

# Case Report

## Implanon® Failure

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A 28-year old woman, P1-0-1-1 presented with 5-month amenorrhea after having had single - rod 68 mg - etonorgestrel contraceptive implant (Implanon®) for 18 months. Pregnancy was diagnosed by physical examination and confirmed by ultrasonography. At first, she wanted to have her pregnancy terminated because of a financial problem and anxiety about fetal anomaly as well as pregnancy complication. However, after counseling, she decided to continue her pregnancy and had a normal male infant delivered by cesarean section. This pregnancy is considered as product failure, which is very rare and is the first report in Thailand. Clinical counseling on medical risk of pregnancy and fetal anomaly can reduce the mother's anxiety and assure her to carry on her pregnancy as done in this case.

**Keywords:** Implanon®, Failure

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Single - rod 68 mg - etonorgestrel implant (Implanon®) was introduced to Thailand in 2000. Because of the single rod system, long acting method, convenient insertion, and fast removal procedure with high efficacy, the acceptance of Thai women to Implanon® was rapidly increasing. Failure is very rare and this is the first case report of unintended pregnancy associated with Implanon® in Thailand that was specified as product failure.

### Case Report

A 28-year-old woman, para 1-0-1-1, presented with a history of 5-month amenorrhea. She had used Implanon® for 18 months since her first child's birth and noticed breast engorgement and frequent urination for 3 months, but thought that these were side effects of the implant. Four days earlier, she had done a self-urine pregnancy test with a positive result, so she came for consultation.

Physical examination revealed a healthy woman, height 157 cm. and weight 57 kg (BMI 24.75 kg/m<sup>2</sup>) with blood pressure 110/70 mmHg, pulse rate 76/min, normal chest and cardiovascular examination. Implanon® rod was palpated on the medial side of the

left upper arm. The uterus was palpated about 10 cm above the pubic symphysis. Pelvic examination revealed congested vaginal mucosa and cervix, uterus was 14-16 week-sized and soft. Transabdominal ultrasonography showed intra-uterine pregnancy, single viable fetus with BPD 30.1 mm, head circumference 112 mm, abdominal circumference 97.6 mm and femur length 15.3 mm. The average gestational age was 15 weeks.

In her past medical history, she had spontaneous incomplete abortion in the first pregnancy 5 years ago at a gestational age of about 2 months, curettage was performed. On the second pregnancy, the male infant was delivered by low transverse cesarean section due to cephalopelvic disproportion on Dec 4, 2002. The post partum examination at 6 weeks later revealed normal finding. At that time, she asked for contraception and Implanon® was inserted on Jan 16, 2003. Her physical examination at 1 and 6 weeks after insertion revealed no abnormality; Implanon® was in place and can be palpated on the medial side of the left upper arm. After implant insertion, her period was still regular; the interval was 28-30 days with duration of 2-3 days until the last 5 months.

She had her annual physical examination and laboratory testing was normal. She had no history of diarrhea, serious illness and no history of anti-convul-

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sant or anti-tuberculosis medication. She had never taken any kind of alcohol and cigarette smoking.

After diagnosis of pregnancy, the initial management was ultrasonography to confirm the location of the implant and then implant was removed without difficulty. The implant looked normal, 40 mm in length and there was no rupture of the outer membrane. Blood examination for liver function test was normal. Serum etonorgestrel could not be done because there was no service available at the hospital. At first, she wanted her pregnancy to be terminated because of financial reasons, anxiety about fetal abnormality and pregnancy complication. However, after physician's counseling, she decided to continue the pregnancy and had 8 ANC visits from 15 to 36 weeks of gestation without any complication. Her laboratory tests including CBC, UA, thalassemia screening, VDRL, HBsAg and anti-HIV revealed normal. Transabdominal ultrasonography was performed at 20, 28, 32 and 34 weeks of gestation for screening of fetal anomaly and fetal well-being surveillance.

She was in labor on March 3, 2005 at the gestational age of 37 weeks and cesarean section with tubal resection was performed. A male infant weighing 3,250 grams was delivered with Apgar scores of 8 and 10 at one and five minutes. No congenital anomaly was found by a neonatologist. There was no post partum complication and she was discharged with her baby on the third post-operative day.

