

Lactogenesis After Early Postpartum Use of the Contraceptive Implant

A Randomized Controlled Trial

Shawn E. Gurtcheff, MD, MS, David K. Turok, MD, MPH, Greg Stoddard, MPH, Patricia A. Murphy, CNM, DrPH, Mark Gibson, MD, and Kirtly P. Jones, MD

OBJECTIVE: To evaluate lactogenesis after early postpartum insertion of the etonogestrel contraceptive implant.

METHODS: Healthy peripartum women with healthy, term newborns who desired the etonogestrel implant for contraception were randomly assigned to early (1–3 days) or standard (4–8 weeks) postpartum insertion. The primary outcomes, time to lactogenesis stage II and lactation failure, were documented by a validated measure. The noninferiority margin for the mean difference in time to lactogenesis stage II was defined as 8 additional hours. Secondary data (device continuation and contraceptive use, breast milk analysis, supplementation rates, side effects, and bleeding patterns) were collected at periodic intervals for 6 months.

RESULTS: Sixty-nine women were enrolled. Thirty-five were randomly assigned to early insertion and 34 to standard insertion. There were no statistically significant differences between the groups in age, race, parity, mode of delivery, use of anesthesia, or prior breastfeeding experience. Early insertion was demonstrated to be noninferior to standard insertion in time to lactogenesis stage II (early: [mean±standard deviation] 64.3±19.6 hours; standard: 65.2±18.5 hours, mean difference, –1.4 hours, 95% confidence interval [CI] –10.6 to 7.7 hours). Early

insertion was also demonstrated to be noninferior to standard insertion in incidence of lactation failure (1/34 [3%] in the early insertion group, 0/35 [0%] in the standard insertion group [risk difference, 0.03, 95% CI –0.02 to 0.08]). Use of formula supplementation was not significantly different between the groups. Milk composition at 6 weeks was not significantly different between the groups.

CONCLUSION: Breastfeeding outcomes were similar in women who underwent early compared with standard postpartum insertion of the etonogestrel implant.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, www.clinicaltrials.gov, NCT00847587.

(*Obstet Gynecol* 2011;117:1114–21)

DOI: 10.1097/AOG.0b013e3182165ee8

LEVEL OF EVIDENCE: I

Effective, reversible postpartum contraception is important to decrease the chance of rapid repeat pregnancy and poor perinatal outcome in a subsequent pregnancy.^{1,2} Current standards for provision of contraception at the postpartum visit are inadequate because 10% to 40% of women do not return for postpartum care.^{3,4} Fewer than half of women who express desire for an intrauterine device on the postpartum ward actually receive it at their outpatient follow-up visit.^{4,5} Provision of long-acting reversible contraception in the hospital after delivery is ideal: there is no chance of pregnancy, motivation for contraception is high, and a return visit is not required. The etonogestrel implant (Implanon, Schering-Plough) is a single-rod subdermal implantable contraceptive that releases the progestin etonogestrel (3-keto-desogestrel). It offers contraceptive effectiveness with an excellent safety profile for up to 3 years with rapid return of fertility on removal.⁶

A woman's plan for contraception must not interfere with her ability to breastfeed her infant success-

From the Department of Obstetrics and Gynecology, Study Design and Biostatistics Center, and College of Nursing, University of Utah, Salt Lake City, Utah.

The authors thank the Department of Obstetrics and Gynecology, Division of Reproductive Endocrinology and Infertility at the University of Utah for financial assistance, as well as Dr. C. Matthew Peterson for editorial support. Study design and analysis support was provided through Public Health Services research grant numbers UL1-RR025764 and C06-RR11234 from the National Center for Research Resources. A number of the contraceptive implants used were graciously provided by an anonymous donor.

Corresponding author: Shawn E. Gurtcheff, University of Utah Department of Obstetrics and Gynecology, 30N 1900E Suite 2B200, Salt Lake City, UT 84132; e-mail: sgurtcheff@calalum.org.

Financial Disclosure

The authors did not report any potential conflicts of interest.

