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## GYNAECOLOGY

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# Bleeding Patterns after Use of Single-rod Etonogestrel Implant in Postpartum Adolescents

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### ABSTRACT

**Objectives:** To study bleeding patterns in postpartum adolescents after use of single-rod etonogestrel implant and to identify its side effects.

**Materials and Methods:** This was a 6-month prospective study of 60 postpartum adolescents aged 10-19 years old who underwent single-rod etonogestrel implant after giving birth at Rajavithi Hospital. They were followed-up on three further occasions in order to fill vaginal bleeding chart diary and undergo physical examination.

**Results:** A total of 2,767 women gave birth at Rajavithi Hospital between August 1<sup>st</sup> and Dec 30<sup>th</sup>, 2015. Of these, 249 were postpartum adolescents aged 10-19 years old; 75 of them received single-rod etonogestrel implants, were included in the study. There were 15 dropouts, 60 of them completed the follow-up visits. Bleeding patterns after the implants were: amenorrhea 41.6%; prolonged bleeding 30.0%; infrequent bleeding 11.7%; regular bleeding 11.7%; and irregular bleeding 5%. Side effects, such as emotional instability, dysmenorrhea, nausea and vomiting, weight gain and headache were noted in 28.3% of the participants. Four participants (6.6%) had the device removed due to an experience with prolong bleeding.

**Conclusion:** The most common bleeding pattern after single-rod etonogestrel implant in postpartum adolescents was amenorrhea. Prolonged bleeding was the main reason for device removal. Minor side effects such as emotional instability, headache were noted in participants.

**Keywords:** Implanon, etonogestrel, contraception, abnormal vaginal bleeding, bleeding pattern, adolescent.

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# รูปแบบเลือดที่ออกทางช่องคลอดภายหลังการใช้ยาฝังคุมกำเนิดชนิดหนึ่งแท่งในวัยรุ่นหลังคลอด

เจียมจิรา อินทะรังษี, ทรงพล พุทธิศิริ

## บทคัดย่อ

**วัตถุประสงค์:** ศึกษารูปแบบเลือดที่ออกทางช่องคลอดภายหลังการใช้ยาฝังคุมกำเนิดชนิดหนึ่งแท่งในวัยรุ่นหลังคลอดบุตร และหาผลข้างเคียงจากการใช้ยาฝังคุมกำเนิดชนิดหนึ่งแท่งในวัยรุ่นหลังคลอดบุตร

**วัสดุและวิธีการ:** เป็นการศึกษาแบบไปข้างหน้า เป็นระยะเวลา 6 เดือน ภายหลังการใช้ยาฝังคุมกำเนิดชนิดหนึ่งแท่งในวัยรุ่น อายุ 10-19 ปี หลังคลอดบุตรที่โรงพยาบาลราชวิถี จำนวนทั้งหมด 60 ราย โดยนัดตรวจติดตาม 3 ครั้งหลังฝังยาคุมกำเนิด และเก็บข้อมูลจากแบบสอบถาม แบบบันทึกรูปแบบเลือดที่ออกทางช่องคลอด และการตรวจร่างกาย

**ผลการศึกษา:** สตรีตั้งครรภ์ที่คลอดบุตรที่โรงพยาบาลราชวิถี ตั้งแต่วันที่ 1 สิงหาคม 2558 ถึง วันที่ 30 ธันวาคม 2558 ทั้งหมด 2,767 ราย สตรีตั้งครรภ์วัยรุ่น อายุ 10-19 ปี 249 ราย ใช้ยาฝังคุมกำเนิดจำนวน 146 ราย ใช้วิธีการคุมกำเนิดชนิดอื่น 103 ราย ฝังยาคุมกำเนิดชนิดหนึ่งแท่ง (Implanon®) 112 ราย ฝังชนิดสองแท่ง (Jadelle®) 34 ราย เข้าร่วมโครงการฝังยาคุมกำเนิดชนิดหนึ่งแท่ง 75 ราย ไม่มาติดตามอาการ 15 ราย และมาติดตามอาการจนครบ 6 เดือน ทั้งหมด 60 ราย พบว่ารูปแบบเลือดที่ออกทางช่องคลอดหลังฝังยาคุมกำเนิด พบว่าประจำเดือนไม่มามีร้อยละ 41, ประจำเดือนมานานผิดปกติร้อยละ 30, ประจำเดือนมาไม่สม่ำเสมอร้อยละ 12, ประจำเดือนมาสม่ำเสมอร้อยละ 12 และประจำเดือนมาบ่อยกว่าปกติร้อยละ 5 และพบผลข้างเคียงอื่นๆ เช่น อารมณ์แปรปรวน ปวดท้องประจำเดือน คลื่นไส้ อาเจียน น้ำหนักเพิ่ม และปวดศีรษะ ทั้งหมดร้อยละ 28.3 จากผู้เข้าร่วมโครงการทั้งหมด

