One-Year Assessment of Women Receiving Sub-Dermal Contraceptive Implant at Siriraj Family Planning Clinic

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Background: *The single-rod Implantable contraceptive method, called 'Implanon', has been introduced for use in Thailand since the 1990s. The outstanding attribute was that it requires only a few minutes for insertion and removal as it has only one capsule. The single-rod implant was used in women at Siriraj Hospital in 2006. The present study looked at characteristics of women, complications of insertion and removal, menstrual events that occurred to women during one year of use and reason for removal of the method.*

Material and Method: *This was a retrospective clinic based study. All women's record files were examined at Siriraj Hospital's Family Planning Clinic. There were 166 women enrolled to undergo this method, and only 89 women (54.6%) came back for the one-year follow-up visit. Women's accounts on irregularity of menses, complaints during method used and reason for discontinuation, pregnancy and body weight change were assessed.*

Results: *Most women (68%) using the implant contraceptive method were 29 years of age with 74% of vocational or lower education. Their BMI was 22.66 $\pm$ 4.06. Insertion time was about 1 minute with no difficulty or complication. Of those women, 40.4% of them considered having regular menstrual cycle and 30.3% had regular menstrual flow for a few months alternately with no menses for a few months. Prolonged menstrual bleeding was the most complaint in this group of women. Amenorrhoea was also reported. Vertigo had occurred to some women without reported medication. One woman asked for the removal of the method due to pain at the implanted site after 8 months of use. Removal time was around 2-3 minutes. There was no pregnancy that occurred in the course of one year of use.*

Conclusion: *Of 89 women using the implant contraceptive method, menstrual irregularity was the important issue that women complained about. However, the removal of the method in one woman was due to the pain at the implanted site. There was no difficulty or complications in insertion or removal of the implant. Close counseling about side effects of the method is emphasized during use to maintain long-term use or until completion of the duration of the device.*

Keywords: *Sub-dermal contraceptive implant, Menstruation, Side effects*

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Sub-dermal implant system, the progestin oriented hormonal method with six rods capsules and a 5-year duration of use, has been introduced for purpose of preventing pregnancy in the 1980s as a choice for women who cannot comply well with daily pill taking or those who are reluctant to have the hormonal injection or women who have contraindication to the intrauterine devices. This method has many advantages over other methods of contraception, such as long duration of use, convenience, high efficacy, need for minimal maintenance, absence of oestrogen and rapid

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return of fertility after discontinuation. However, many disadvantages of this sub-dermal implantable contraception have also impeded many women from adoption of the method as well as premature discontinuation of the method for those who adopt it. The most important side effects that women experience and lead to termination of the method are unpredictable menstrual regularity[1,2], weight gain or weight loss, skin changes, hair loss and mood changes[3]. Moreover, as this is a provider-dependent method, removal of the sub-dermal implant method has sometimes led to a procedure performed in the operating theatre[4]. In order to improve the unacceptable side effects caused by the old generation of the implantable method and to provide women with a shorter duration of use, a new development of the implantable method has been introduced into the market, the Implanon that has only a single rod and provides 3 years of protection against pregnancy. Implanon (Organon, OSS-the Netherlands) has been in the Thai market since 1990s. The implant is a small cylinder that is 40 mm long and has a diameter of 2 mm. It contains 68 mg of etonogestrel, the active metabolite of desogestrel. Contraceptive efficacy is for a period of 3 years. Thailand was also one of the study sites. This method has been reported as better than the other methods launched previously[5]. The present study looks into women who obtained a single-rod implantable "Implanon" as a method of contraception to prevent them against pregnancy for at least 3 years at Siriraj Reproductive Health Research and Training Center, Siriraj Hospital, Bangkok, Thailand. The objectives were to assess socio-economic background of users of the method, to assess the continuation rate of use among these users and to identify reasons for removal of the device.

