REVIEW ARTICLE

Reducing Early Discontinuation Rates of Subdermal Contraception in Your Clinical Practice

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Unintentional pregnancy

Almost half of all pregnancies in the United States are unintentional, leading to negative social and financial impacts on families. With its less than 1% failure rate, the use of subdermal contraception is on the rise; however early discontinuation of the product deters physicians from considering it as a successful and cost-effective means of birth control. In this study, patients' charts from two teaching services at an academically oriented community based hospital were reviewed and compared to previously published data to identify risk factors for early discontinuation of subdermal contraception. In addition, counseling methods were compared between the two teaching services to help determine ways to improve premature removal of the product. It was concluded that early discontinuation was most commonly due to bleeding, and through building good physician-patient rapport and taking the time to counsel patients on the adverse effects of subdermal contraception, physicians can successfully implement its use into their practice and work towards decreasing the rates of unintentional pregnancies.

INTRODUCTION

A 2006 study showed 49% of pregnancies in the United States are unintentional, making only half of the pregnancies planned[1]. Finer et al. also found that independent risk factors leading to higher rates of unintended pregnancies are women who are black, have a low-income, or are between the ages of 20-24 years old[1]. In addition, 1 in 5 of unintended pregnant women are also teenage mothers, who were found to be less likely to graduate from high school, to earn less income, and to draw almost twice as much Federal aid[2]. With these overwhelming statistics, this topic becomes an important one for family medicine practitioners.

In December 2010, Healthy People 2020 launched its ten-year agenda to improve the overall health of all Americans. Through this agenda, various topics and objectives were created to help meet overarching goals, which include attaining higher-quality living, achieving health equity, creating conducive social and physical environments to support good health, and promoting healthy behaviors across all ages[2]. Amongst these topics was to decrease unintended pregnancies to 44% by 2020.

With numerous birth control methods currently available on the market, it is a physician's responsibility to work closely with his patient to figure out the most effective method of preventing unplanned pregnancies. Options available include intrauterine devices, hormonal patches, vaginal rings, subdermal contraception, and birth control pills. While each birth control method has its pros and cons, it is important for a physician to take into consideration the patient's goals and values.

One of the more unique long-term contraceptive methods available on the market today is subdermal contraception, currently known as Nexplanon®. Nexplanon® recently replaced Implanon®, which was a small 4cm by 2mm rod that was inserted subdermally into the patient's upper inner arm[3]. Produced by Merck & Co., Inc., it provided a continual release of progesterone, more specifically etonogestrel, for up to three years. Nexplanon® is essentially identical to Implanon® in its size and hormonal release. However, Nexplanon® is radiopaque, allowing physicians to view it on X-rays and confirm proper placement[4], and has a different insertion device. This study was undertaken using Implanon®, prior to the market conversion to Nexplanon®.

Subdermal implantable devices fall under the category of long-acting reversible contraception (LARC), which also includes intrauterine devices. LARCs are unique in that they are inserted by a physician and last for up to 3-10 years depending on the product. Because they are long-term, non-compliance becomes less of an issue, making it a more efficacious form of birth control. Subdermal contraception has been found to have less than a 1% failure rate, which is comparable to tubal sterilization[9]. In addition, if a patient decides she wants to become pregnant during her course of contraception, the rod can easily be removed and has been shown to have a rapid return to fertility[9]. Another benefit of subdermal contraception is it does not use estrogen, which

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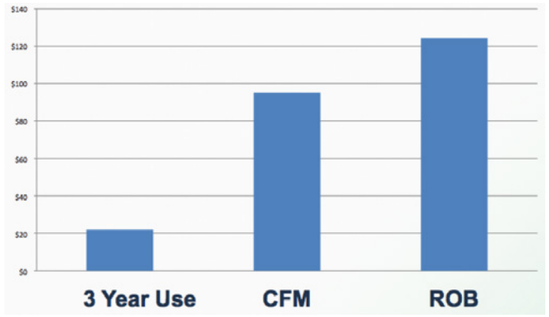

Figure 5. Cost per month of Implanon® compared to full three-year term with average due to early discontinuation rates and CFM and ROB.

has been found to increase a patient's risk for thromboembolic events[9]. However, it is important to remember that continuous progesterone therapy also has its own adverse effect profile, and irregular bleeding has been found to be the most common reason for early discontinuation of subdermal contraception. Although subdermal contraception is more expensive when compared to other forms of birth control, it is found to be cost-effective if used for its full three-year course (Figure 5).

Nexplanon® may seem to be an obvious choice for physicians due to its efficacy, ease of use, and its theoretical cost-effectiveness. However, established discontinuation rates have been found to be up to 33% at 12 months[7], making the product more expensive and returning the physician to the original issue: how to avoid an unintentional pregnancy. In this paper, we review causes of early discontinuation of subdermal contraception, and how physicians can work with their patients to make Nexplanon® a successful form of birth control. The goals of this study were to:

1. Compare counseling methods and discontinuation rates of a family medicine teaching service (CFM) and an OB/GYN teaching service (ROB) at an academically oriented community based hospital to established rates.

