Implant contraception in Singaporean women: one decade of experience in KK Women's and Children's Hospital

W Kang, K H Tan

ABSTRACT

Introduction: The aim of this study was to assess user acceptability and effectiveness of implant contraception in Singaporean women.

Methods: A prospective study was carried out on 553 patients who received Norplant implant in our hospital from 1 January 1992 to 31 December 2000, and followed-up till 15 July 2003. The patients' profile, side-effects, satisfaction and continuation rate of Norplant implant were studied.

Results: The mean age of the subjects was 29.4 (± 5.1) years. The mean parity was 2.1 (± 1) live births. More than one-half (55.2 percent) of the subjects had used other methods of contraception before. The main reason for them to switch to implant contraception was convenience (63.6 percent). Of the 516 users on follow-up, the common side-effects were menstrual irregularity (51 percent), secondary amenorrhoea (9.6 percent) and weight gain (15.7 percent). 29.3 percent of users did not experience any side-effect. There was only one contraceptive failure, which may be related to drug interaction. The Pearl Index was 0.054 per hundred women years. There was only one serious adverse event of a patient (0.2 percent) who developed severe hypertension requiring treatment. The continuation rate was 92.4 percent after one year, 80.8 percent after two years, 68.9 percent after three years and 58.5 percent after four years. The main reasons for early implant removal were side-effects and desire for future pregnancy. Re-insertion was carried out in 53.7 percent of users who had completed five years of Norplant contraception.

Conclusion: This largest sub-dermal hormonal implant contraception study in multi-racial Singapore showed that Norplant contraception had a high degree of effectiveness with relatively high user satisfaction and continuation rate.

Keywords: contraceptive, hormonal implant, implant contraception, Norplant

Singapore Med J 2004 Vol 45(10):482-486

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INTRODUCTION

One of the most promising advances in contraceptive technology has been the development of long-acting contraceptive implants. Norplant is the first-generation implant. It began in 1966 as a research project by the Population Council. More than 60,000 women worldwide participated in its clinical trials, making it the most well-studied contraceptive agent prior to its distribution. In 1983, a Finnish company was licensed by the Population Council to produce Norplant[1]. To date, Norplant has been registered in over 60 countries and about 6 million women worldwide have used Norplant[2].

Norplant is a sub-dermal implant. It comprises six small, flexible, sealed silastic capsules; each contains 36mg of Levo-norgestrel. It is a reversible method of contraception that can last for five years. It was approved by the Food and Drug Administration in the United States in 1990, and was available in Singapore since the end of 1991. A Norplant clinic was set up in our hospital in January 1992. This was because good counselling, which is very important prior to insertion, as well as the process of implant insertion and removal takes time, and is difficult to carry out during the normal busy clinic sessions. A prospective study on Norplant implant was carried out in our hospital to evaluate patients' profiles, side-effects, user acceptability and continuation rates. This was by far the largest implant contraception study in Singapore. This study assessed user acceptability, effectiveness and continuation rate of implant contraception (Norplant) in Singapore women.

METHODS

A total of 553 patients who came for Norplant contraception from 1 January 1992 to 31 December 2000 were recruited in this study. They were followed-up till 15 July 2003. Ninety-five percent of Norplant implants were inserted by a single gynaecologist who was running the Implant clinic in our hospital during this period. The rest were inserted by other gynaecologists from our hospital.

The patients were given information on different methods of contraception. They were screened for contraindications to progestin, and were informed of the possible side-effects of implant prior to Norplant insertion. All implant users were followed up at three months, six months and 12 months until the implant was removed. Visits at four to six months were conducted if side effect(s) arose. The patients' age, race, religion, marital status, parity, previous abortions, previous contraceptive use and information source were studied. Side-effects and degree of satisfaction based on five objective scales (very good, good, satisfactory, poor and very poor) were recorded during each follow-up visit.

Information was also obtained from the medical records and telephone conversation, if they defaulted follow-up. The failure rate, discontinuation rates and re-insertion after removal were analysed in 516 patients as 37 of them were lost to follow-up and were not contactable after Norplant insertion. Amenorrhoea was defined as absence of menses for six months or longer. Regular cycle was defined as periodic withdrawal bleeding within 28 ± 7 days. Irregular cycles were defined as inter-menstrual, frequent or prolonged menses. Cumulative continuation rate was calculated using the Kaplan-Meier method. Cause-specific rate was calculated using competing method, where appropriate.