Material and Method

The present study was a retrospective medical record-based study by examining the patients' files of women who came to obtain contraceptive implants, especially those who adopted the single-rod implant or the Implanon at Siriraj Reproductive Health Research and Training Center, Department of Obstetrics and Gynaecology, Faculty of Medicine Siriraj Hospital, Mahidol University. Women who registered to use the implant method as a mean of preventing pregnancy from January to December 2006 were included in the study. All these women were treated as regular routine clinic clients. Women were fully informed about the advantages such as convenience in use, long duration of protection against pregnancy and disadvantages, such as irregularity of menses of the device, needs a small cut to insert the device into the body before the insertion. Once they accepted the attributes of the device, procedure of insertion was arranged. Only the contraindication to hormonal implantable method was used to grant women's choice of the single-rod contraceptive implant. There were 163 women registered to the single-rod contraceptive implant. Of these, only 89 came back for the first year follow-up for the analysis, which constituted 54.6% of those women who received the devices. Data for analysis have been involved with women's socio-economic background (such as age, parity, religious beliefs, education), contraceptive history, body weight at admission and at the end of one year of use or at removal. SPSS version 12 was used to analyze the data for frequency, percentage, and mean.

Results

Characteristics of women

Those women who came back for the one-year follow-up accounted for 54.6% of the total 'Implanon' implant insertion in 2006. Table 1 shows background characteristics of the users. Women's mean body mass index (BMI) was 22.66 ± 4.06. All of them had had normal menstrual cycle, and flow, table not shown.

One in five women was 19 years of age or younger and over two-thirds of them (70%) were between the ages of 20-34. Those who were 35 or older accounted for 9.8%. Their mean age was 25.8 ± 6.4 with the youngest at 14 and oldest at 40. In addition, 95.7% of them expressed themselves as Buddhists and the rest were Christians and Muslims. Over half (55.6%) of the users had attained their education level of secondary school and lower, and over one-forth of them (25.9%) held a bachelor's degree or higher. Half of the women (52.9%) had a monthly family income of 10,000 Baht or less, (US$ 313) and over one-third of them (37.6%) could earn 10,001 - 30,000 Baht a month (US$ 313-938). Only one in three women (32.5%) worked at home and the rest could generate income to the family. From this gorup, 13.5% of the women were students in colleges and 7.4% worked as professionals, such as teachers or flight attendants. One-fifth (20.2%) of the women had no child, nearly half (45.4%) had one living child, 25.8% had two living children and only a few had three children (8.6%). It is interesting to note that women whose children's age had not yet reached 12 months accounted for 47.4%. The majority of them, 73%, reported no experience with abortion or miscarriage in

Table 1. Characteristics of women

Characteristics of women	No.	%
Age		
≤ 19	33	20.2
20-24	36	22.1
25-29	42	25.8
30-34	36	22.1
≥ 35	16	9.8
Total	163	100.0
Religious belief		
Buddhist	156	95.7
Christian	2	1.2
Muslim	5	3.1
Total	163	100.0
Education		
Primary	35	21.6
Secondary	55	34.0
Vocational	30	18.5
Bachelor's degree	41	25.3
Higher	1	0.6
Total	162	100.0
Family income		
≤ 5000	29	18.5
5001-10000	54	34.4
10001-30000	59	37.6
≥ 30001	15	9.6
Total	157	100.0
Occupation		
House work	53	32.5
Student	22	13.5
Trader/small business owner	19	11.7
Office worker	26	16.0
Casual work	31	19.0
Other	12	7.4
Total	163	100.0
No. of living children		
0	33	20.2
1	74	45.4
2	42	25.8
3	14	8.6
Total	163	100.0
No. of Abortion		
0	119	73.0
1	36	22.1
2	8	4.9
Total	163	100.0
Age of last living child		
No children	33	21.2
1-12 months	74	47.4
13-36 months	21	13.5
37-96 months	19	12.2
≥ 97 months	9	5.8
Total	156	100.0
Last contraceptive use		
Oral contraceptive pills	50	34.7
Injectable method	42	29.2
Implantable method	13	9.0
Condoms	26	18.1
Safe period/withdrawal	12	8.3
Dermal Contraceptive Patch	1	0.7
Total	144	100.0
Reason for stopping use of last method		
side effects of last methods	28	23.2
Fear of missing appointment date	5	4.0
Wanted a method with long duration	73	57.9
Do not want a child	20	15.9
Total	126	100.0
Mean BMI	22.66 ± 4.06	

the past. Over one in five women, 22.1%, said that they had a miscarriage in the past years and 4.9% of them said that they had had a miscarriage two times in their life.