**สรุป:** รูปแบบเลือดที่ออกทางช่องคลอดภายหลังการฝังยาคุมกำเนิดชนิดหนึ่งแท่งในวัยรุ่นหลังคลอดบุตรที่พบมากที่สุดคือ ประจำเดือนไม่มา โดยสาเหตุหลักของการถอดยาฝังคุมกำเนิดก่อนกำหนด คือ ประจำเดือนมานานผิดปกติ และพบผลข้างเคียงจากการฝังยาคุมเพียงเล็กน้อย ดังนั้นจึงแนะนำให้ใช้ยาฝังคุมกำเนิดชนิดหนึ่งแท่งในวัยรุ่น เนื่องจากเป็นวิธีการคุมกำเนิดประสิทธิภาพสูง และเหมาะสำหรับวัยรุ่น

**คำสำคัญ:** ยาคุมกำเนิดชนิดฝัง, อิมพลานอน, เอโทโนเจสเตรล, ยาคุมกำเนิดแบบชั่วคราวที่ออกฤทธิ์นาน

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## Introduction

The World Health Statistics 2013 report revealed that the average live birth rate among mothers aged 15-19 years old around the world from 2006-2010 was 48.9 per 1,000 population<sup>(1)</sup>. Africa had the highest live birth rate for this age group at 115 per 1,000, and Europe had the lowest at 23 per 1,000 population. Thailand had a rate of 74 per 1,000 population, the same as that of Malaysia. Ranking among these countries, both Thailand and Malaysia were joint second highest in Southeast Asia after the neighboring Laos People's Democratic Republic.

Adolescent pregnancies have increased rapidly and caused economic and social problems. Thai teenagers have shown a tendency to have first-time sexual intercourse early, at 13-15 years old. They seldom use any contraception and have unprotected sex. As a consequence, the World Health Organization and the American Congress of Obstetricians and Gynecologists have recommended the use of progesterone implant in adolescents due to its most effective and convenient method for this group.

From May 1<sup>st</sup>, 2014 to the present time, the Department of Health and National Health Security Office, Ministry of Public Health (MPH) has been providing free single-rod etonogestrel implants for postpartum adolescents, which is considered to be the most effective and long-acting reversible contraception (LARC). The progesterone implant has been the first-choice contraceptive for adolescents and others in need of contraception. Furthermore, this method can be used in women who may have risks of estrogen used<sup>(2)</sup>. The most common side effect of progesterone implant in all age groups is abnormal menstrual bleeding such as amenorrhea, infrequent bleeding, frequent bleeding and prolonged bleeding, but the patterns are unpredictable<sup>(3)</sup>. Other side effects are weight gain, headache, acne and emotional instability<sup>(4)</sup>.

This research aimed to examine bleeding patterns in postpartum adolescents after they had undergone single-rod etonogestrel implant. The result from this study can serve as a useful guide and source of information for women before deciding to adopt this particular method to meet their ultimate goal of child delaying or child

spacing.

## Materials and Methods

The protocol of this research was reviewed and approved by the ethics committee of Rajavithi Hospital (No. 109/2558). Pregnant women giving birth at Rajavithi Hospital from August 1<sup>st</sup> - Dec 30<sup>th</sup> 2015 were enrolled in the study. The inclusion criteria were patients who: 1) were aged 10-19 years old and 2) wished to use the single-rod etonogestrel implant. The exclusion criteria were patients who: 1) could either speak and read Thai; 2) had been diagnosed with abnormal vaginal bleeding before pregnancy; 3) had contraindication for this device; 4) had a history or suspicion of breast cancer; 5) had severe liver disease; 6) were allergic or hypersensitive to any of the implant materials and 7) lost to follow-up.

