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# Postplacental or Delayed Insertion of the Levonorgestrel Intrauterine Device After Vaginal Delivery:

## A Randomized Controlled Trial

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## Abstract

**OBJECTIVE—**To estimate whether 6-month use of the levonorgestrel-releasing intrauterine device (IUD) would be higher when insertion occurred within 10 minutes of placental delivery compared with 6–8 weeks postpartum.

**METHODS—**We enrolled pregnant women planning vaginal deliveries and desiring a postpartum levonorgestrel-releasing IUD. Patients were randomly assigned when admitted in labor to postplacental or delayed IUD insertion. The women followed up in person at 6–8 weeks and 6 months and were contacted by telephone at 3 months. Women were ineligible for a study IUD postenrollment for intrapartum events including infection, hemorrhage, and cesarean delivery; these women were contacted by phone at 3 and 6 months. Expelled IUDs were replaced per patient preference.

**RESULTS—**Successful IUD placement occurred in 50 of 51 participants (98.0%) and 46 of 51 participants (90.2%) in the postplacental and delayed groups, respectively (*P*=.2). Expulsion within 6 months occurred in 12 of 50 (24.0%; 95% confidence interval [CI], 13.1–38.2) and two



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of 46 (4.4%; 95% CI 0.5–14.8) participants, respectively (*P*=.008). Intrauterine device use at 6 months was 43 of 51 (84.3%; 95% CI 71.4–93.0) and 39 of 51 (76.5%; 95% CI 62.5–87.2), respectively (*P*=.32). For ineligible patients, only 11 of 41 (26.8%) women were using IUDs at 6 months and two (4.9%) had become pregnant.

**CONCLUSION—**Intrauterine device use 6 months after delivery is similar in women who have postpartum or scheduled delayed IUD placement through a study after replacement of expelled IUDs. Expulsions are significantly higher with postplacental compared with delayed IUD placement. Women asked to follow up with their own health care providers for delayed insertion are significantly less likely to receive an IUD.

**CLINICALTRIALREGISTRATION—**ClinicalTrials.gov, www.clinicaltrials.gov, NCT00476021.

**LEVEL OF EVIDENCE—**I

The United States has the highest unintended pregnancy rate of any developed country. Of the 6.4 million pregnancies in the United States each year, almost half are unintended (49%).[1] Postpartum women are particularly susceptible with an unintended pregnancy rate of 10–44% in the first postpartum year.[2–6] These unintended pregnancies occur despite the recommendation that a contraceptive method should be selected before hospital discharge.[7]

Long-acting reversible contraceptives such as the intrauterine device (IUD) can theoretically help decrease the rate of unintended pregnancy through providing reliable, effective, long-term contraception. However, women who desire an IUD for postpartum contraception often do not receive one for various reasons, including loss of insurance coverage, inability to return for insertion, lack of a health care provider experienced in IUD insertions, and early repeat pregnancy. A US study of 193 women who desired a postpartum IUD found that 35% did not return for a postpartum visit and only 60% actually received an IUD.[5] Seven (3.6%) of these women became pregnant before they were able to receive an IUD.

Immediate postplacental IUD insertion is defined as IUD insertion within 10 minutes of the expulsion of the placenta. Although this practice is common in developing countries, it is rare in the United States. The expulsion rate associated with interval insertion of T-shaped IUDs is approximately 1–4.5% in the first year.[8–10] Postplacental insertion has an expulsion rate ranging from 6% to 20% for T-shaped IUDs over 1 year.[11–14] The expulsion rate is lower for immediate postplacental compared with early (11 minutes to 72 hours) postpartum insertion and is also lower when skilled health care providers insert the IUD.[11,12] The method of postpartum insertion, whether inserted by ring forceps or by hand, does not appear to affect expulsions.[11,13] Although the expulsion rate in postplacental insertion is higher than interval insertion, the benefits of highly effective contraception immediately after delivery may outweigh the risks of expulsion.