Nearly all women experienced at least one kind of contraceptive method in the past. The last method that they used before adoption of the current implantable methods were oral contraceptive pills (34.7%), injectable method (29.2%), implantable contraceptive (9%), condoms (18.1%) and one woman had used the hormonal contraceptive patch. When asked them why they deserted the last method, over half of the women (57.9%) said that they needed a method with long duration of use, 23.2% had fear of the side effects of the last method, 15.9% of them did not want any more children, and 4% said that they feared missing the appointment day for the next supply of the injectable method or the oral contraceptive pills.

Menstruation and problems with menstrual bleeding

Not all women who came back for the 1-year follow-up visit contacted the clinic on the scheduled date. Many of them, on average, visited the clinic about 10-18 months after the insertion of the currently used implantable contraceptive. Their menstrual characteristic during use is shown in Table 2. Of 89 women who came back for the one-year follow-up. About two in five women (40.4%), considered their menstruation as a regular cycle. That is, they had seen their bleeding each month for a few days. Some women reported that they had only scanty spotting that needed no sanitary pad, however, this sign appeared each month. The rest

of the women experienced different kinds of menstrual irregularity.

One third (30.3%) of women said that their menses came regularly for a few months and thereafter became amenorrhoea for another few months. Moreover, 23.6% considered their menstruation as 'no cycle' because there was slight bleeding and/or spotting for a few days for many episodes within one month. There was no need for sanitary pad protection. Another 5.6% of women said that they had prolonged menstrual bleeding that needed sanitary pad protection, it bled for at least 10-15 days.

Moreover, a number of women reported having bleeding and/or spotting after cessation of menstruation. Twenty women reported having bleeding often intermenstrual cycle, but no sanitary pad for protection was required. Another seven women said that they needed sanitary pad to protect the bleeding each time it occurred, Table 3.

Complaints during method use

Some women had experienced some side effects or irregularity of menses during the course of method use. Table 4 shows that of 89 women who came back for the 1-year follow-up visit, there were 58 complaints. One woman could express more than one complaint. Prolonged bleeding was the most prevalent complaint among this group of women, 20 complaints. Eleven women reported having vertigo. Only some women asked for medication. There were two complaints each about body weight loss and body weight gain. Nine women said that they had no menstrual flow at all throughout one-year course of use of the device. Eight women complained about having lower abdominal pain during menstrual bleeding. One woman had fatigue, which occurred with other symptom, such as prolonged bleeding and lower abdominal pain. There was one report about galactorrhoea as a few women were breast-feeding their child while using this device. Hair loss was also reported in the present study. Moreover, two women reported having pain at the implanted site. One was successfully counseled and continued using the device. However, the other woman, who had experienced more than one side effect of the device, could not tolerate the pain and had the device removed at the clinic after 8 months of insertion. This woman reported that a few months after insertion of the device, her child fell down and hit her arm where the device was lodged. She had experienced pain every day, ever since. The pain at the implanted site increased day by day until she asked for its removal.

Table 2. Menstrual characteristics

Characteristics	No.	%
Regular menstrual cycle	36	40.4
Irregular menstrual cycle	27	30.3
No menstrual cycle	21	23.6
Prolonged menstrual bleeding	5	5.6
Total	89	100.0

Table 3. Reported having intermenstrual bleeding

Characteristics	No.
Bleeding without sanitary pad	20
Bleeding with sanitary pad	7
Total	27

Table 4. Complaints of women at one year follow-up

Complaints	No.
Vertigo	11
Body weight gain	2
Vomiting	1
Prolonged menstrual bleeding/spotting	20
Amenorrohea	9
Hair loss	1
Fatigue	1
Lower abdominal pain	8
Galactorrhoea	1
Pain at implanted site	2
Body weight loss	2
Total	58

Insertion and removal problems

No difficulty in insertion and removal of the devices reported in all 163 women with the 'Implanon' implant method. The average insertion time was about 1 minute and the removal time was 2-3 minutes. There were no serious complications after insertion or removal.