## Discussion

The contraceptive action of etonorgestrel implant (Implanon<sup>®</sup>) is mainly inhibition of ovulation that lasts for 3 years. Before 2004, there had been no reports of pregnancy while using etonorgestrel implant, but in 2005<sup>(1)</sup> the largest series of unintended pregnancy with etonogestrel implant was reported which categorized the cause of failure as 1: pregnancy prior to contraception (already pregnant at the time of insertion), 2: incorrect timing of insertion, 3: implant expulsion, 4: drug interaction, 5: non-insertion, 6: product/method failure and 7: insufficient information. No case of pregnancy with etonogestrel implant specified as product/method failure had been reported in Thailand before.

This pregnancy occurred while using Implanon<sup>®</sup> for 18 months with the rod still being in the right place and outer membrane being intact as well; no underlying disease or other regular medication, including alcoholic consumption and tobacco smoking,

was found. All these findings were evident that this pregnancy resulted from product failure. Generally, inhibition of ovulation is the prime contraceptive mechanism of progestogen contraception and Implanon<sup>®</sup> as well<sup>(2,3)</sup>, as shown that only 8.7-11.8% of Implanon<sup>®</sup> users had regular menstruation while most had amenorrhea and vaginal spotting. The regular menstrual cycle of this case indicates that regular ovulation was still happening during the use of Implanon<sup>®</sup> so the contraceptive mechanism did not inhibit the ovulation. It failed after 18-months of use. This is too difficult to predict since only regular menstruation is not yet discovered as the risk factor for product failure. The important thing to be aware of when there is failure of contraception involving the use of the long acting contraceptive implant is the patient's problem *e.g.* unintended pregnancy, financial limitation, anxiety about pregnancy complications or fetal anomaly. Medical negligence claims involving an allegation or 'wrongful birth' can be the most serious problem for physicians<sup>(4,5)</sup>. Risk management strategies to minimize the possibility of a claim<sup>(4,5)</sup> should consist of 1) identified risks associated with the procedure *e.g.* underlying disease, regular medication, 2) guidelines for Implanon<sup>®</sup> use with a consent form, and 3) checklists for doctors and patients. Clinical counseling on medical risks of pregnancy and fetal anomaly can reduce the mother's anxiety and assure her to carry on her pregnancy as done in this case.

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## การตั้งครรภ์ในขณะที่คุมกำเนิดด้วยยาฝังคุมกำเนิด Implanon®

สุทธา หามนตรี, วัชรภรณ์ วีรกุล

รายงานผู้ป่วยตั้งครรภ์ ภายหลังจากการรับยาฝังคุมกำเนิด Implanon® แล้วเป็นระยะเวลา 18 เดือน ผู้ป่วยได้รับการยืนยันการวินิจฉัยการตั้งครรภ์โดยการตรวจร่างกายและการตรวจด้วยคลื่นเสียงความถี่สูง ในเบื้องต้นผู้ป่วยต้องการยุติการตั้งครรภ์ เนื่องจากมีความกังวลมากในเรื่องความผิดปกติของทารกและภาวะแทรกซ้อนของการตั้งครรภ์ แต่เมื่อได้รับคำปรึกษาจากแพทย์ ผู้ป่วยตัดสินใจที่จะตั้งครรภ์ต่อ ผู้ป่วยคลอดโดยการผ่าตัดคลอดขณะอายุครรภ์ 37 สัปดาห์ ได้ทารกเพศชาย สุขภาพแข็งแรง ไม่มีภาวะแทรกซ้อนแต่กำเนิด ไม่มีภาวะแทรกซ้อนหลังคลอด

การตั้งครรภ์นี้เกิดจาก product failure ซึ่งพบได้น้อยมากและยังไม่เคยมีรายงานในประเทศไทยมาก่อน แพทย์หรือผู้ให้บริการคุมกำเนิดต้องตระหนักถึงความกังวลของผู้ป่วยต่อความพิการของทารกในครรภ์และภาวะแทรกซ้อนจากการตั้งครรภ์ การให้คำปรึกษาที่ชัดเจนช่วยการตัดสินใจของผู้ป่วยในการตั้งครรภ์ต่อ

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