase ($P < 0.001$) in mean weight (56.9 ± 11.4 kg) and a significant decrease ($P < 0.001$) in the mean duration of menstrual cycle (24.27 ± 4.11 days).

Table IV. Side effects of norplant.

Side effect	Number	Percentage
Continuous bleeding	18	4.2
Amenorrhoea	17	4.0
Irregular bleeding	8	1.8
Excessive menses	12	2.8
Prolonged menses	1	0.2
Shortened cycle	4	0.9
Spotting	8	1.8
Insomnia	1	0.2
Backache	5	1.1
Psychological	1	0.2
Weight gain	1	0.2
Pain at site of implant	1	0.2
General weakness	2	0.4
No complaints	346	81.4
Total	425	100

Table IV summarizes the side effects reported by 425 acceptors who were regularly followed-up. Seventy nine acceptors (18.5%) developed various side effects.

Table V. Primary reasons for removal of norplant.

Reasons	Number	Percentage
Menstrual problems	25	67.6
Personal reasons	2	5.4
Side effects	2	5.4
Medical reasons	3	8.1
Husband's dislike	2	5.4
Pregnancy	1	2.7
Not recorded	2	5.4
Total	37	100.0

Table V shows the primary reasons for removal of norplant. The major reason for discontinuation (67.6%) was menstrual problems. During the study period of 2 years, there was only one pregnancy (0.26%). A follow-up of those who got norplant removed showed that 78.4% were not using any contraception, 5.4% each had opted for condoms and sterilization and 2.7% each were using injectable and withdrawal (Table VI).

Table VI. Contraception chosen after discontinuation of norplant.

Contraceptive method	Number	Percentage
None	29	78.4
Injectable	1	2.7
Condom	2	5.4
Sterilization	2	5.4
Withdrawal	1	2.7
Not recorded	2	5.4
Total	37	100.0

Discussion

In the area of family planning and fertility, age plays a significant part. The mean age of the acceptors was 30.7 years. This shows that a large component of study population consists of those women, who still have a lot of reproductive years remaining and thus have a potential to contribute to family size. When translated into demographic terms, this observation indicates that the programme is hitting the right group and can create a demographic impact. Education has often been described as an important correlate of attitudes and knowledge towards family planning. Among norplant acceptors, a sizeable number (55%) of the respondents were illiterate, which clearly suggests that a person, if properly