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ISSN: 0029-7844/11



fully. The American Academy of Pediatrics Policy Statement on Breastfeeding notes significant health benefits for both mother and child.⁷ Numerous studies have found the initiation of progestin-only contraceptives after 6 weeks to be safe for both the breastfeeding infant and mother, resulting in statements from the World Health Organization and International Planned Parenthood Foundation recommending unrestricted use of progestins after 6 weeks postpartum.^{8,9} A recent review also concluded that the available evidence for progestin use while breastfeeding is consistently reassuring.¹⁰ Specifically, the use of the etonogestrel implant has been studied in breastfeeding women initiated at 4–8 weeks postpartum. No change in the volume or composition of breast milk was noted, and there were no effects associated with the small amount of etonogestrel ingested by the infant.¹¹ Three-year follow-up of child growth and development in this population showed no difference between implant users and copper intrauterine device users,¹² suggesting no adverse effect of the hormone in breast milk.

The initiation of progestin-containing contraceptives before 4 weeks has been less well studied. In nonbreastfeeding women, the safety of progestins in the early postpartum period is well established.¹³ However, theoretical concerns for delay in lactogenesis time (defined as the time between delivery and onset of lactogenesis stage II) and an effect on the amount or constitution of breast milk have generated controversy in breastfeeding. This concern has been raised based on anecdotal evidence from clinicians.¹⁴ The Centers for Disease Control and Prevention and World Health Organization offer different recommendations with regard to early administration.^{9,15} Several observational studies and a recent pilot randomized trial have been reassuring but not definitive.^{16–18} Thus we performed a randomized controlled noninferiority trial to evaluate lactogenesis after early postpartum insertion of the etonogestrel contraceptive implant.

MATERIALS AND METHODS

This was a randomized controlled noninferiority trial. Healthy peripartum women with healthy, term newborns who desired the etonogestrel implant for contraception were randomly assigned to early (1–3 days) or standard (4–8 weeks) postpartum insertion. The primary outcome, time to lactogenesis stage II, was documented by maternal perception as described and validated by Chapman and Perez-Escamilla.¹⁹ The noninferiority margin for the mean difference in time to lactogenesis stage II was defined as 8 hours, such

that noninferiority would be demonstrated if the two-sided 95% confidence interval (CI) around the mean difference was within the bounds of an 8-hour delay.

From January to October 2009, women who recently had delivered or planned to deliver at the University of Utah Health Sciences Center were counseled regarding risks and benefits of contraceptive options. The obstetric service at the University of Utah Hospital is a teaching facility, and care is delivered by a team of nurses, students, residents, and attending clinicians. Comprehensive handouts and a discussion including all options for contraception with their individual efficacies, risks, and benefits, were presented to patients by the postpartum team as per the standard of care at the hospital at the time. Those patients interested in the implant as a contraceptive device were then referred to study personnel for discussion of possible participation in the study. Patients were offered inclusion in the study if they were healthy, intended to breastfeed, and agreed to be randomly assigned. Appropriate counseling about the risks and benefits of subdermal contraception was given, including efficacy, common side effects, and risks such as pain and bleeding. Appropriate counseling regarding the unknown effects of early progestin administration on breastfeeding was also provided.

Participants were assigned with equal probability to one of the two test groups using computer-generated random numbers in blocks of varying sizes of two, four, and six. The sequence was generated and maintained by statistical support staff. Allocation concealment was ensured by enclosing assignments in sequentially numbered, opaque, sealed envelopes. Envelopes were opened sequentially and only after the participant's name and study number were written on the envelope by the clinician enrolling the participant. Follow-up and data collection for participants in each group were identical.

Exclusion criteria were onset of lactogenesis before randomization, hemorrhage requiring transfusion, severe pregnancy-induced hypertension, prolonged hospitalization, coagulopathy, liver disease, undiagnosed genital bleeding, or other relative contraindication to etonogestrel implant insertion (known or suspected pregnancy; known, suspected, or history of breast cancer; or hypersensitivity to any of the components in the etonogestrel implant). Women taking inducers of hepatic enzymes were also excluded, including barbiturates, griseofulvin, rifampin, phenylbutazone, phenytoin, carbamazepine, felbamate, oxcarbazepine, topiramate, modafinil, protease inhibitors, and herbal products including St. John's wort. Enrollment was



ended when the predefined number of participants was reached based on the sample size calculation. The study was approved by the Institutional Review Board at the University of Utah.