Data on postplacental insertion of the levonorgestrel-releasing intrauterine system after vaginal delivery in the United States are limited. A pilot study in the United States of 20 participants who received ultrasonography-guided postplacental insertion of the levonorgestrel-releasing IUD showed an acceptable expulsion rate of 10% and no infections over a 10-week follow-up.[15] The purpose of this study was to compare use of the levonorgestrel-releasing IUD at 6 months postpartum when placed postplacentally after vaginal delivery compared with delayed insertion 6–8 weeks postpartum.

## MATERIALS AND METHODS

This prospective trial was conducted between May 2007 and October 2008 at Magee-Womens Hospital, Pittsburgh, PA. The study was approved by the University of Pittsburgh

Institutional Review Board. We enrolled pregnant women aged 18 years and older who were greater than or equal to 24 0/7 weeks of gestation at the time of enrollment, anticipated undergoing a vaginal delivery, interested in using the levonorgestrel-releasing IUD for postpartum contraception, and able to sign a consent form in English. Potential participants were identified after counseling for postpartum contraception by their primary obstetrician or midwife. If a woman expressed interest in the study, she was referred to one of the study investigators to discuss the study. All participants provided written informed consent before enrollment. Participants received routine prenatal care and were delivered by their primary obstetrician or midwife.

Patients were excluded if they: 1) planned to undergo a scheduled cesarean delivery; 2) had an allergy to polyethylene or levonorgestrel or other contraindications to use of the levonorgestrel-releasing IUD; 3) were treated for gonorrhea, *Chlamydia*, or trichomoniasis during the pregnancy without a subsequent negative test of cure; 4) had one or more leiomyomata greater than 3 cm in diameter impinging on the uterine cavity; 5) had a uterine anomaly (other than a repaired septate uterus); 6) had current cervical cancer or carcinoma in situ; or 7) desired repeat pregnancy within 1 year of delivery.

At time of enrollment, participants completed a questionnaire and quality-of-life assessment. Additional data, including demographic information, medical, pregnancy, contraceptive, and sexually transmitted infection history, were collected. Further contraceptive counseling was performed to determine the method of contraception to be used after delivery in the event of randomization to delayed insertion or in the event of postenrollment ineligibility as a result of antepartum or intrapartum events.

Participants were randomly assigned when they presented to the hospital in anticipation of delivery. The primary obstetrician or midwife informed the investigator on-call of the participant’s admission and the investigator opened the next sequentially numbered, opaque, sealed envelope containing the group assignment of immediate postplacental or delayed IUD insertion. A statistician not involved with the clinical conduct of the study prepared the envelopes using computer-generated random allocations in permutated blocks.

Additional exclusion criteria were assessed intrapartum for postenrollment ineligibility. These included: 1) cesarean delivery; 2) clinical diagnosis of chorioamnionitis or treatment for presumed chorioamnionitis; 3) sexually transmitted infection during pregnancy diagnosed after enrollment without a subsequent negative test of cure; 4) rupture of membranes for more than 24 hours; 5) postpartum hemorrhage as defined by need for transfusion, estimated blood loss greater than 1,000 mL, or use of three or more doses of uterotonic medications such as methylergonovine, carboprost, misoprostol, or oxytocin; 6) rupture of membranes at less than 34 weeks of gestation; 7) participant no longer desired a levonorgestrel-releasing IUD; or 8) precipitous delivery such that the investigators were unable to begin placement of the levonorgestrel-releasing IUD within 10 minutes of placental delivery or if the investigators were not notified of the participant’s labor and delivery.

If a participant was found to be ineligible as a result of postenrollment criteria, she was instructed to follow up with her primary obstetrician or midwife for postpartum contraception and delayed IUD insertion. Levonorgestrel-releasing IUDs were not provided to ineligible patients through the study. We followed-up with these participants by phone at 3 and 6 months to assess quality of life, contraceptive use, and unintended pregnancy rates. All eligible participants received a free levonorgestrel-releasing IUD through the study with planned follow-up, which included a visit at 6–8 weeks postdelivery, a phone contact at

approximately 3 months, and a visit at approximately 6 months. Study staff performing the 3- and 6-month evaluations were blinded to the randomization assignment.