2. Identify risk factors for possible early discontinuation in patients.

3. Propose ways to decrease early discontinuation of three-year subdermal contraceptive devices through identifying effective counseling techniques.

METHODS

To accomplish the goals of this study, two outpatient clinics' charts were reviewed: CFM and ROB, and compared to published data. Criteria for patient inclusion were the patient had to be female, 18 years old or older, and have received an Implanon® placement over a period of 24 months, between January 2010 and December 2011. There were a total of 193 patients who received Implanon® at ROB and 84 patients at CFM. Of those, 23 ROB patients and 9 CFM patients had early discontinuation of their Implanon®.

There were two phases of data collection. Phase 1 was to determine the current early discontinuation rates at the two outpatient clinics. To be consistent with previously published data, early discontinuation was defined as removal of the Implanon® within one year of its placement. Data was gathered for both six months and one year after placement. These rates were then compared to established discontinuation rates. The goal of phase 2 was to identify trends of the population and risk factors for early discontinuation. A detailed chart review was done of those patients who had the device removed early, including age, BMI, and side effects reported by the patients.

RESULTS

Discontinuation rates. Data was analyzed using the Chi Square method to determine differences in discontinuation rates found in the chart reviews compared to a previous study done in the United Kingdom. Smith, et al. collected data from three contraception and sexual health services at 6 and 12 months after placement of subdermal contraception on women ages 13-51 years with median 24 years of age; discontinuation rates were found to be 12-16% at six months, and 22-33% at 12 months[7]. Table 1 and table 2 as well as Figure 2 show CFM discontinuation rates at 6 and 12 months respectively to be 2.3% and 10.7%, and ROB discontinuation rates at 6 and 12 months respectively to be 7.6% and 11.0%. CFM had the lowest early discontinuation rate at both 6 and 12 months when compared to ROB and published data. Both CFM and ROB had lower early discontinuation rates at both 6 and 12 months when compared to published data (Figure 1).

	Discontinuation Rate	X^2	P-value
6 months	2.3%	8.75	P<0.01
12 months	10.7%	16.719	P<0.001

Table 1. Center for Family Medicine data on discontinuation rates at 6 and 12 months.

Table 2. Regional OB data on discontinuation rates at 6 and 12 months.

	Discontinuation Rate	X^2	P-value
6 months	7.6%	13.186	P<0.001
12 months	11.9%	22.635	P<0.001

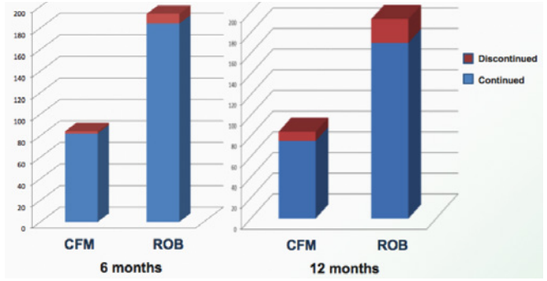

Figure 2. Comparison of CFM and ROB continuation rates with discontinuation rates at 6 and 12 months.

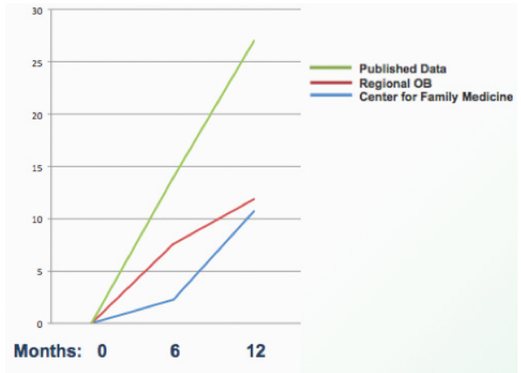

Figure 1. Comparison of discontinuation rates of ROB and CFM to published data from 0-12 months.

Counseling methods. ROB provided verbal counseling to patients receiving Implanon®, in comparison to the verbal and video counseling provided by CFM.

Patient demographics. When reviewing demographics of the patient population receiving subdermal contraception at CFM and ROB, the average age of patients at CFM was less than ROB, 20.6 years old and 23.8 years old respectively. The average BMI at CFM was also found to be greater when compared to ROB, 30.1 and 28 respectively. CFM patients kept their subdermal contraception for a longer period than ROB patients before having it removed prematurely (Table 3).

	CFM	ROB
Average Age	20.6	23.8
Average BMI (kg/m²)	30.1	28
Minimum Months Implant was in Place	5	0.5
Average # Months for Early Removal	8.33	6.37

Table 3. Demographics of patients with Implanon® use at CFM and ROB.