RESULTS

The patients' profiles are shown in Table I. The age group of the patients ranged from 16 to 45 years old. The peak age group for insertion was 24 to 31 years old. The mean age was 29.4 ± 5.1 years. The mean parity was 2.1 ± 1 live births. The mean duration of follow- up was 3.4 ± 1.8 years. The side-effects of implant users are shown in Table II. Thirty-seven cases were lost to follow-up after insertion. Of the remaining 516 implant users on follow-up, 29.3% did not experience any side effect. The most frequent side effect of Norplant was menstrual irregularity (51%). Other common side-effects included weight gain (15.7%), secondary amenorrhoea (9.6%) and headache, nausea and vomiting (6.6%).

One implant user developed a severe adverse event. She was a 29-year-old, gravida 6 para 6, married woman who had a normal baseline blood pressure of 120/80 mmHg. She developed persistent severe high blood pressure measuring 160/110 mmHg after Norplant insertion, and required anti-hypertensive treatment for two months until the Norplant was removed. Her blood pressure returned to normal

Table I. Characteristics of implant users (n=553).

Characteristics	No.	%
Race		
Chinese	282	51
Malay	162	29.3
Indian	65	11.8
Others	44	7.9
Religion		
Catholic and Christian	63	11.4
Muslim	171	30.9
Buddhism, Taoism and ancestor worship	111	20.1
Hinduism	83	15
Free thinker	125	22.6
Number of abortion s		
0	343	62
1	143	25.9
2	48	8.7
>3	19	3.4
Marital status		
Single	24	4.3
Married	529	95.7
Reason for insertion		
Premarital contraception	32	5.8
Child spacing	215	38.9
Completed family	306	55.3
Preceding events: within six months		
Following termination of pregnancy	84	15.2
Following delivery	305	55.2
None	164	29.6
Information on Norplant implant		
Mass media	83	15
Friends and relatives	152	27.5
Nurses and doctors	269	48.6
Others	49	8.9
Previous contraception		
None	248	44.8
Oral contraceptive	138	25
Intra-uterine contraceptive devices	91	16.5
Barrier methods	87	15.7
Natural methods	38	6.9
Injectable methods	24	4.3
Malay medicine	2	0.4
Reason for switch to implant contraceptive		
Convenience	194	63.6
Experienced side-effect with other contraceptive methods	111	36.4
Contraceptive failure	33	10.8

Table II. Side-effects experienced with Norplant contraception (n=516).

Side-effects	No	%
None	151	29.3
Menstrual disorders		
Menstrual irregularity	263	51.0
Secondary amenorrhoea	49	9.6
Weight gain	81	15.7
Weight loss	6	1.2
Headache, nausea, vomiting and dizziness	34	6.6
Depression and mood changes	11	2.1
Skin disorders		
Dermatitis	8	1.5
Acne	15	2.9
Alopecia	14	2.7
Facial pigmentation	4	0.8
Insertion site itch and pain	18	3.5
Mastalgia	1	0.2
Hypertension	1	0.2
Asthma worsening	1	0.2
Backache and bodyache	3	0.6
Contraceptive failure (pregnancy)	1	0.2

four weeks after Norplant removal. Another implant user had a history of mild asthma since childhood. Her asthma worsened after Norplant insertion and she required continuous high-dose of anti-asthma treatment. Her condition improved after the Norplant was removed two weeks after insertion.

A third patient developed allergy to plaster that was applied over the insertion site after Norplant insertion. The severe itch made her scratch the insertion site constantly. Hence, one end of a Norplant rod was extruded. The rod was removed and reinserted under antibiotics coverage. She was well after the re-insertion. However, she decided to remove Norplant five months later because of menstrual irregularity and weight gain. Another patient, a 39-year-old woman, had a 3.3 cm submucosal fibroid and menorrhagia. Her menorrhagia persisted after Norplant insertion. She finally underwent total hysterectomy and Norplant removal five months after insertion.

There was only one contraceptive failure out of a total of 22,413.8 cycles of Norplant study. The Pearl Index was 0.054 per hundred women-years (HWY) (95% confidence interval, 0.008 to 0.380). She was a 35-year-old, gravida 3 para 2, married woman who conceived 23 months after Norplant insertion. There was no excessive weight gain and her weight remained constant at 53kg. She was on carbamazepine 200mg twice daily for epilepsy. She decided on termination of pregnancy, Norplant removal and laparoscopic sterilisation after counselling.

The five-year gross cumulative continuation rates and reasons for Norplant removal are presented in Table III. Two hundred and three users completed five years of Norplant usage. By the 6th year, 95.7% of users had their implant removed. The main reasons given were the side-effects experienced with Norplant and the desire for further pregnancy. The degree of satisfaction was rated to be very good by 239 (46.3%) patients, good by 161 (31.2%) patients, satisfactory by 61 (11.8%) subjects, poor by 35 (6.8%) subjects, and very poor in 20 (3.9%) cases. Of the 203 users who had completed five years of usage of implant, 109 (53.7%) opted for Norplant re-insertion. Of the 116 users who removed Norplant because they were planning to have another baby, 79 (68.1%) intended to use Norplant again in future.