Postplacental levonorgestrel-releasing IUD insertion was performed under transabdominal ultrasonography guidance using the prepackaged levonorgestrel-releasing IUD inserter. If the IUD could not be placed using the inserter, ring forceps or hand insertion could be attempted. Intrauterine device strings were trimmed to be flush with the external cervical os. Participants were asked to abstain from intercourse or to use a condom consistently until the 6- to 8-week postdelivery visit. At this visit, participants underwent a urine pregnancy test, pelvic examination to trim the strings of the IUD, and ultrasonography to assess location of the IUD.

Participants eligible for delayed IUD insertion were prescribed postpartum contraception by their primary obstetrician or midwife until the 6- to 8-week postdelivery visit. A follow-up appointment time for IUD insertion was confirmed in person by research staff before hospital discharge. Participants received a reminder phone call before their appointment. A urine pregnancy test was performed before IUD insertion. The levonorgestrel-releasing IUD was inserted in the standard fashion and the strings were trimmed to be approximately 3 cm from the external os. Participants who did not return for delayed IUD insertion by 60 days post-delivery were followed up with only by phone at 3 and 6 months to assess quality of life, contraceptive use, and unintended pregnancy rates.

At each scheduled contact, all eligible participants completed a questionnaire about the primary contraceptive method used until the appointment, pain, bleeding, breast feeding, and resumption of intercourse. At the 6-month postdelivery visit, a pregnancy test, pelvic examination, and ultrasonography evaluation were also performed.

The primary outcome was use of the levonorgestrel-releasing IUD at 6 months postpartum. Additional outcomes included continuation of the IUD, expulsion, pregnancy, infection, uterine perforation, pain with insertion, quality of life, and contraceptive use. A complete expulsion was defined as no levonorgestrel-releasing IUD inside the uterus and either a clinical history consistent with expulsion or an abdominal radiograph confirming absence of the IUD. A partial expulsion was defined as an IUD protruding from the cervical os or transvaginal ultrasonography showing the distal end of the IUD below the internal os of the cervix. Participants who underwent a complete or partial expulsion could have a replacement IUD placed if they desired. If a postplacental participant experienced an IUD expulsion before their 6- to 8-week follow-up visit, the IUD was replaced at the visit.

To estimate sample size, we expected 40% of delayed insertion participants would not return for insertion.[5] We anticipated that 4% of inserted IUDs would be discontinued within 6 months as a result of requests for removal and that expulsion would occur in 11%[14,15] of women in the postplacental group and 2% in the delayed group. These rates provided estimated proportions of women continuing the IUD at 6 months in the postplacental and delayed groups of 0.850 and 0.564, respectively. Accordingly, 92 total participants meeting all eligibility criteria (46 per group) would achieve 80% power to detect a difference of 34% in use at 6 months at a significance level of .05. The number was increased to 51 per group to allow for 10% loss to follow-up. We expected 40% of participants would not be eligible for insertion as a result of postenrollment ineligibility criteria,[15] increasing the total number of women to enroll to 168 participants.

Statistical analysis was performed using Stata 10. Primary analysis used modified intention-to-treat data. The modified intention-to-treat groups were defined as all participants randomly assigned to post-placental or delayed IUD insertion who were eligible for placement (ie, did not meet postenrollment ineligibility criteria). A secondary analysis was

performed to examine participants who were excluded from IUD insertion through the study as a result of postenrollment ineligibility criteria. Proportions were compared using chi square tests or Fisher's exact tests as appropriate. Exact binomial 95% confidence intervals were calculated for expulsions and IUD use at 6 months postpartum. The D'Agostino test of skewness–kurtosis was used to evaluate normality. Non-normally distributed variables were compared using the Kruskal-Wallis test. Survival analysis (time to IUD expulsion) was analyzed using the log-rank test and Cox regression. Multivariable analysis of 6-month IUD use was performed using logistic regression.

## RESULTS

Between May 2007 and October 2008, 163 women were enrolled in the study (Fig. 1). Demographic information was not significantly different among the three groups (Table 1).