Inclusion and exclusion criteria were verified and informed consent obtained by study personnel. Randomization occurred on the postpartum floor. Trained physicians performed all insertions. Early insertions were performed shortly after randomization on the postpartum floor, and standard insertions were performed at a follow-up visit. Lactogenesis time was documented by maternal perception, as described and validated by Chapman and Perez-Escamilla.¹⁹ Beginning on the first postpartum day, participants were interviewed three times daily. Participants were asked, "Has your milk come in? Some women experience this as a prickly feeling or tingling in the breast, dripping from the other nipple when nursing, milk running from the baby's mouth, or gulping by the baby." If the response was positive, women were then asked, "When did your milk come in?" and the response recorded to the nearest hour. If lactogenesis had not occurred before hospital discharge, the patient received at least daily phone calls from study personnel until lactogenesis could be confirmed and recorded. Clinical follow-up was as follows: postpartum telephone calls or clinic visits to collect additional data would occur as needed for up to 5 days after hospital discharge and at 2 weeks, 6 weeks, 3 months, and 6 months postpartum. Information obtained at these points included breastfeeding status, infant weights, side effects and bleeding patterns, resumption of sexual activity, and use of contraceptive method. Specifically, participants were asked at follow-up visits if they were using the etonogestrel implant for contraception. If no, they were asked if they were using any form of contraception, including abstinence or withdrawal, and if so, what method. Monetary compensation for travel and inconvenience was given at the 6-week and 6-month visits.

Participants were asked to give a milk sample for analysis at their 6-week visit. A mid-sample of breast milk was self-expressed at 6 weeks postpartum. The sample was snap-frozen and stored at -20°C until analysis was performed. Determination of creatinocrit is a simple method for estimating the fat and energy content of human milk based on the centrifugation of milk in a hematocrit centrifuge. The method for creatinocrit measurement was as described by Lucas et al²⁰ using a standard hematocrit centrifuge, standard hematocrit glass capillary tube, and Vernier calipers. Measurements were performed in duplicate and the mean for each measurement used for analysis.

The sample size calculation was based on the two primary study aims. For the first aim of lactation failure, it was assumed that both groups would have 5% failure. Setting the noninferiority margin at 15%, which allowed for the early group to have no more than 20% failure, using an alpha 0.05 level comparison, to achieve 80% power, a sample size of $n=27$ evaluable individuals was required for each group. Incidence of lactation failure has been reported as 3–35%.^{21,22} Thus an incidence between 5% and 20% would still be within the possible background risk. For the second aim of hours to lactogenesis stage II, it was assumed that both groups would have a mean of 54 hours to lactogenesis with a common standard deviation (SD) of 12 hours based on previous reports of lactogenesis in women with uncomplicated vaginal deliveries.^{22,23} Setting the noninferiority margin at 8 additional hours, using an alpha 0.05 level comparison, to achieve 80% power a sample size of $n=34$ evaluable participants was required in each group. A noninferiority margin of 8 additional hours was chosen to be clinically relevant because many common medical interventions (such as epidural anesthesia, cesarean delivery, labor induction, and general stress) have been reported to delay time to lactogenesis stage II by up to 12 hours.^{22,24} A sample size of $n=34$ per group was selected to allow 80% power for both study aims. The calculation was performed using N Solution 2007 Professional (PharmaSoftware Solutions, Inc).