Reasons for early discontinuation. The most common reason for early discontinuation of Implanon® at CFM and ROB was found to be bleeding, followed by "other" and unintentional pregnancy (Figure 3). Among the three patients found to be pregnant, patient #1, stated she had irregular menstrual cycles and had a negative urine hCG on insertion of the contraception. Ultrasound performed 3 weeks after contraceptive placement showed a gestational sac too small for measurement, indicating that she had a luteal phase pregnancy at the time of insertion. She was later lost to follow up. Patient #2 had a negative urine hCG at an appointment 12 days prior to insertion at which time she had a colposcopy. Later ultrasound showed she conceived after her colposcopy and prior to insertion of the subdermal contraception. Lastly, patient #3 claimed abstinence and stated she was on her menses at the time of insertion. She did not have a urine hCG done. Patient #3 later admitted that she intentionally deceived the provider, as she was hoping the subdermal contraception would lead to a desired miscarriage.

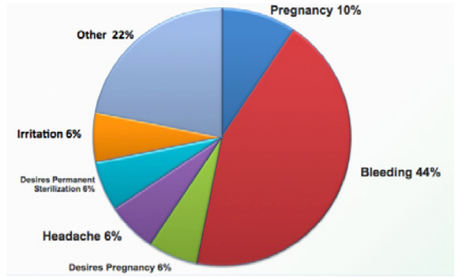

Figure 3. Documented reasons for Implanon® removal combined at ROB and CFM combined.

When comparing and contrasting early removal of Implanon® between CFM and ROB, bleeding was the most common reason for premature removal at both locations. However at CFM, headache was found to be the second most common reason for early discontinuation (Figure 4). This data seems to be fairly consistent with previously published data, which found bleeding to be the number one reason for early discontinuation, followed by mood swings and headaches[7].

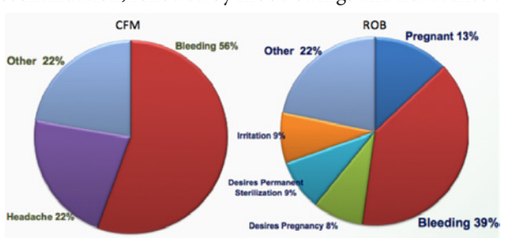

Figure 4. Documented reasons for Implanon® removal at CFM vs. ROB.

Cost. At our hospital, the total allowable cost of Implanon® was calculated to be $789, which included the cost of the device at $595, the insertion fee of $90, and the removal fee of $1048. When calculating the cost per month of the device if used for its full three-year term, we find the cost is $22 per month. Due to early discontinuation rates, cost per month was found to average $95 at CFM and $124 at ROB.

DISCUSSION

Both the Center for Family Medicine and Regional OB had significantly lower discontinuation rates than published data, especially at the 12-month mark. In addition, CFM also had lower discontinuation rates when compared to ROB. One of the reasons behind these findings may be the rapport physicians build with their patients. At CFM, family medicine residents have continuity of care with their patients, seeing and following the same patients regularly. These patients build a relationship with their physician, and physicians work to gain the trust of their patients. Through these relationships, family medicine physicians have the opportunity to closely follow their patients and provide continuous counseling. On the contrary, patients at ROB are likely to see different physicians at every visit. This lack of continuous care may cause patients to receive valuable information and counseling in a disorganized fashion. Also, if a trusting relationship is not built between a physician and his patient, it makes it easier for a patient to disregard the doctor's advice.

This also seems to be the case when comparing findings from CFM and ROB to published data. In the study done in the United Kingdom, patients were referred to physicians who were qualified to insert Implanon®[7]. To follow up on the success rate of Implanon®, information was gathered from follow-up visits, as well as surveys sent through the mail to those who did not follow-up with the physician. Because patients did not necessarily receive their Implanon® from their primary physician, one can again infer that a physician's rapport with the patient can help achieve more successful counseling.

Counseling methods also seem to play a role in the success of subdermal contraception. CFM provided standard counseling through a video, whereas ROB physicians provided verbal counseling to their patients one to two weeks prior to device insertion. Because the effectiveness of counseling can vary from physician to physician, showing patients a standard video to discuss benefits and adverse effects of subdermal contraception can guarantee all of the valuable information is consistently reviewed with each patient.

Demographic data was also taken into consideration in this study so population trends can be evaluated and compared between CFM and ROB. CFM's patient population receiving Implanon® included slightly younger patients and a greater BMI when compared to ROB. In a previously published study, it was found that as the patient's age increased, rates of early discontinuation of Implanon® decreased[7]. However, in our study, CFM had younger patients and lower rates of early discontinuation. Although these rates are more likely to be affected by counseling methods, it is important to consider age as a possible risk factor for premature removal of subdermal contraception based on several factors. For one, differences in hormone levels may put older females at an increased risk for bleeding from subdermal contraception. In addition, given that the highest rates of unintended pregnancies are amongst the younger patient population, physicians may feel more obligated to encourage younger patients to continue their contraception.