Women birth the 1<sup>st</sup> - 2<sup>nd</sup> week postpartum were enrolled into study. After the participants signed the informed consent, demographic data, menstrual patterns, sexual intercourse data, history of contraception and social history were collected by questionnaire. Physical examination and pelvic examination were completed before an insertion of the etonogestrel implant. A vaginal bleeding chart diary was given to all participants to keep a record of their bleeding patterns. Sanitary napkins (of uniform brand and type) were provided free to all participants who were instructed to change the napkins twice a day. Follow-up visits were scheduled at the 4<sup>th</sup>, 12<sup>th</sup> and 24<sup>th</sup> weeks

We provided advice for patients about differentiating between normal lochia and abnormal bleeding by lochia occurs in the first 3-4 days postpartum then gradually changes color to brown and then yellow over period of about 1 week and changes to whitish, turbid fluid about another 1-2 weeks postpartum while abnormal bleeding could appear after implant was given.

Bleeding patterns were categorized in accordance with the definitions of the World Health Organization<sup>(5,6,9)</sup> (Table 1), and the diary was adapted from Wyatt, et al<sup>(7)</sup> and Janssen, et al<sup>(8)</sup>.

The discontinuation criteria were patients who: 1) had severe vaginal bleeding which affected their daily life; 2) did not respond to medical treatment (including

oral estrogen and tranexamic acid) on 3 episodes; and 3) strongly desired to discontinue the implants for any reason.

The sample size was calculated by the following formula

$$n = \frac{Z_{\alpha/2}^2 p(1-p)}{d^2}$$

Abnormal bleeding pattern sensitivity of 0.614 from Guazzelli et al's study(9) as a proportion ( ) and maximum tolerated error ( ) of 0.123 were used for calculation. A total sample size were 60 cases. Statistical analysis was performed using SPSS for Windows version 17.0 (SPSS Inc., Chicago, Illinois, USA). Data were presented as frequency, percentage,

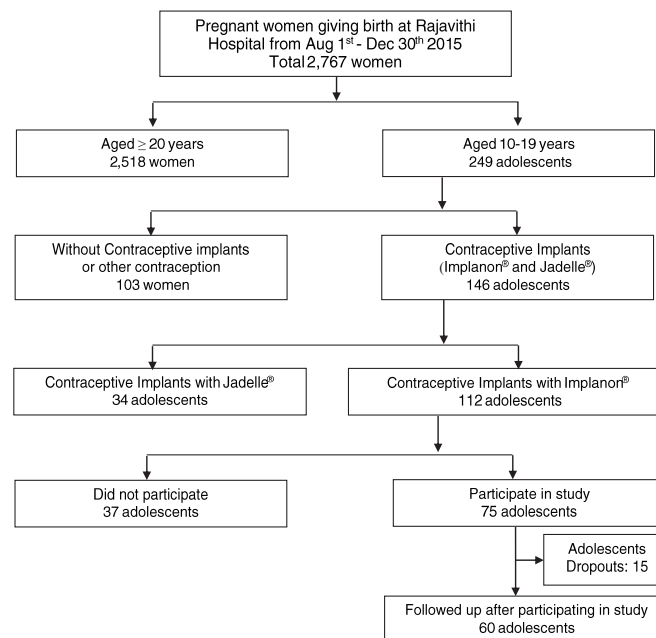
means, mean ± standard deviation (SD) and median (min-max).

## Results

A total of 2,767 pregnant women gave birth at Rajavithi Hospital between August 1st and Dec 30th 2015. Of these, 249 were postpartum adolescents (aged 10-19 years), 146 had undergone contraceptive implants while the other 103 had used other forms of contraception. Of the 146 progesterone-implant adolescents, 112 adolescents received Implanon® while the other 34 received Jadelle®. 75 of the 112 Implanon® users were included in the study, 15 adolescents dropped out and 60 participants completed follow-up (Fig. 1).