For aims 1 and 2, a noninferiority analysis was used. Noninferiority was established if the lower bound of a two-sided 95% CI did not cross the noninferiority bound. A two-sided CI is preferred by the authors of the CONSORT statement for noninferiority trials,²⁵ likely because it allows a reader to also assess significance in the opposite direction. For all other end points, a traditional superiority analysis (test for significant differences; t test or χ^2 as appropriate) was performed. For each of these other end points, a two-sided 95% CI is reported, so a reader could perform a noninferiority analysis by simply noting if the CI covers what the reader would select for a noninferiority margin. If lactation failure occurred, the outcome of time to lactogenesis stage II was set at 120 hours based on 120 hours being the maximum number of hours allowable, after which the diagnosis of lactation failure applies. This statistical approach is known as the truncation approach to outliers²⁶ and is less extreme than simply eliminating the data from the analysis. Both intent-to-treat and per-protocol analyses were performed. Per-protocol analysis is presented to demonstrate the more conservative anal-



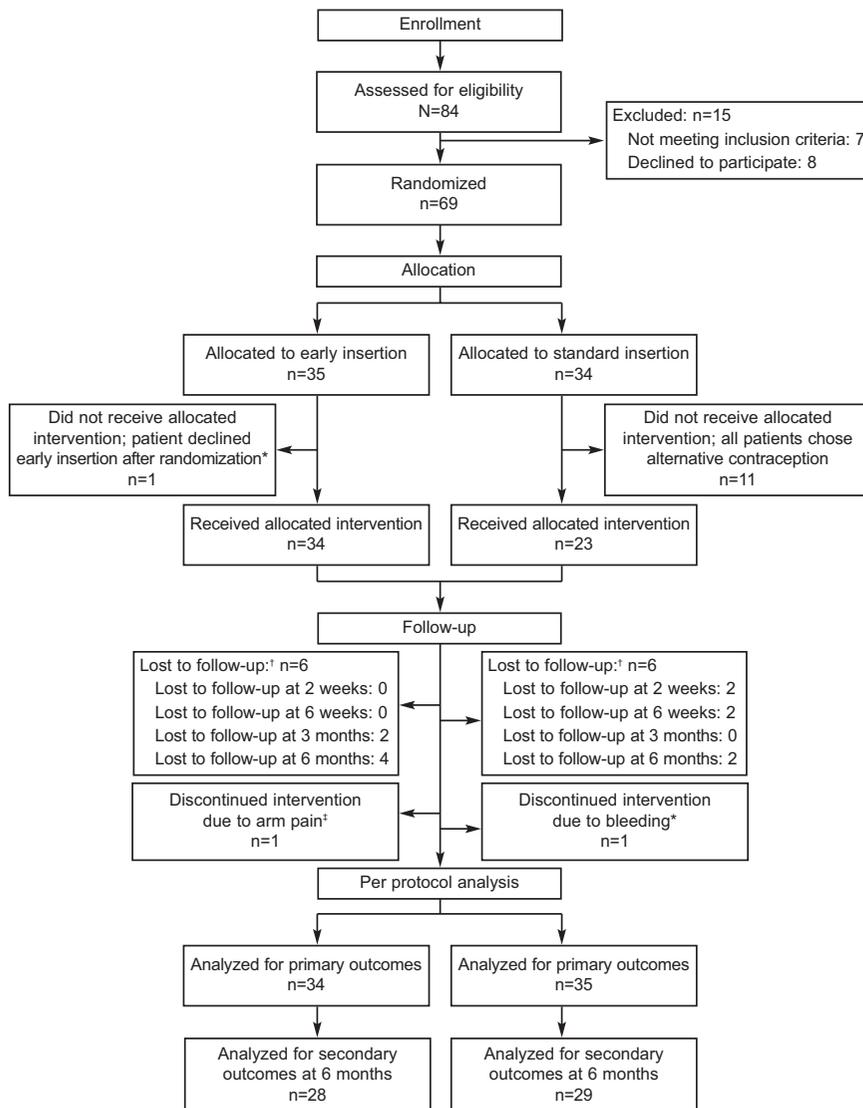


Fig. 1. Study flow. *Participant included in secondary outcome analysis for standard insertion group. †Patients could not be located. ‡Participant included in secondary outcome analysis for early insertion group.

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ysis for the primary outcomes in a noninferiority study.