Body weight complaints

Many women complained about their body weight change during the course of use, either increase or decrease in body weight. Their mean BMI before use was 22.66 ± 4.06. Their BMI at the end of one year follow-up was 22.56 ± 4.42. Even though there was complaint about changes in women's body weight, there was no statistically significant difference between

the pre and post test of their BMI, p = 0.531 at one year of use.

Pregnancy during the course of method use

There was one woman who had had positive test for pregnancy 1 month after the insertion of the implant. She was breast-feeding the baby when the device was removed. After closely studying her case, it turned out that she became pregnant before the insertion of the device. The implant was removed one month after insertion. Overall, no pregnancy occurred in women who were using the 'Implanon' implant for one year of use.

Continuation of the method

Of 89 women using the implant method only one woman had had the device removed due to pain at the implant site. All 88 women continued using the method to complete the third year of use. The continuation rate could be considered as 54% in the first year of use.

Discussion, Conclusion and Recommendation

Of 163 women who inserted the implantable contraceptive method, only 89 women returned to the clinic at one-year follow-up, which constituted 54.6% of the total women who used the method. A high proportion of women were of young age with low educational level, 29 years or less accounted for 68.1% and vocational school or lower accounted for 74.1%, respectively. Most of them were in their middle level career and only a few were professionals. A high proportion of them wanted to use a method with long duration of use. However, many women seem to experience bleeding problems during method use. Amenorrhoea had been one of the important complaints in women. However, it seem that there are more benefit to women than disadvantages when using this method. Other side effects of this method, such as hair loss, weight gain or loss, pain at implanted site and vertigo had contributed to unpleasant use. Those patients complaning required counseling to maintain continuation of use. The average time for insertion was about 1 minutes and removal time was about 2-3 minutes, which is similar to other study[6]. Our study has a few limitations. Firstly, as this was the routine service to all women who need to protect themselves against pregnancy. There was no rigid regulation to include potential users to the study. Thus, it had included many women who lived outside the Bangkok metropolitan areas. This had made it difficult for those women to come back for the follow-up visit. They all were aware of its 3-years efficacity of protection and hopefully, they will come back on the due date for removal. Moreover, for those who did not show up at the first year of use, it might be implied that they were uneventful and happy with the method they were using. Secondly, even though a diary menstrual record had been provided to all women, only a few were returned to the clinic with complete record of women's bleeding. This made it difficult to assess their report about bleeding and/or spotting especially recall of such events might not be reliable. Lastly, as this assessment was not a clinical trial, no incentive had been given to women to comply with the study regulation, which in turn has resulted in quite a low continuation rate of 54% for the first year of use compared to other study that could gain a high rate of continuation of users at the first year of use[7-9]

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การประเมินหลังจากระยะเวลา 1 ปี ในสตรีผู้มารับบริการยาฝังคุมกำเนิด ณ คลินิกวางแผนครอบครัว โรงพยาบาลศิริราช

มานพชัย ธรรมคันโธ, สุภาณี จิวาศักดิ์อภิมาศ, สุรศักดิ์ อังสุวัฒนา, เกศสุดา จิรวัชรเดช, จรัฐภรณ์ อินทะวงศ์