**Table 1.** Definitions of bleeding patterns<sup>(5, 6, 9)</sup>.

Bleeding pattern	Definition
Amenorrhea	Absence of bleeding or spotting
Frequent bleeding	> 4 bleeding-spotting episodes
Infrequent bleeding	1-2 bleeding episodes
Prolong bleeding	≥ 1 bleedings-spotting episode lasting more than 14 days
Irregular bleeding	3-5 bleeding episodes and less than 3 bleeding-free intervals of 14 days or more



**Fig. 1.** Patient Flow Chart.

The 60 participants had an average age of 17 years. Their average weight before pregnancy was 54.3 kilograms and average weight six months after implant was 55.3 kilograms. Their weight did not significant increase. The majority (76.7%) were first pregnancies, while second and third pregnancies accounted for 18.3% and 5.0%, respectively. The average gestational age was 37.7 weeks, and vaginal delivery was the most common birth route at 70%. Most of the mothers (80%) were unemployed, and their most common completed education level was 3rd grade of high school. Their husbands were mostly employed (76.3%) with an average age of 21.3 years.

Regarding menstrual patterns before pregnancy, 96.7% had normal menstruation while 100% had a menstrual cycle of between 21-35 days. They had used sanitary protection about 3 pads per day.

Almost half (46.7%) of participants had experienced first-time sexual intercourse by the age of 15 years. More than half of them (51.7%) had used contraception 3 months before pregnancy. The last method that they used 3 months before pregnancy were oral contraceptive pills (67.7%), injectable method (16.1%), condom (9.7%) and emergency pill (6.5%). Demographic data is shown in Table 2.

**Table 2.** Demographic data.

Characteristics	Total ( N = 60)	N (%)
Age (mean ± SD)	17.8 ± 1.1	
min-max	15 - 19	
Weight before pregnancy (mean ± SD)	54.3 ± 11.1	
min-max	35 - 83	
Weight 6 months after implant (mean ± SD)	55.3 ± 11.8	
min-max	35.0 - 87.5	
Height (mean ± SD)	157.6 ± 5.1	
min-max	148 - 170	
GA (mean ± SD)	37.7 ± 2.2	
min-max	32 - 41	
Gravida		
1	46	76.7
2	11	18.3
3	3	5.0
Para		
1	48	80.0
2	12	20.0
Route of delivery		
Normal delivery	42	70.0
Cesarean section	17	28.3
Vacuum delivery	1	1.7
Complication		
Yes	3	5.0
No	57	95.0
Occupation		
Employ	11	18.3
Unemployed	48	80.0
Student	1	1.7

**Table 2.** Demographic data. (Cont.)

Characteristics	Total (N = 60)	N (%)
Education		
Elementary school	6	10.0
9 <sup>th</sup> grade of high school	36	60.0
12 <sup>th</sup> grade of high school	9	15.0
Vocational certificate	9	15.0
Menarche mean ± SD		12.6 ± 1.3
10	4	6.7
11	6	10.0
12	22	36.7
13	15	25.0
14	7	11.7
15	6	10.0
Regular cycle		
Irregular	2	3.3
Regular	58	96.7
Interval		
21-35	60	100
Duration mean ± SD		5.5 ± 1.5
≤ 3	5	8.3
4-7	53	88.3
> 7	2	3.4
Amount (pads/day) mean ± SD		3.5 ± 1.1
2	8	13.3
3	30	50.0
4	11	18.3
5	7	11.7
6	3	5.0
7	1	1.7
First sexual intercourse mean ± SD		15.5 ± 1.2
13	2	3.3
14	6	10.0
15	28	46.7
16	12	20.0
17	8	13.3
18	3	5.0
19	1	1.7
3-month contraception before pregnancy		
Yes	31	51.7
No	29	48.3
3-month contraception type before pregnancy		
OCP	21	67.7
DMPA	5	16.1
Condoms	3	9.7
Emergency pill	2	6.5

GA: gestational age, SD: standard deviation, OCP: oral contraceptive pills, DMPA: depot medroxyprogesterone acetate

Bleeding patterns after single-rod etonogestrel implants were categorized as: normal bleeding 11.7%, abnormal bleeding 88.3%. Amenorrhea (41.6%) constituted the most abnormal bleeding followed by prolonged bleeding 30%, infrequent bleeding 11.7%, and irregular bleeding 5%. Bleeding patterns are shown in Table 3.