Fifty (98.0%) of the 51 women randomly assigned to postplacental insertion had successful IUD placements. One IUD could not be placed postplacentally. This participant received an IUD at her 6- to 8-week postdelivery visit and was analyzed as part of the postplacental group by intention to treat. The median time to postplacental IUD insertion was 6.5 minutes (range 2–15 minutes) with five insertions occurring between 11 and 15 minutes.

Of 51 participants randomly assigned to delayed insertion, 46 (90.2%) participants returned for delayed insertion and all had the IUD placed successfully. There was no difference in return to sexual activity by the 6- to 8-week postdelivery visit with 25 of 51 (49.0%) and 22 of 46 (47.8%) of women in the postplacental and delayed groups, respectively, reporting intercourse before the scheduled visit ($P>.99$).

Forty-nine (96.1%) participants who had postplacental IUDs inserted had epidural anesthesia during delivery. Of participants who had a postplacental IUD successfully placed, 40 of 50 (80%) reported no or mild pain during IUD insertion. Most (37 of 42 [88.1%]) participants with delayed IUD insertion reported no or mild pain during IUD insertion; four participants with delayed insertion had missing data on pain during insertion.

Expulsions occurred during the 6 months of follow-up in 12 of 50 (24.0%; 95% confidence interval [CI] 13.1–38.2) and two of 46 (4.4%; 95% CI 0.5–14.8) of women in the postplacental and delayed groups ($P=.008$), respectively. Complete expulsion occurred in nine (18.0%) and one (2.2%) participants, respectively. Partial expulsion was noted in three (6.0%) and one (2.2%) participants, respectively. Nine of 12 (75.0%) postplacental expulsions occurred before or were diagnosed at the 6- to 8-week postdelivery visit. Expulsions occurred in 10 of 45 women (22.2%) who had the IUD placed within 10 minutes and two of five women (40.0%) who had the IUD placed between 11 and 15 minutes ($P=.58$). There was no difference in expulsions between investigators ($P=.15$). A Kaplan-Meier graph of time to IUD expulsion is displayed in Figure 2. Age, race, and parity were not predictive of postplacental expulsion in a Cox regression model (Table 2).

Replacement IUDs were inserted in 10 of 12 women with expulsions in the postplacental group and one of two women with expulsions in the delayed group. One participant was not aware of when her postplacental IUD was expelled; it was diagnosed at the 6- to 8-week postdelivery visit when an ultrasonographic examination showed no IUD in the uterus and an abdominal radiograph did not show an intra-abdominal IUD. She later expelled two replacement IUDs and then chose to use a contraceptive vaginal ring. All of the other complete IUD expulsions were identified by the participants.

Of 42 participants whose postplacental IUDs were in place at the 6- to 8-week visit, seven had a visit before 6–8 weeks for a string trim. An additional 25 participants had their strings

trimmed at the 6- to 8-week visit. The mean length of trimmed strings was 5.6±3.2 cm. Other participants may have had strings trimmed by their primary obstetrician and not reported it to study staff. Two participants had missing strings on pelvic examination but had IUDs present in their uterus by ultrasonography. One participant had strings coiled at her cervical os that could not be untangled; this participant expelled her IUD when removing a tampon on study day 110.

Use at 6 months postpartum is presented in Table 3. Of participants in the postplacental and delayed groups who received IUDs, 34 of 46 (73.9%; 95% CI 58.9–85.7) and 38 of 40 (95%; 95% CI 83.1–99.4), respectively, were still using the original IUDs placed at 6 months (*P*=.009) with five lost to follow-up in the postplacental group and seven lost to follow-up in the delayed group. When loss to follow-up was excluded from the analysis, there was no difference in IUD use at 6 months between the two groups after replacement of expelled IUDs (93.5%; 95% CI 82.1–98.6 compared with 88.6%; 95% CI 75.4–96.2; *P*=.48). Intrauterine device use at 6 months was 43 of 51 (84.3%; 95% CI 71.4–93.0) and 39 of 51 (76.5%; 95% CI 62.5–87.2), respectively (*P*=.32) when participants lost to follow-up were considered as not using the IUD. Although power is limited by the small number of outcomes, we performed a multivariable analysis to see if any factors were strongly correlated with our outcome. Age, race, and parity were not predictive of IUD use at 6 months postpartum in a multivariable logistic regression model (Table 4).