DISCUSSION

Our study showed that Norplant implant contraception was fairly well accepted by Singaporean women of different reproductive age groups. The main reason

Table III. Five-year gross cumulative incidence and reasons for removal (n=516).*

Event	Year 1	Year 2	Year 3	Year 4	Year 5
Continuation rate (%)	92.4	80.8	68.9	58.5	29.0
Termination rate (%)	7.6	19.2	31.1	41.5	71.0
Reasons for removal (%)					
Side-effect(s)	6.4	13.9	20.6	26.7	28.4
Desire further pregnancy	1.7	6.4	11.8	16.0	21.0
Completed usage	0	0	0	0	26.2
Others	0	0.6	0.8	1.2	1.5

*There may be more than one reason for Norplant removal.

they chose Norplant was because of its convenience. It entailed only one insertion procedure to provide contraceptive effect for up to five years. Majority (77.5%) of the women rated it as very good or good. Only 10.7% rated it as poor or very poor because of its side effects. There was also a relatively high cumulative continuation rate. This could be explained by availability and good quality of counselling prior to Norplant insertion. The high continuation rate is comparable to a smaller study done earlier in Singapore[3].

Menstrual irregularity was the most common side-effect and reason for early discontinuation of Norplant in our cohort, similar to other studies[4-8]. Prolonged and frequent bleeding was more frequently observed during the early months of Norplant insertion. It became less frequent and bothersome after one year of implant use. Adequate counselling and early warning were very important prior to Norplant insertion to achieve a high degree of satisfaction and continuation rate. Secondary amenorrhoea (9.6%) was less common in our report compared to a Thai study[4], but more common than the China study[5]. A negative urine pregnancy test was very reassuring to patients. With time, many users became happy as they did not have the inconvenience of monthly menstrual cycle.

Weight gain was the second most common side-effect and was comparable to other studies[6,9]. It was important to counsel users to monitor their weight regularly. They were referred to a dietician for dietary advice, encouraged to have regular exercise and prescribed slimming medications, if necessary. Headache, giddiness, nausea and vomiting were experienced by 6.6% of users. These symptoms were usually transient and subsided spontaneously after a few months[7]. Reassurance, mild analgesia and evaluation at one month were advised.

There was only one contraceptive failure in this study. The patient did not gain excessive weight, which is a possible factor for failure as observed in a Thai study[4]. However, she was on carbamazepine treatment for seizure. This hepatic enzyme inducing drug increased the metabolism of progestogen, and was likely the cause of contraceptive failure. The calculated Pearl Index was 0.054 per HWY. This was lower than the International Committee for Contraceptive Research (ICCR) study[10] (2.7 per 100 acceptors). The reason for our low pregnancy rate could be because Norplant was mainly inserted between day 1 to 7 of the menstrual cycle. Careful counselling was provided if the users insisted on having Norplant insertion after day 7 of menstrual cycle. This was performed only if they had used other method(s) of contraception reliably prior to insertion. They were informed of the small risk of pregnancy and were advised to use condom for two more weeks after the insertion.

There was only one serious adverse event. This occurred in a patient who developed severe hypertension towards Norplant contraception. Other serious adverse events that were reported in other studies[11-13], such as pseudotumour cerebri, thrombotic thrombocytopaenic purpura, thrombocytopaenia, stroke and infection of the insertion site were not observed in this study.

Our experience with Norplant implant in Singapore women showed that the main reasons for removal were side-effects followed by the completed five-year usage and desire for pregnancy. This was slightly different from those reported in previous studies[4,14-15], where the desire for pregnancy was the main indication for removal. Our study showed that 68.1% of women who removed Norplant because they desired pregnancy intended to use it in the future as they were very happy with Norplant contraception. It is evident that the Norplant implant is fairly well accepted by this group of women. Adequate counselling, early warning on possible side-effects, and follow-up by an experienced doctor to manage any side-effects that arise are important to achieve optimal implant contraception.

With continuing research and development, three other new contraceptive implants, Jadelle (second-generation Norplant implant), Implanon and Elcometrine are available in the market[2]. Currently, the single rod implant, Implanon, is available in Singapore. It contains etonorgestrel and provides contraceptive effect for up to three years. This implant resulted in fewer procedure-related complications[16]. As shown by this large local first-generation implant contraception study on Norplant, implant contraception had been fairly well accepted by our local patients, and was highly effective and reversible. With the advent of second-generation implant contraception with better safety profile and ease of use, it is envisaged that implant contraception would become more popular in Singapore.

ACKNOWLEDGEMENTS

The authors would like to thank Mr Chung Hing Ip, Dr Cheung Yin Bun and Ms Gao Fei for their kind assistance in statistical analysis.

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