RESULTS

Of 84 patients assessed for eligibility, 69 were randomly assigned (Fig. 1). There were no statistically significant differences between the groups in age, race, parity, mode of delivery, use of anesthesia, or previous breastfeeding experience (Table 1). Early insertion was performed between the first and third postpartum day (mean±SD 39±13 hours after delivery, minimum 11 hours, maximum 60 hours). One patient randomly assigned to early insertion changed her mind, declined early insertion, and ultimately failed to receive the device. This patient was analyzed in the standard insertion group for the per-protocol analysis. Standard insertion was performed after 4 weeks

postpartum. Thirty-two percent (11/34) of patients randomly assigned to standard insertion failed to receive the device. Seven of these women did not return for their postpartum visits despite multiple attempts to reschedule, and four were lost to follow-up.

Figure 2 demonstrates noninferiority results for the two primary outcomes. One patient in the early insertion group and no patients in the standard group experienced lactation failure, thus early insertion was demonstrated to be noninferior to standard insertion in risk of lactation failure (risk difference 0.03, 95% CI −0.02 to 0.08). Early insertion was also demonstrated to be noninferior to standard insertion in time to lactogenesis stage II (early: [mean±SD] 64.3±19.6 hours; standard: 65.2±18.5 hours, mean difference, −1.4 hours, 95% CI −10.6 to 7.7 hours). Figure 3 illustrates time to lactogenesis stage II evaluated by the log-rank test ($P=.994$) and



Table 1. Demographic and Clinical Data

Variable	Early (n=34)	Standard (n=35)	P
Age (y)	27±6	25±6	.9
Race			.6
White	7 (21)	10 (29)	
White, Hispanic	25 (73)	21 (60)	
Other	2 (6)	4 (11)	
Mode of delivery			.7
Vaginal	22 (65)	20 (57)	
Cesarean	12 (35)	15 (43)	
Epidural use	28 (82)	27 (77)	.6
Multipara	28 (82)	25 (71)	.3
Previous breastfeeding experience	25 (74)	21 (60)	.5
Gestational age (wk)	39±1	39±1	.4
Neonatal sex			
Male	15 (44)	20 (57)	.3
Female	19 (56)	15 (43)	
Recent patient weight (lb)	170±31	171±32	.5
Plan for current breastfeeding (mo)			.4
Less than 6	10 (29)	14 (40)	
More than 6	24 (71)	21 (60)	
Full-time employment	8 (24)	11 (31)	.5

Data are mean±standard deviation or n (%) unless otherwise specified.

presented as a Kaplan-Meier curve. Exclusive breastfeeding and use of formula supplementation were not significantly different between the groups at any of the study time periods (Fig. 4).

Patient-reported bleeding patterns at 6 months were not statistically different between the groups. Forty-nine percent (24/49) noted amenorrhea.

Slightly more than half¹³ were fully breastfeeding, six were supplementing with food or formula, and five were not breastfeeding. Another third (18/49, 37%) reported light or infrequent bleeding. Ten percent (5/49) reported heavy or frequent bleeding, one of whom had the device discontinued for this reason. All five women who reported heavy or frequent bleeding had ceased breastfeeding at least 3 months previously. There was one device removal in the early insert group at 4 weeks (1/29, 3%) for arm pain. There was one removal in the standard insert group at 6 months (1/22, 5%) for bleeding. The difference was not statistically significant ($P=.84$). Women randomly assigned to early insertion were more likely to be using contraception at 3 months than women randomly assigned to standard insertion (100% compared with 87%, $P=.04$).

Breast milk was collected at 6 weeks postpartum from 21 of the 32 women breastfeeding in the early insert group and 22 of the 26 women breastfeeding in the standard insert group. Mean creatocrit values were not significantly different between the groups (early: [mean±SD] 7.5±3.0%, standard: 6.8±3.2%, mean difference 0.61% [95% CI -1.3 to 2.5%]).