Minor side effects were experienced by 28.3% of participants. These included emotional instability 11.7%, dysmenorrhea 8.3%, nausea and vomiting 3.3%, weight gain 3.3% and headache 1.7% (Table 4).

This study found that 90.0% of the participants did not nurse their babies, and 63.3% planned to

resume their education. Their reasons for choosing single-rod etonogestrel implant were: 1) they believed it to be a long-acting reversible contraception and they wanted to take a break from pregnancy (43.3%); 2) they thought it was the most effective contraceptive method (40.0%); and 3) they did not want any further pregnancies (16.7%). Side effects included dysmenorrhea, headache, nausea and vomiting, cyclical breast pain and emotional instability were noted in 28.3% of the participants. The adoption of this device was chosen by the participants themselves (48.3%), followed by family (30%) and medical professionals (21.7%)

**Table 3.** Vaginal bleeding patterns.

Characteristics	Total (N = 60)	N (%)
Amenorrhea	25	41.6
Prolonged bleeding	18	30.0
Infrequent bleeding	7	11.7
Regular bleeding	7	11.7
Irregular bleeding	3	5.0

**Table 4.** Minor side effects.

Characteristics	Total (N = 60)	N (%)
Emotional instability	7	11.7
Dysmenorrhea	5	8.3
Nausea and vomiting	2	3.3
Weight gain	2	3.3
Headache	1	1.7

## Discussion

Thailand has ranked the second highest rate of adolescent pregnancies in Southeast Asia. The Department of Health and National Health Security Office, MPH have launched a campaign to encourage long-acting contraceptive method to lower the rate of repeated adolescent pregnancies, by providing free single-rod etonogestrel implant for all adolescent mothers who request it. In Rajavithi Hospital, the use of LARC increased from 16.9% in 2014 to 43.7 % in 2015. In this study, the most common bleeding pattern after

use of single-rod etonogestrel implant was amenorrhea (41.6%) and this was similar to the results of the study of Guazzelli et al (40.9%)<sup>(9)</sup>. However, the second most common pattern was prolonged bleeding (30.0%) while in the study by Guazzelli et al<sup>(9)</sup>, it was acceptable (29.5%) and follow by infrequent bleeding (13.6%). Darney et al<sup>(4)</sup> and Mansour et al<sup>(3)</sup> studied bleeding patterns after use of single-rod etonogestrel implant in women aged 18-40 years old and found that there were infrequent bleeding in 33.3-33.6% of cases and amenorrhea in 21.4-22.2%.



Similar results were also reported in Thai studies, for first example, the patterns during the first three months of Implanon® used in 16-45 years old women was amenorrhea (40.2%)<sup>(10)</sup> and the menstrual patterns at 6-month follow-up in Implanon® acceptors in above 35 years old women was amenorrhea (35.3%)<sup>(11)</sup>. However, the menstrual characteristic in women receiving sub-dermal contraceptive implant after one-year assessment, considered their menstruation as regular cycle (40.4%), irregular (30.3%) and absent menstrual cycle (23.6%)<sup>(12)</sup>.

From the present study, emotional instability (11.7%) was the main side effects. In contrast to others, headache and dizziness were the most frequent complaint among non-menstrual adverse events (27.2-33.6%)<sup>(10,11)</sup>.

The participant dropout rate was very high at 20%. Five participants (8.3%) had the hormone contraceptive implant removed, 4 women experienced prolong bleeding, and 1 had uncontrolled weigh gain. The number of participants withdrawing was similar to those of the studies by Darney et al (11.1%)<sup>(4)</sup> and Mansour et al (11.3%)<sup>(3)</sup>.

Strength of study were inclusion of only adolescent, a prospective study, and an objective evaluation of bleeding pattern by use of the vaginal bleeding chart diary. This study had limitations due to its short duration of 6 months follow-up and small sample size.

## Conclusion

The most common bleeding pattern after single rod implants was amenorrhea (41.6%), followed by prolonged bleeding (30.0%), infrequent bleeding (11.7%), regular bleeding (11.7%) and irregular bleeding (5.0%). Side effects were experienced by 28.3% of the participants, these were emotional instability, dysmenorrhea, nausea and vomiting, weight gain and headache. Six point six percent of 30% reported having prolonged bleeding that had to remove the device.

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## Potential conflicts of interest

The authors declare no conflicts of interest.

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