Thai Journal of Obstetrics and Gynaecology
December 2002, Vol. 14, pp. 291-295

GYNAECOLOGY

Effects of A Single Rod Etonogestrel Used in Healthy Thai Women Aged between 17 and 35 Years in King Chulalongkorn Memorial Hospital

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ABSTRACT

Objective To study the menstrual patterns and side effects of a single rod etonogestrel use in healthy Thai women aged between 17 and 35 years.

Study design Prospective descriptive study.

Setting Family Planning Unit, Department of Obstetrics and Gynecology**,** King Chulalongkorn Memorial Hospital.

Methods Prospective descriptive study was conducted at the Family Planning Unit, King Chulalongkorn Memorial Hospital since1January 2002.The study duration was 6 months.The data was obtained from each patient's medical record. The descriptive statistics was percentage,mean, SD and 95% CI. The statistical analyses were performed by using the paired t test for comparison of means.

Results There were no pregnancies in this study. Women were exposed to a single rod etonogestrel for 372 women-months. The most common menstrual patterns in 3 and 6-month follow-up were irregular bleeding and amenorrhea. The common nonmenstrual adverse effect were acne, alopecia and nausea. No clinically significant changes in body weight, systolic and diastolic blood pressure were founded.

Discussion The most common menstrual patterns that founded in this study were irregular bleeding and amenorrhea followed by regular cycle. The common nonmenstrual adverse effect were acne alopecia and nausea. There were no pregnancies in 6-month follow-up period. A single rod etonogestrel was an effective implant contraceptive method and acceptable bleeding pattern. Overall acceptability are good. This should become a one of choice contraception methods in Thai women.

Key words : Implanon®, a single rod etonogestrel, contraception, menstrual pattern, side effects

There are many contraceptive methods for women. The acceptors are able to choose the proper contraceptive method for themselves. The Implanon® implant system, a long-acting, low dose etonogestrel[1] and reversible contraceptive, is safe, effective and suitable for women who need long term fertility control. However, a few of a single rod etonogestrel studies have been done in women in many parts of the world. There was a little information of a single rod etonogestrel effects in Thai women aged between 17

and 35 years. The objectives of this study were to evaluate the menstrual patterns and side effects of the etonogestrel single rod implant use in Thai women between 17 and 35 years of age during 6 months follow-up period.

Materials and methods

This six months prospective study was conducted at the Family Planning Unit, Department of Obstetrics and Gynecology, Faculty of Medicine, Chulalongkorn University, Bangkok, beginning in January 2002. Sixty-two women aged between 17 and 35 years were enrolled in this study. The inclusion criteria for the study were age between17and35 years, normal medical history, normal physical and pelvic examination, acceptance the used of a single rod etonogestrel at least 6 months. The exclusion criteria were contraindication for hormonal use, abnormal uterine bleeding and unable to follow up for 6 months. All participants voluntarily received a single rod etonogestrel insertion. All acceptors enrolled in the study had physical and pelvic examinations, including body weight, height and blood pressure measurements. Follow-up visits were scheduled for the third and sixth month after a single rod etonogestrel placement. At each follow-up visit, they were given a repeated physical and pelvic examination, including weight and blood pressure. The menstrual bleeding patterns were recorded in a menstrual diary card. Subjective complaints as well as side effects were recorded on questionnaire forms. The period of follow-up was 6 months. Telephone calls and letters were used in cases of missed appointments.

The insertion of a single rod etonogestrel was performed by the doctor at the Family Planning Unit. Amenorrhea was defined as the absence of menstruation for 3 months or longer. A regular cycle was defined as a periodic withdrawal bleeding within 28$\pm$7 days. Irregular cycles were defined as intermenstrual, prolonged or heavy bleeding at irregular interval.[2] Weight gain was defined as the increase of the body weight after a single rod etonogestrel placement. Descriptive and analytic statistics were run on all data where appropriate. SPSS/PC (Chicago, IL) for Windows, a statistical package program, was used to analyze data. The sample size was calculated by using the formula for descriptive study (p = abnormal uterine bleeding = 0.2[3], d = 0.1, $Z_{\alpha/2}$= 1.96). The number of participants was approximately 62 cases. All data was coded, recorded, and analyzed by the investigators. The descriptive statistics was percentage, mean, SD, and 95% CI. The statistical analyses were performed by using the paired t test for comparison of means. Significance was expressed at the level of 0.05 for all analyses.

Results

A single rod etonogestrel implant was used by 62 women between 17 - 35 years of age, for a total of 372 women -months. The characteristics of the acceptors are shown in table 1. The mean age was 28.5 ± 4.83 years; minimum was 17 years and maximum was 35 years. Most of the acceptors (54.8%) had completed primary school, and 58.1% were employed. The most common contraceptive method used by these acceptors prior to a single rod etonogestrel insertion was implantation(24.2%). There were no complications with the insertion procedure, and no pregnancy occurred during the 6-month follow-up period. Considering the menstrual patterns, the most common bleeding pattern at 3 months was irregular bleeding (43.5%), followed by regular cycle (33.9%), and amenorrhea (22.6%), and the most common bleeding pattern at 6 months was amenorrhea (54.8%), followed by irregular bleeding (24.2%), and regular cycle (21.0%).(table 2.) The major nonmenstrual side effects reported at 6 months of follow-up were weight gain (59.7%), acne (9.7%), nausea (1.6%) and alopecia (1.6%)(table 3.). When using paired *t* test there were no significant differences in body weight, systolic or diastolic blood pressure between the time of insertion and the 6-month follow-up. The details are summarized in table 4.