ภูมิหลัง: *Implanon เป็นยาฝังคุมกำเนิดชนิดแท่ง ซึ่งได้เริ่มมีการนำมาใช้ในประเทศไทย ตั้งแต่ปี พ.ศ. 1990 จุดเด่นของยาฝังคุมกำเนิด Implanon คือการใช้เวลาเพียงเล็กน้อยในการฝังหรือถอดออก เนื่องจากมีจำนวนเพียงแท่งเดียว ยาฝังคุมกำเนิดแท่งเดียวมีการเริ่มใช้ในโรงพยาบาลศิริราชในปี พ.ศ. 2006 การศึกษานี้เพื่อดูลักษณะของสตรีผู้มารับบริการ, ผลแทรกซ้อนจากการฝังหรือถอดยาฝังคุมกำเนิด, ประจำเดือนในระยะเวลา 1 ปีหลังการฝังยา และเหตุผลในการขอเลิกใช้ยาฝังคุมกำเนิด*

วัสดุและวิธีการ: *การศึกษานี้เป็นการศึกษาย้อนหลังเชิงคลินิก โดยศึกษาจากเวชระเบียนบันทึกข้อมูลของสตรีผู้มารับบริการ ณ คลินิกวางแผนครอบครัวโรงพยาบาลศิริราช สตรีจำนวน 166 คน เข้ารับบริการ โดยวิธีดังกล่าว และพบว่าสตรี 89 คน (ร้อยละ 54.6) กลับมาสำหรับการนัดตรวจครบ 1 ปี สตรีผู้มารับบริการ พบภาวะผิดปกติของประจำเดือนระหว่างใช้ยาฝังคุมกำเนิด มีการประเมินเหตุผลในการเลิกใช้, การตั้งครรภ์ และน้ำหนักที่เปลี่ยนแปลง*

ผลการศึกษา: *ร้อยละ 68 ของสตรีผู้มารับบริการยาฝังคุมกำเนิดมีอายุ 29 ปี และมีระดับการศึกษาต่ำ หรืออาชีวศึกษาร้อยละ 74 ดัชนีมวลกายคือ 22.66 $\pm$ 4.06 การฝังยาคุมกำเนิดชนิดแท่งเดียว ใช้เวลาประมาณ 1 นาที โดยไม่พบความยุ่งยากหรือภาวะแทรกซ้อนขณะฝังยา ร้อยละ 40.4 พบประจำเดือนเป็นปกติ ในขณะที่ 30.3% มีภาวะประจำเดือนผิดปกติ กล่าวคือ พบประจำเดือนปกติ 2-3 รอบ สลับกับประจำเดือนที่หายไป 2-3 รอบ ภาวะประจำเดือนมากผิดปกติเป็นปัญหาที่พบมากที่สุดในกลุ่มสตรีผู้มาขอรับบริการ และภาวะขาดประจำเดือนก็สามารถพบได้ การเวียนศีรษะพบได้บ้างในสตรีผู้มาขอรับบริการ โดยไม่พบประวัติ การให้ยารักษา สตรี 1 คน ขอถอดยาฝังเนื่องจากความเจ็บปวด ณ ตำแหน่งที่ฝังยาหลังการฝังมานาน 8 เดือน ระยะเวลาในการถอดยาฝังประมาณ 2-3 นาที ไม่พบการตั้งครรภ์ในระยะประเมิน 1 ปี*

สรุป: *ในสตรีผู้มารับบริการตรวจติดตาม 1 ปี หลังฝังยาคุมกำเนิด พบภาวะรอบเดือนมาไม่สม่ำเสมอ เป็นประเด็นสำคัญที่สตรีไม่พอใจ อย่างไรก็ตาม พบการถอดยาฝังคุมกำเนิดเนื่องจากการปวด ณ ตำแหน่งฝังยา แต่ไม่พบภาวะแทรกซ้อนหรือความยากลำบากในขั้นตอนการฝังยาหรือถอดยาฝังคุมกำเนิด การให้บริการคำแนะนำปรึกษาอย่างละเอียดเกี่ยวกับผลข้างเคียงของวิธีการคุมกำเนิดดังกล่าว ควรได้รับการเน้นเพื่อให้มีการใช้วิธีคุมกำเนิดแบบฝังยาต่อเนื่องและยาวนานครบตามระยะเวลาที่กำหนดใช้*