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Risk of luteal phase pregnancy with any-cycle-day initiation of subdermal contraceptive implants☆

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Abstract

Objectives: To determine rates of luteal phase pregnancy (LPP) in young women initiating subdermal implants on any day of the menstrual cycle.

Study design: We assessed a retrospective cohort of young women receiving contraceptive implants at an adolescent Title-X clinic. Patients with negative pregnancy tests were eligible for same-day insertion, regardless of cycle day, contraceptive use, or last intercourse. We computed LPP rates for those within manufacturer guidelines for insertion (≤5 days of menstrual onset or ≤7 days post-discontinuing hormonal contraception) and outside these guidelines. We reviewed medical records for last menstrual period (LMP), current hormonal contraception, emergency contraception (EC) provision, and pregnancy tests ≤12 weeks post-implant placement, or later evidence of pregnancy. For patients with positive pregnancy tests or reports, we used standard obstetrical dating (LMP and ultrasound) to determine if conception occurred ±2 weeks of implant placement.

Results: Of 3180 insertions, 1868 (58.8%) were outside recommended guidelines. Women with insertions within-guidelines were older (20.2 vs. 19.3 years; $p<0.001$) and more likely to be white (40.4% vs. 29.5%; OR=1.6, 95% CI: 1.4–1.9). Definitive pregnancy data was documented for 1726 patients: 660 (50.3%) in the within guidelines group, and 1066 (57.0%) in the outside guidelines group. Rates of LPP were 0.3% (2/660; 95% CI=0.0–1.1%) in the within guidelines group and 0.9% (10/1066; 95% CI=0.5–1.7%) in the outside guidelines group.

Conclusion: The risk of LPP following any-cycle-day insertion of contraceptive implants with negative pregnancy testing is low, regardless of menstrual cycle timing, recent contraceptive use or use of EC.

Implications: Adopting a protocol of contraceptive implant placement that includes insertion on any cycle day with a negative pregnancy test, and EC as indicated, does not increase the risk of luteal phase pregnancies, even in a young population with complex reproductive behaviors and challenging historical narratives.

Keywords: Quick start; Contraception; Adolescents; LARC; Contraceptive implant

1. Introduction

Long acting reversible contraceptives (LARC; intrauterine devices and contraceptive implants) are increasingly recommended as first line birth control for adolescents and young adults because they are highly effective and do not depend on user adherence [1–3]. Implants in particular are gaining in popularity in this population with use increasing from 0.6% (2006–2010) to 3% (2011–2013) in 15–24 year olds [4]. This is encouraging as adolescents and young women have the highest rates of unintended pregnancy [5]. The increasing popularity of implants may be due to the easy insertion technique for providers and its effectiveness and ease of use for adolescents. A potential barrier that remains for patients choosing this method is requirements regarding the timing of insertion.

Traditionally, hormonal contraception was initiated with menses. Over the past decade, several authors have found that initiating short-acting hormonal contraceptives on the same day as the consultation visit, regardless of menstrual cycle day, is safe and effective [6–9]. The American College

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of Obstetricians and Gynecologists and the Centers for Disease Control and Prevention (CDC) have issued recommendations to adopt same-day initiation protocols for LARC as well [2,10]. The option to offer same-day initiation of LARC is important in the adolescent and young adult populations because rates of follow-up may be particularly low [11,12].

Product labeling for the contraceptive implant directs that insertion occur within 5 days of menses or ≤7 days from discontinuation of another hormonal method, and with a negative urine pregnancy test. These guidelines present a challenge to same-day implant initiation for adolescents due to the frequency of inconsistent contraceptive use, menstrual cycle irregularities, and opportunistic scheduling in this population.

One concern limiting the use of same-day initiation of LARC is the risk that a patient in the luteal phase of her menstrual cycle may have undergone egg fertilization or implantation of a pregnancy and not yet have a positive pregnancy test. Because the subdermal contraceptive implant changes bleeding patterns, identification of such a luteal phase pregnancy (LPP) may be delayed. However, the risk of subsequent unintended pregnancy in patients leaving with no method or a short-acting "bridge" method may be significantly higher than the risk for LPP [9,13–15]. We hypothesized that the risk of LPP in adolescents and young women receiving a contraceptive implant under an any-cycle-day protocol would be similar for women who did and did not meet current product labeling guidelines.

2. Materials and methods

We conducted a retrospective cohort study of young women who received contraceptive implants at the BC4U clinic at the Children's Hospital Colorado from April 2009 to December 2013. BC4U is a youth-oriented Title X-funded family planning clinic that offers free and confidential reproductive health services, including pregnancy testing, comprehensive contraceptive counseling, and options counseling with referral to abortion services, to young women and men ≤24 years of age.

2.1. Study sample

During the study period, any woman who desired contraceptive initiation could receive a contraceptive implant at any visit, regardless of cycle day, prior contraceptive use, or last sexual intercourse, as long as she had a negative urine pregnancy test (Pregnancy hCG Rapid Test, Cardinal Health; analytic sensitivity 20 mIU/mL urine). Patients were offered emergency contraception (EC; levonorgestrel 1.5 mg p.o., dispensed and ingested immediately) at the discretion of the provider, or per patient request. Ulipristal acetate was not available at the clinic during this study period. All patients were advised to use back up contraception for 7 days. Those outside of the product label guidelines were advised to repeat pregnancy testing (in clinic or at home) in 2–4 weeks. Patients were not scheduled for routine follow-up, but were counseled regarding reasons to call or return to clinic, including suspected pregnancy.

2.2. Data collection and ascertainment

All data for this study were obtained from the electronic medical record (EMR, Epic Systems Corporation, Verona WI). This EMR includes records from the Children's Hospital Colorado main site, as well as all affiliated clinics and hospitals, and the Epic Colorado Care Everywhere Network providers, which include the University of Colorado Health system, Kaiser Permanente, and Denver Health and Hospitals. This network includes some clinics that provide pregnancy termination services but there are other community-based abortion clinics that are not included in this network. Variables abstracted from EMR included last menstrual period, method of contraception used immediately preceding the implant insertion visit, EC provision, and all pregnancy tests administered ≤12 weeks following implant placement. Implant insertions were ascertained by querying the EMR for 1) implant medication orders 2) procedure code description ("insertion of implantable subdermal contraceptive"), 3) billing codes (V25.5, "insertion of implantable contraceptive device"), and 4) review of the mandatory Title X tracking field in the EMR for documentation of contraceptive method change to subdermal implant. Lastly, the final data set derived from the above queries was compared to the number of implants purchased through the Title X program for this period.

After identification of all implant placements, patient demographic variables were abstracted electronically into a secure database. Each medical record was then opened and reviewed. Data abstracted by hand included date of last menstrual period reported at the insertion visit, use of hormonal contraception at the time of implant placement, EC medication orders, reason EC dispensed and all follow-up visits including pregnancy testing, routine return visits, prenatal visits, obstetrical ultrasound, and device removal through 12 months post-insertion. For patients with positive pregnancy tests or reports, we used standard obstetrical dating (LMP and ultrasound) to estimate the date conception occurred. Luteal phase pregnancy (LPP) was defined as any pregnancy in which conception was estimated to have occurred within two weeks of implant placement.

2.3. Statistical analyses

We created two groups: those who had implants inserted within product label guidelines (negative pregnancy test and insertion within 5 days of menses or ≤7 days from discontinuation of hormonal contraception) and those who had the implant inserted outside these guidelines.

Based on prior literature [16], we estimated that the occurrence of LPP when following the manufacturer's guidelines to be 0.5%. This study was designed to