Complications were infrequent in both groups. Of women who were randomly assigned to a postplacental IUD, 11 participants (21.6%) received group B strep prophylaxis. There was one (2.0%) infection in the postplacental group with a diagnosis of *Chlamydia* and pelvic inflammatory disease at the 6- to 8-week postdelivery visit, one (2.0%) in the delayed group with a diagnosis of trichomoniasis and pelvic inflammatory disease at the 6-month postdelivery visit, and none in the ineligible group (*P*>.99). One participant in the postplacental group had died as a result of unrelated causes. She was considered lost to follow-up in the final analysis of contraceptive use at 6 months.

There were four complications of interest that occurred in this study: 1) a participant who underwent a postplacental insertion experienced a vaginal laceration when the IUD strings were cut with scissors, requiring repair with suture; 2) a participant was unable to have a postplacental IUD placed by the investigator as a result of the posterior curvature of the postpartum uterus. Attempts were made to place the IUD with ring forceps but were unsuccessful. The participant was too uncomfortable to attempt a hand insertion of the IUD as a result of inadequate epidural anesthesia; 3) a participant who received a postplacental IUD noted something sticking out of her vagina on study day 7 and pulled out a portion of the IUD insertion tube with the IUD still inside. The insertion tube appeared to have detached from the IUD inserter and had been left inside her uterus during the postplacental IUD placement. On evaluation, she had no signs of infection. She had a new IUD placed at her 6- to 8-week postdelivery visit. This was considered a complete expulsion for the analysis; and 4) a participant who received a postplacental IUD had a malpositioned IUD by ultrasonographic examination at her 6-month visit. The IUD was positioned obliquely in the uterus with the arms of the IUD against the right uterine wall and the base of the IUD in the left cornua. The IUD was pulled into the correct position by ultrasonography with the IUD strings; however, at a follow-up visit 2 weeks later, the IUD had reverted to an oblique position. The participant was counseled that the IUD was likely still effective for contraception as a result of the hormonal mechanism of action. Because the participant was asymptomatic, the IUD was left in place.

Of participants ineligible for IUD insertion through the study (n=41), only 11 (26.8%) received an IUD through their primary gynecologist or midwife by 6 months postpartum.

Nine of these women (81.8%) had received the IUD by 3 months postpartum. There were no expulsions in this group. Two participants in the ineligible group were pregnant by 6 months (4.9%), whereas no pregnancies occurred in the postplacental or delayed IUD insertion groups (*P*=.08). Final contraceptive use for all groups at 6 months by modified intention to treat is listed in Table 5.

## DISCUSSION

We found that use of the levonorgestrel-releasing IUD at 6 months postpartum was not different between women who received postplacental or delayed IUDs. Although the number of expulsions are significantly higher with postplacental compared with delayed IUD insertion, the majority of women in our study who expelled their IUDs desired replacement, accounting for the lack of difference in 6-month use between groups.

Expected follow-up rates for delayed insertion will affect the use of postplacental IUD insertion in increasing IUD use. In our study, only 10% of eligible women did not follow up for delayed IUD insertion per protocol, although in the ineligible group, 73% of women did not obtain an IUD. Thus, if the expected follow-up for delayed insertion is low, postplacental IUD insertion may increase IUD use. However, if the expected follow-up for delayed insertion is high, postplacental IUD insertion cannot be recommended as a result of the high numbers of expulsions and replacement IUDs.

Although there are a considerable number of studies of postplacental insertion of the Copper T 380A, there are relatively few such studies with the levonorgestrel-releasing IUD. An important study of the Copper T 380A by Celen et al[14] monitored 235 women with a follow-up rate at 12 months of 78%. The expulsion rates at 6 weeks, 6 months, and 12 months were 5.1%, 7.0%, and 12.3%, respectively. However, this study included both vaginal deliveries and cesarean deliveries, and the published expulsion rates are not stratified by method of delivery. Another recent study from Turkey found a complete expulsion rate of 14.3% and a partial expulsion rate of 22.6% in 12 months for immediate postplacental insertion of the Copper T 380A.[16] For interval insertion, the rates were 3.8% for complete expulsion and 3.1% for partial expulsion. Only one small study of postplacental insertion of the levonorgestrel-releasing IUD in the United States has been performed. Hayes et al[15] reported on 20 participants who received ultrasonography-guided postplacental insertion and found no infections and two expulsions (10%; 95% CI 0–24.3) at 10 weeks.