Table 1. Characteristics of a single rod etonogestrel implant acceptors

Characteristics	n = 62
Ages (years) (mean ± SD)(95%CI)	28.50 ± 4.83 / (27.27, 29.73)
Education (%)	
Primary	54.8
Secondary	29.1
Above secondary	16.1
Occupation (%)	
Housewife	37.1
Employee	58.1
Others	4.8
Parity (%)	
None	3.2
One	56.5
Two	29.0
More than two	11.3
Most recent contraception (%)	
None	32.3
Oral pill	19.4
Injection	14.5
Condom	6.5
IUD	3.1
Implantation	24.2
Body weight at insertion (kg)(mean ± SD) (95%CI)	54.56 ± 7.67 / (52.61, 56.51)
Blood pressure at insertion (mmHg) (mean ± SD) (95%CI)	
Systolic	110.94 ± 10.26 / (108.33, 113.54)
Diastolic	68.58 ± 8.31 / (66.47, 70.69)

Table 2. Menstrual patterns at 3 and 6-month follow-up in a single rod etonogestrel acceptors

Menstrual patterns	n = 62	%
3-month follow-up		
Amenorrhea	14	22.6
Regular cycle	21	33.9
Irregular cycle	27	43.5
6-month follow-up		
Amenorrhea	34	54.8
Regular cycle	13	21.0
Irregular cycle	15	24.2

Table 3. Reported side effects of a single rod etonogestrel acceptors at 3 and 6-month follow-up

Side effect	at 3 months		at 6 months	
	n = 62	%	n = 62	%
Irregular bleeding				
Yes	27	43.5	15	24.2
No	35	56.5	47	75.8
Weight gain				
Yes	30	48.4	37	59.7
No	32	51.6	25	40.3
Acne/chloasma				
Yes	5	8.1	6	9.7
No	57	91.9	56	90.3
Alopecia				
Yes	1	1.6	1	1.6
No	61	98.4	61	98.4
Nausea/vomiting				
Yes	1	1.6	1	1.6
No	61	98.4	61	98.4

Table 4. Comparison of body weight and blood pressure at insertion and 6-month follow-up

Variable	At insertion (n=62) (Mean ± SD)	at 6 months (n=62) (Mean ± SD)	95% CI
Body weight (Kg)	54.56 ± 7.67	54.81 ± 8.01	-0.76, 0.26
Blood pressure (mmHg)			
Systolic	110.94 ± 10.26	110.85 ± 6.78	-1.86, 2.02
Diastolic	68.58 ± 8.31	69.71 ± 6.14	-2.70, 0.44

Discussion

A single rod etonogestrel is the newest implant contraceptive method in Thailand. A single rod etonogestrel implant is a useful method for couples who want no more children but who are not yet ready to consider sterilization. There are a few studies about the menstrual patterns and side effects of a single rod etonogestrel in Thailand. In this study, the data of 62 healthy Thai women aged between17 and 35 years with etonogestrel use was collected for 3 and 6 months after implantation.

This study demonstrated that the most common menstrual pattern was irregular bleeding followed by regular cycle and amenorrhea followed by irregular bleeding in 3-month and 6-month follow-up respectively. The common nonmenstrual adverse effect was acne. No pregnancy was founded in this study. The study on the efficacy of a single rod etonogestrel showed that the contraceptive efficacy of Implanon® was high, with zero pregnancies during 53,530 cycles (4,103 women-years), resulting in a Pearl index of 0.0 (95%CI,0.00-0.09).[3] The previous study in healthy Thai women

found that there was no pregnancy during the study, amenorrhea occurred in 24-39%during the first 2 years and the most common drug-related adverse event was headache.[4] The result of this study was the same result in the Affandi B's study in women aged between 18 and 40. In his study founded that the most common menstrual pattern in a single rod etonogestrel used in 2 years was amenorrhea followed by bleeding-spotting episode. And the most common menstrual pattern in the norplant-6 use was bleeding-spotting episode followed by amenorrhea.[5] The most common nonmenstrual adverse effect of a single rod etonogestrel use in Urbancsek J's study in the women aged between 18 and 40 years was acne followed by mastalgia, headache, weight increase and abdominal pain.[6] The nonmenstrual adverse effect of this study is not much difference from Urbancsek J's study. The study in healthy women in China found that there was no pregnancy during their study. The most common adverse events were related to disturbed bleeding pattern and amenorrhea. A slight increase in mean body weight was observed.[7] The study in Indonesian women founded that the incidence of irregular bleeding was highest and no clinically significant changed in systolic, diastolic blood pressure, body mass index, and hemoglobin level.[8] This study demonstrated that a single rod etonogestrel user did not have an adverse effects on body weight, systolic and diastolic blood pressure. The other side effects that founded in this study were acne, nausea and alopecia.

In conclusion, the most common menstrual patterns that founded in this study were irregular bleeding and amenorrhea followed by regular cycle. The nonmenstrual adverse effect was acne alopecia and nausea. There were no pregnancies in 6-month follow-up period. A single rod etonogestrel is safe and effective implant contraceptive method and acceptable bleeding pattern. Overall acceptability are good. This should become a one of choice of contraception methods in Thai women. The effective counseling and explanation of the side effects of a single rod etonogestrel will minimize the problem of side effects and improve continuation and acceptability of a single rod etonogestrel use.

Acknowledgements

The authors would like to thank Chairman of the department of Obstetrics and Gynecology and staff of family planning clinic. Faculty of Medicine, Chulalongkorn University for their support.

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