informed about family planning, though illiterate, might accept it. This agrees with the findings of Pakistan Contraceptive Prevalence Survey (1984-85), where ligation and oral pills were more popular methods among those who had no schooling or were illiterate⁷. This indicates that illiteracy is not a barrier in making a decision for family size. Continuation rates have been high in the clinical studies and field trials of norplant users conducted to date. In the original ICCR study conducted in Brazil, Denmark, Finland, Chile, the Dominican Republic and Jamaica, the first year net continuation rate was 74.6 per 100 women⁸. Later analysis of all ICCR- monitored trials⁹ showed somewhat higher first year continuation rates, ranging from 76% in Scandinavia to 90% in Chile. In the US, the first year continuation rate was 82% and the rate over four years was 44. The continuation rate in the present series was 91.2% at the end of two years period. This is almost the same as reported by above mentioned studies. During the study period, only one woman became pregnant (0.26%) in the first year. There was no pregnancy during the second year. This failure rate is compatible with norplant studies¹⁰⁻²², which include thousands of women from Chile, China, Colombia, the Dominican Republic, Ecuador, Egypt, Indonesia, Scandinavia, (Finland and Sweden), Singapore, Sri Lanka, Thailand and the United States. While the pregnancy rates vary from country to country, the Pearl index for all countries based on 12,133 woman- years of use is 0.2% for the first two years of use and 0.9, 0.5 and 1.1% for the subsequent three years. These rates include data from the large Chinese experience which had a relatively low incidence of pregnancy and the Egyptian and Sri Lanka experience which includes some pregnancies that occurred prior to placement of the implants⁹. In the clinical trials centrally monitored by the ICCR, which represent the largest cohort of norplant users, the most common side effects were related to the type of symptoms often associated with steroid contraception². Such symptoms may include: headache, nervousness, nausea, dizziness, ovarian enlargement, dermatitis, acne, change of appetite, mastalgia, weight gain and effects on hair (hirsutism, hypertrichosis and scalp hair loss). Similar side effects were observed in the present study (Table VI). In another study²³, 95% of interviewed women mentioned that they experienced at least one side effect of the implants: 82% had changes in their menstruation; 32% experienced changes in weight; 24% had headaches; 16% cited mood changes and 15% cited acne. Nearly one-quarter reported "other" side effects which included decreased libido, more frequent chest pains, numbness in the arm and increases in hair growth, uterine cramp. In g, premenstrual syndrome or blood pressure; individually each of these "other" side effects was cited by no more than 4%. Weight changes were noticed in the present study also, where a significant weight gain was seen among norplant users. The evaluation of the pooled ICCR studies revealed that approximately 15% women discontinued owing to some adverse experience in the first year of use. The incidence of discontinuation decreased in subsequent years. In the present study the discontinuation rate was comparatively low (8.71%). Virtually all studies^{9,24-28} confirm that the predominant side effect observed during use of norplant is the disruption of the menstrual cycle: more bleeding days than usual, spotting between periods, fewer bleeding days or no bleeding at all, or a combination of these. In one trial²⁶, bleeding patterns were studied in 492 levonorgestrel implant users in Latin America and Scandinavia. The results showed increased bleeding in some norplant users and decreased bleeding in others. Another study conducted in the Philippines and Sri Lanka found that almost all women experienced some change in menstrual bleeding pattern. However, the changes experienced by these Asian women tended more to the decrease rather than increase in menstrual bleeding compared to those noted in the above study²³. A similar picture emerges from the present study where the length of menstrual cycle was significantly reduced ($P < 0.001$) among norplant users. In the present study, 86% of all side effects pertained to menstrual disturbances. Out of those who complained of menstrual disturbances, 26.4% had continued bleeding, 25% amenorrhoea, 17.6% excessive bleeding, 11.7% irregular bleeding, 5.8% short cycles and 1.4% had prolonged bleeding. Similar findings have been reported for a cohort of acceptors from San Francisco. Their findings

included: irregular bleeding (38%); prolonged bleeding (40%); spotting or bleeding between periods (32%) and more frequent bleeding (25%). Smaller proportions reported heavier bleeding (16%); amenorrhea (12%); lighter bleeding (10%) and “other” changes (9%). The “other” changes included cramping, less frequent menses and more regular menses²⁸. The Population Council’s data² shows that problems at the site of implant placement have been rare, with infection at the site occurring at rates between 0 and 1.6%. Implant expulsion occurred in 7 of 2,467 insertions (0.28%). In our series one implant got expelled (0.26%). One implant (0.26%) was removed due to infection at the site of insertion, while one capsule of another implant got expelled after development of infection at the site of insertion (0.26%). Thus the infection accounted for 0.52 cases per 100 women. The most disturbing finding of the study is the non-use of any contraception by 78.4% of those who got the implant removed (Table VI). Despite the bleeding disturbances caused by norplant, the high rate of continuation in the present study shows that this contraceptive is acceptable to the women. However, medical characteristics of a new contraceptive are not the sole determinants of its successful use; other reasons for adopting the new method maybe more important factors in helping women avoid unwanted pregnancies. In countries like Pakistan, where due to socio-cultural norms and early marriages, the desired number of children is attained at very young age and inspite of having completed their family size, these young mothers are hesitant to accept contraceptive surgery, because of its irreversible nature, there is a need to promote a long acting, easy to use and reliable contraceptive. Two years of the study in Pakistan suggest that norplant system is a safe, acceptable and effective contraceptive. The high rate of continuation indicates that despite the changes in menstrual pattern, it is a method of choice for spacing the births.

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