BMI may also be a risk factor for early discontinuation, and should not be disregarded. Patients at CFM were found to have a slightly higher average BMI, 30.1, than patients at ROB, 28. Although the average BMI of patients at ROB was in the overweight category, it is important to note the average BMI of patients at CFM placed those patients into the obese category. Because obesity affects female sex hormones[10], it is important to consider whether more obese women may have less adverse effects of bleeding associated with subdermal contraception.

It is evident the number one reason for early discontinuation of subdermal contraception is its adverse effect of bleeding (Graphs 3 and 4). Headaches were found to be the second most common reason for early removal of Implanon® at CFM. By focusing pre-contraceptive counseling on these two common adverse effects, physicians can work with their patients to weigh the benefits with the unfavorable consequences of subdermal contraception and help decrease the rate of premature removal of contraception.

Because the failure rate of subdermal contraception is less than 1%, it is unlikely the unintentional pregnancies found in this study were due to failure of the contraception. Because it was too early to determine patient #1's gestational age at her initial obstetrical appointment and her menstrual cycles were irregular, it cannot be determined if the Implanon® was placed during the luteal phase of her cycle causing her to have a negative hCG at that time; though this is most likely the scenario. On the other hand, patient #2 and patient #3 show us the importance of checking a urine hCG at the time of insertion of subdermal contraception. To lessen the future possibility of unintended pregnancy with the use of subdermal contraception, within the ROB office it has been opted that any patient not currently on a physician administered long acting contraceptive must currently be on her menses in addition to having a negative urine pregnancy test

on the day of insertion. This will avoid the unnecessary insertion and removal of the contraception, as well as complication risks associated with using hormonal contraception during pregnancy.

CONCLUSIONS

In conclusion, both CFM and ROB were found to have lower early discontinuation rates when compared to the published baseline, and CFM was found to have lower rates of early discontinuation when compared to ROB. By identifying risk factors for early discontinuation, family physicians can target their pre-insertion counseling to include the most common adverse effects of subdermal contraception. In addition, physicians must consider additional reasons for early removal of Implanon® that may not have been documented.

Limitations of this research are the limited time frame of the data collected, patient population limited to 18 years of age and older, as well as non-parametric data analysis. Future directions can include evaluating patient complaints and data for the entire three years of the device, as well as comparing patient demographics of those inserted and removed. In addition, further exploration of why CFM and ROB early discontinuation rates are better than published results can help physicians work to decrease rates of premature discontinuation of subdermal contraception.

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2015 Calendar of Events

March 5, 2015
DO Day on the Hill
Washington, DC
www.acofp.org

March 12-15, 2015
ACOFP Annual Convention
& Scientific Seminars
The Cosmopolitan Hotel
Las Vegas, Nevada
www.acofp.org

April 16-19, 2015
Virginia Osteopathic Medical
Association Spring CME Conference
The Great Wolf Lodge
Williamsburg, VA
www.voma-net.org

April 18, 2015
MAOFP Spring Family Medicine
Update Conference
Okemos, MI
www.maofp.org/cme

April 30-May 3, 2015
Oklahoma ACOFP
Norman, OK
www.okosteo.org

June 4-7, 2015
Maine ACOFP
www.mainedo.org

July 30-August 2, 2015
MAOFP Summer Family Medicine
Update Conference
Grand Traverse Resort
Acme, MI
www.maofp.org/cme

August 6-9, 2015
CA-ACOFP 39th Annual Scientific
Medical Seminar
Disneyland Hotel
Anaheim, CA
31 1-A AOA CME Hours Anticipated
www.acofpca.org

August 7-9, 2015
Pennsylvania ACOFP
Hershey Lodge
Hershey, PA
www.poma.org

July 10-12, 2015
Direct Primary Care Summit
InterContinental Kansas City
at the Plaza
Kansas City, MO
www.acofp.org

August 21-23, 2015
ACOFP Intensive Update &
Board Review
Loews Chicago O'Hare
Rosemont, IL
www.acofp.org

October 17-21, 2015
OMED 2015: ACOFP/AOA's 121st
Annual Osteopathic Medical
Conference & Exhibition
Hyatt Hilton and Convention
Center
Orlando, FL
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April 7-10, 2016
ACOFP Annual Convention &
Scientific Seminars
Puerto Rico Convention Center
San Juan, Puerto Rico
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JANUARY/FEBRUARY 2015 ANSWERS: **1.** B **2.** D **3.** C **4.** B **5.** B **6.** C **7.** C **8.** B **9.** C **10.** A