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Bleeding patterns of subdermal implants (Norplant[®]-6) in Thai acceptors

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Bunyavejchevin S, Sitavarin S, Wisawasukmongchol W. Bleeding patterns of subdermal implants (Norplant[®]-6) in Thai acceptors. Chula Med J 2001 Dec; 45(12): 1039 - 45

- Objective** : *To study bleeding patterns and mean total bleeding days during the 1st year period of subdermal implants use in thai acceptors.*
- Design** : *Descriptive study*
- Setting** : *Family planning clinic, King Chulalongkorn Memorial Hospital*
- Material & Method** : *From September, 1996 to August 1997, 35 women attending family planning clinics, using subdermal implants (Norplant[®]-6), were recruited for this study. The menstrual patterns were recorded by the menstrual diary card at 3, 6, 9, 12 month periods.*
- Results** : *The frequent bleeding pattern was 68.75 % in the first 3 months, 14.28 % in the second 3 months, 62.86 % in the third 3 months and 57.14 % in the last 3 months. The cyclic bleeding was 17.15 % in the first 3 months, 14.28 % in the second 3 month, 25.71% in the third 3 months and 31.43 % in the fourth 3 months. The mean total bleeding days were 28.86 days in the first 3 months, 31.63 days in the second 3 months, 22.34 days in the third 3 months and 13.60 days in the last 3 months.*

Conclusion : *Most women had frequent bleeding patterns in the first year, but the mean total bleeding days declined by the end of the first year. Bleeding pattern counseling was encouraged to increase the acceptability of this method.*

Key words : *Subdermal contraception, Bleeding patterns.*

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สุวิทย์ บุญยะเวชชีวิน, สมเกียรติ สีตวาริน, วิรัช วิศวสุขมงคล. รูปแบบเลือดออกทางช่องคลอด ภายหลังใช้ยาฝังคุมกำเนิด Norplant®-6 ในกลุ่มสตรีไทย. จุฬาลงกรณ์เวชสาร 2544 ๓.๓; 45(12): 1039 - 45

- วัตถุประสงค์** : เพื่อศึกษาถึงรูปแบบเลือดออกทางช่องคลอดและค่าเฉลี่ยจำนวนวันรวมของเลือดออกทางช่องคลอดของยาฝังคุมกำเนิดชนิด Norplant®-6
- ชนิดของการวิจัย** : การวิจัยเชิงพรรณนา
- สถานที่ทำการวิจัย** : หน่วยวางแผนครอบครัว โรงพยาบาลจุฬาลงกรณ์
- วัสดุและวิธีการ** : ระหว่างเดือนกันยายน 2539 ถึง 2540 สตรีไทยจำนวน 35 ราย ที่ต้องการคุมกำเนิดชนิดกึ่งถาวร ทำการนัดตรวจติดตามเป็นเวลา 3, 6, 9, 12 เดือน ผู้รับบริการจะได้รับคำแนะนำให้บันทึกข้อมูลประจำเดือนในแบบฟอร์มที่กำหนด (Menstrual Diary Card)
- ผลการศึกษา** : ลักษณะประจำเดือนมาบ่อยพบ 68.75 % ในช่วงเดือนแรก, 14.28 % ในช่วง 3 เดือนที่ 2, 62.86 % ในช่วง 3 เดือนที่ 3 และ 57.14 % ในช่วง 3 เดือนที่ 4 ลักษณะรอบระดูปกติพบ 17.15 % ในช่วง 3 เดือนแรก, 14.28 % ในช่วง 3 เดือนที่ 2, 25.175 % ในช่วง 3 เดือนที่ 3 และ 31.43 % ในช่วง 3 เดือนที่ 4 ค่าเฉลี่ยของวันที่มีเลือดออกคือ 28.56 วัน ในช่วง 3 เดือนแรก, 31.63 วัน ในช่วง 3 เดือนที่ 2, 22.34 วัน ในช่วง 3 เดือนที่ 3 และ 13.60 วันในช่วง 3 เดือนที่ 4
- สรุปผลการศึกษา** : สตรีส่วนใหญ่มีลักษณะเลือดออกกะปริดกะปรอยตลอดปีแรกของการศึกษาแต่ค่าเฉลี่ยของวันที่มีเลือดออกในแต่ละช่วง 3 เดือนลดลงเมื่อสิ้นปี ข้อมูลนี้จะช่วยในการให้คำปรึกษาผู้ช่วยถึงลักษณะเลือดประจำเดือนที่เปลี่ยนแปลงไปเพื่อช่วยเพิ่มการยอมรับวิธีคุมกำเนิดวิธีนี้ต่อไป