Our study found a 6-month postplacental IUD expulsion rate of 24.0% (95% CI 13.1–38.2) with the levonorgestrel-releasing IUD, which is higher than most other studies.[11–14,16] Nine of 12 postplacental expulsions in our study occurred before the 6- to 8-week postdelivery visit and one postplacental IUD expulsion was not recognized by the participant. Because an unrecognized IUD expulsion can result in unintended pregnancy, follow-up after postplacental insertion is important to ensure that the IUD is in situ before relying on it for contraception and to trim strings. In our study, nearly half of women in both groups resumed intercourse before the 6- to 8-week postdelivery visit; thus, counseling regarding abstinence or using condoms for contraception before confirming IUD location at the follow-up visit is essential.

One possible reason for the higher expulsions in our study is that we used the levonorgestrel-releasing IUD inserter for postplacental insertion, whereas postplacental IUDs are often inserted by hand insertion or ring forceps.[12] High fundal placement is recommended to decrease expulsion rates.[12] We chose to use the levonorgestrel-releasing IUD inserter because it is longer than ring forceps, readily available on opening the levonorgestrel-releasing IUD packaging, and likely to be less painful than manual insertion.

Unfortunately, other studies did not assess pain during postplacental IUD placement,[14–16] although Hayes et al[15] inserted the IUD by ring forceps if the participant could not tolerate hand insertion. In their study, 20% of participants required ring insertion. We feel that the use of the inserter is unlikely to affect postplacental expulsion because we were able to verify high fundal placement by transabdominal ultrasonography.

A limitation of this study is that six investigators were involved in inserting the postplacental IUDs, only one of whom had prior experience with postplacental IUD insertions. Although there was no difference in expulsions between investigators, the limited experience of each investigator may have contributed to the number of expulsions. However, high fundal placements were confirmed by ultrasonography and each investigator was experienced at using the levonorgestrel-releasing IUD inserter; thus, this is unlikely to have had a major effect. Overall, this issue would reflect what would happen in clinical practice with initial implementation of a postplacental IUD insertion program.

There were two unusual complications in our study. One participant experienced a vaginal laceration when the IUD strings were cut during a postplacental insertion. For another participant, a portion of the IUD inserter had detached during postplacental insertion and had not been recognized at the time of the insertion until the participant pulled out the portion of the detached inserter on study day 7. Both of these events resulted in a change in listed risks of the informed consent document. To the best of our knowledge, these two events have not previously been reported in the medical literature.

The difference in delayed insertion follow-up between participants eligible for delayed insertion and ineligible participants is striking, with 90% of women following up for delayed insertion per protocol and only 27% of ineligible women following up for delayed insertion by their primary health care provider. In comparison, Ogburn et al[5] found that of women who were interested in a postpartum IUD, 60% received an IUD. Reasons for lack of follow-up for IUD insertion in our study for the ineligible group are unclear, but 39% of women were using a less effective form of contraception at 6 months and 29% were lost to follow-up. Even if all of the women lost to follow-up received an IUD from their primary health-care provider, only 56% of women who had previously been interested in a postpartum IUD would have received an IUD.

The differences in follow-up in the ineligible group may reflect barriers to IUD insertion. Women in the delayed arm of the study all had been seen postpartum by study staff to schedule the IUD insertion appointment, had a reminder phone call for the appointment, were reimbursed for the insertion visit, and had no financial barrier to the IUD because there was no charge or copay. All of these actions were not performed for the ineligible group, which may, in total or in part, account for the differences in follow-up.