DISCUSSION

We found that receiving the contraceptive implant in the early postpartum period before hospital discharge did not adversely affect a woman's ability to breastfeed her newborn. In our study population, average times to lactogenesis stage II were longer than what has been published for women with

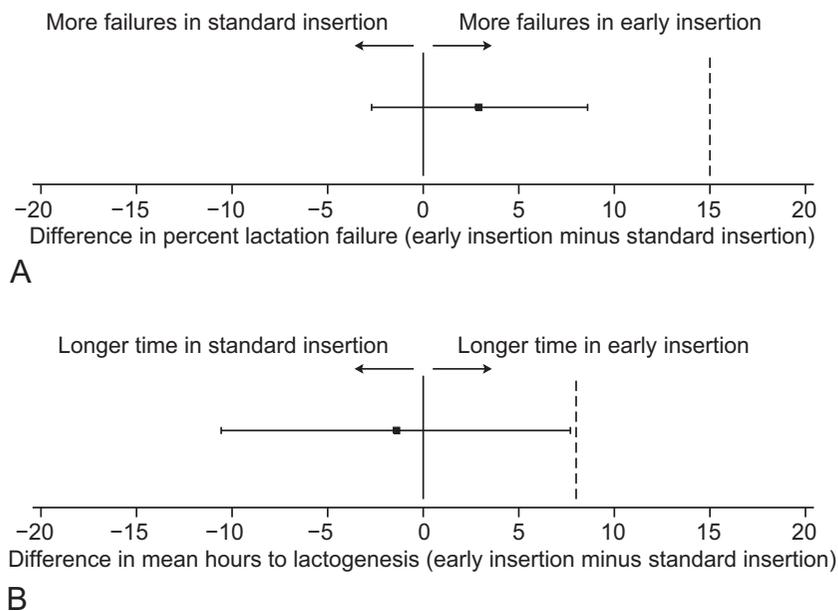


Fig. 2. Error bars indicate two-sided 95% confidence intervals. The dotted lines denote the presupposed noninferiority boundaries. Noninferiority was accepted because the upper bound did not cross for either outcome.

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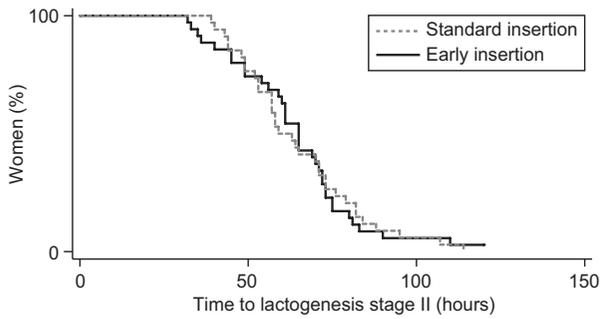


Fig. 3. Time to lactogenesis stage II graphically represented as a Kaplan-Meier survival curve.

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completely uncomplicated deliveries.¹⁹ However, despite our patients being healthy women with term pregnancies, there was a high rate of interven-

tion (including a 90% conduction anesthetic use rate and a 30% cesarean rate); these factors may have resulted in the increased time. The frequency of supplementing with formula in our study population was consistent with previously published studies of American women.²⁷

One third of women randomly assigned to standard insertion never received their implants, compared with just 3% of those who were randomly assigned to early insertion, despite being enrolled in a study in which they were consistently reminded, rescheduled as desired, and offered incentives. This highlights the need for provision of contraception before hospital discharge, especially in women perceived to be at high risk for noncontraception and short interbirth intervals.³

Strengths of our study include the randomized, controlled noninferiority design. Most of the studies