Subdermal contraception (Norplant®-6) was the safe, effective contraceptive method with relatively few side effects and Norplant® has been used in Thailand since 1980.⁽¹⁾ The pregnancy rates were only 0.1 in the first year use and the continuation rate of 90, 75 and 58 per cent in 1st, 2nd and 3rd years respectively.^(1,2) Norplant® composed of 6 silastic silicone rubber rods with a diameter of 2.4 mms. and a length of 3.4 cms. A Levonorgestrel level of 80 micrograms was released during the 5 years of use.⁽³⁾ 4) The most common side effect was abnormal uterine bleeding which may be intermenstrual spotting or amenorrhea.⁽⁵⁻⁹⁾ The frequent or prolonged uterine bleeding was the most common reason to remove the Norplant®⁽⁵⁻⁹⁾

There are many reports of the health profile of Norplant® and training in the National Family Planning Program of Thailand.⁽¹⁰⁻¹³⁾ It can be used for groups of women who had the immediate postpartum⁽¹⁴⁻¹⁵⁾ and were acceptable in the low rate - contraception use such as hill-tribe people.⁽¹⁰⁾ The aim of this study was to examine the vaginal bleeding patterns from the counseling information to increase the continuation rate of this method.

Materials and Methods

From September 1, 1996 to August 30, 1997, 35 women aged 15-44 years attending family planning clinics, using subdermal implants (Noplant®-6) were recruited for this study. All subjected lived in Bangkok and the area nearby. The inclusion criteria were : normal menstrual patterns 3 months before, no contraindications for Norplant,⁽¹⁶⁾ no history of prior hormonal use, willing to be examined on a continual basis for 1 year, and willing to follow up at the King Chulalongkorn

Memorial Hospital. After the informed consents were given, the menstrual patterns were recorded by the menstrual diary card at 3, 6, 9, 12 month periods. They were scheduled for follow up and recording of the menstrual patterns. Instructions were given by the well-trained nurses of the clinic. The bleeding patterns were categorized using the criteria described by Indian Council of Medical Contraception Research task force study.⁽¹⁷⁾

1. Frequent/Prolonged bleeding

- Bleeding runs ≥ 5 days
- Average episode length ≤ 21 days
- Total bleeding days > 20 days
- Longest bleeding runs > 10 days

2. Reduced/Infrequent bleeding

- Bleeding runs 0-1 days
- Average episode length > 35 days
- Total bleeding days ≤ 5 days

3. Cyclic/Normal bleeding pattern which

couldn't be categorized in 1 and 2

Results

All acceptors returned to be examined until the end of the study.No case of heavy uterine bleeding that required treatment was found. No cases of severe side effects were noted.

Table 1. Acceptor's Characteristics. (N = 35)

	$\bar{X} \pm SD.$
Age (yr)	28.17 \pm 5.08
Height (m)	1.53 \pm 0.04
Weight (kg)	48.69 \pm 6.05
BMI (kg/m ²)	20.75 \pm 2.39

Most acceptors had frequent bleeding patterns during the first year use. (Table 2) The mean of total bleeding days decreased gradually from the 28.86 days to 13.60 days by the end of the year. (Table 3).

endometrium effect of levonorgestrel.⁽²³⁻²⁴⁾ The bleeding days tended to decrease by the end of the year. There was no case of heavy bleeding that requested the norplant removal. This can help increasing the acceptability for longer use. The

Table 2. Bleeding patterns.

Type	1 st - 3 rd months n (%)	4 th - 6 th months n (%)	7 th - 9 th months n (%)	9 th -12 th months n (%)
Frequent bleeding	24 (68.75)	25 (71.44)	22 (62.86)	20 (57.14)
Reduced bleeding	5 (14.28)	5 (14.28)	4 (11.43)	4 (11.43)
Cyclic bleeding	6 (17.15)	5 (14.28)	9 (25.71)	11 (31.43)

Table 3. Mean \pm SD of total bleeding days.

Time	Mean \pm SD (days)
1 st -3 rd months	28.86 \pm 18.46
4 th -6 th months	31.63 \pm 23.72
7 th -9 th months	22.34 \pm 16.80
9 th -12 th months	13.60 \pm 12.82

Discussion

There were many reports of the efficacy and health benefits of Norplant in Thai acceptors,^(2, 4, 10-12) This was the first report relating directly to the bleeding patterns of women in Thailand. In our study, we used the standard criteria and definition of bleeding patterns for comparison to other international studies.^(17, 19-20) From our study, most bleeding patterns were frequent bleeding patterns and there was a low incidence of cyclic bleeding which can be explained by the different ethnic group. The high number of incidents of frequent bleeding in Norplant can be explained by the increased endometrium micro vascular density and thin atrophic

participants should be reassured about the alterations of the menstrual cycle in the first year use and about the total number of bleeding days which will decline as time passed. Bleeding pattern counseling was encouraged to increase the acceptability of this method. This study is a preliminary report of the first year use of subdermal contraception. Longer study and more cases are required. We expected to extend this study in higher number and longer period of follow up to prove the reliability of the outcome.

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