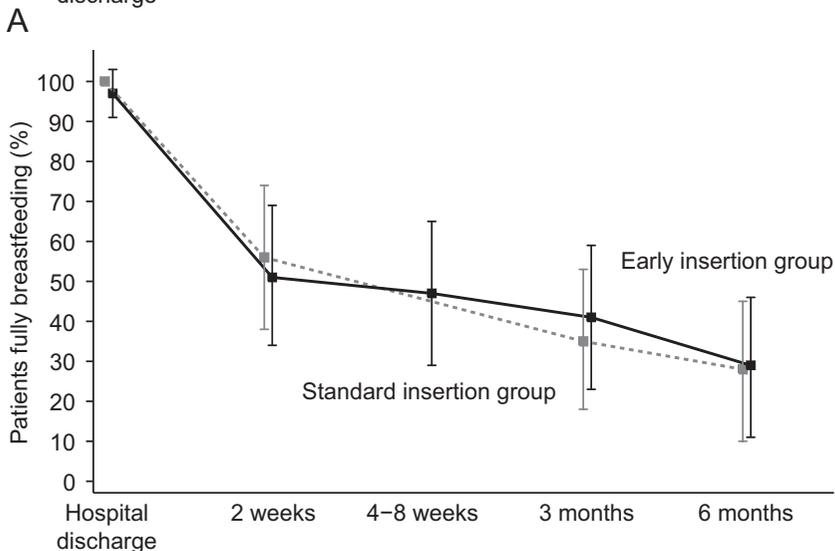
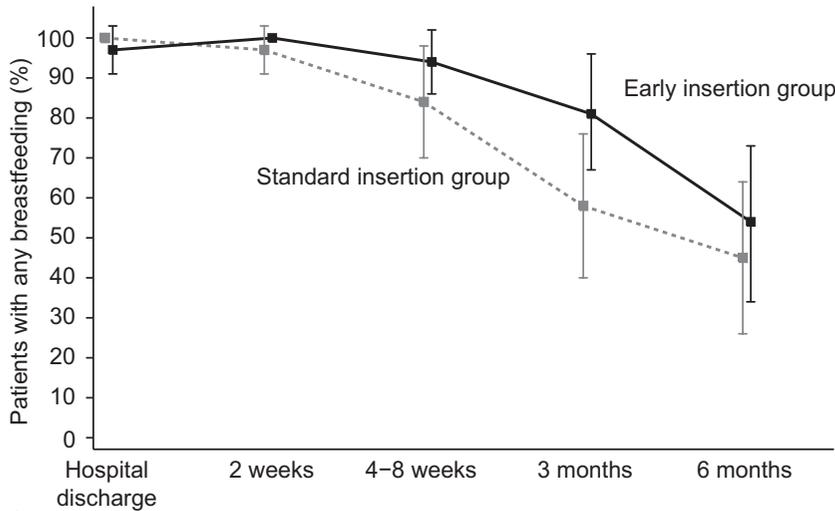


Fig. 4. Percentage of patients with any breastfeeding (A) or fully breastfeeding (B) at each study time point. Data are presented as percentage of total with 95% confidence intervals.

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published in this area are observational or fail to use clinically relevant primary outcomes.¹⁰ Also, in our study there was a single protocol deviation for primary outcome analyses, offering similarity and consistency between per-protocol and intent-to-treat analyses. This is one of few studies published that evaluates the effects of early hormonal contraception on breastfeeding, and one of very few utilizing the etonogestrel implant. Whereas we do not intend this study to be the definitive word on the matter, it is hoped that it will facilitate collection of even more robust and clinically useful data.

Limitations are that the study was not blinded, and that early insertion was allowed as late as the third postpartum day. Blinding would have required use of placebo contraceptives and was not considered feasible. Insertion on the first through third postpartum days was allowed so long as lactogenesis had not already occurred because we hoped to mimic what might occur in normal clinical practice. However, this may have allowed for insertion of the device to occur relatively late in regard to the subsequent time of onset of lactogenesis. Future studies may minimize this bias by restricting insertion to no later than 48 hours after delivery. That said, this is a study of early administration, and not a study of immediate postpartum administration (such as what might occur with insertion of a levonogestrel-containing intrauterine contraceptive after placental delivery). Information regarding the effect of immediate progestin administration is also lacking and is much needed.

External validity or generalizability is a concern in any randomized trial. Our population was not ethnically representative of the entire U.S. population, nor were they likely representative of all women giving birth in the United States (ie, high intervention rates, high numbers of multiparous women, and so forth.) We conclude that breastfeeding outcomes are similar in women randomly assigned to early compared with standard postpartum insertion of the etonogestrel implant. However, our population was limited to those women having term pregnancies with few complications, and thus our results should not be extrapolated to women with premature birth, severe pregnancy complications, or whose infants have medical problems. Additional studies in varied populations will be needed to confirm these results. It will also be important that future studies continue to address long-term outcomes in exposed neonates.

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