In summary, we found that postplacental levonorgestrel-releasing IUD insertion is feasible and results in similar IUD use at 6 months postpartum when compared with delayed IUD insertion. However, given the 6-month expulsion rate of 24%, post-placental IUD insertion may not be practical if expected follow-up rates for delayed IUD insertion are high. If expected follow-up rates for delayed IUD insertion are low, then postplacental IUD insertion will increase use of a highly effective, long-acting contraceptive.

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## References


1. Finer LB, Henshaw SK. Disparities in rates of unintended pregnancy in the United States, 1994 and 2001. Perspect Sex Reprod Health. 2006; 38:90–6. [PubMed: 16772190]
2. Kershaw TS, Niccolai LM, Ickovics JR, Lewis JB, Meade CS, Ethier KA. Short and long-term impact of adolescent pregnancy on postpartum contraceptive use: implications for prevention of repeat pregnancy. J Adolesc Health. 2003; 33:359–68. [PubMed: 14596957]
3. Templeman CL, Cook V, Goldsmith LJ, Powell J, Hertweck SP. Postpartum contraceptive use among adolescent mothers. Obstet Gynecol. 2000; 95:770–6. [PubMed: 10775745]
4. Shulman JJ, Merritt CG. Postpartum contraception: subsequent pregnancy, delivery, and abortion rates. Fertil Steril. 1976; 27:97–103. [PubMed: 1245250]
5. Ogburn JA, Espey E, Stonehocker J. Barriers to intrauterine device insertion in postpartum women. Contraception. 2005; 72:426–9. [PubMed: 16307964]
6. Jackson RA, Schwarz EB, Freedman L, Darney P. Advance supply of emergency contraception: effect on use and usual contraception—a randomized trial. Obstet Gynecol. 2003; 102:8–16. [PubMed: 12850599]
7. Hatcher, RA.; Trussell, J.; Stewart, F.; Cates, WJ.; Guest, F.; Kowal, D. Contraceptive technology. 18. New York (NY): Irvington; 2004.
8. Suhonen S, Haukkamaa M, Jakobsson T, Rauramo I. Clinical performance of a levonorgestrel-releasing intrauterine system and oral contraceptives in young nulliparous women: a comparative study. Contraception. 2004; 69:407–12. [PubMed: 15105064]
9. Sivin I, Stern J, Coutinho E, Mattos CE, el Mahgoub S, Diaz S, et al. Prolonged intrauterine contraception: a seven-year randomized study of the levonorgestrel 20 mcg/day (LNg 20) and the Copper T380 Ag IUDS. Contraception. 1991; 44:473–80. [PubMed: 1797462]
10. Costales A, Jensen J, Nelson A, Korner P, Uddin M. A US multicenter, open-label trial with the levonorgestrel-releasing intrauterine system (LNG-IUS)—clinical and device-related experience. Contraception. 2006; 74:178.
11. Chi IC, Farr G. Postpartum IUD contraception—a review of an international experience. Adv Contracept. 1989; 5:127–46. [PubMed: 2699148]
12. O'Hanley K, Huber DH. Postpartum IUDS: keys for success. Contraception. 1992; 45:351–61. [PubMed: 1516367]
13. Grimes D, Schulz K, Van Vliet H, Stanwood N. Immediate postpartum insertion of intrauterine devices. The Cochrane Database of Systematic Reviews. 2003; (1):Art. No.: CD003036.10.1002/14651858.CD003036
14. Celen S, Möröy P, Sucak A, Aktulay A, Danişman N. Clinical outcomes of early postplacental insertion of intrauterine contraceptive devices. Contraception. 2004; 69:279–82. [PubMed: 15033401]
15. Hayes JL, Cwiak C, Goedken P, Zieman M. A pilot clinical trial of ultrasound-guided postplacental insertion of a levonorgestrel intrauterine device. Contraception. 2007; 76:292–6. [PubMed: 17900440]
16. Eroğlu K, Akkuzu G, Vural G, Dilbaz B, Akin A, Taşkin L, et al. Comparison of efficacy and complications of IUD insertion in immediate postplacental/early postpartum period with interval period: 1 year follow-up. Contraception. 2006; 74:376–81. [PubMed: 17046378]

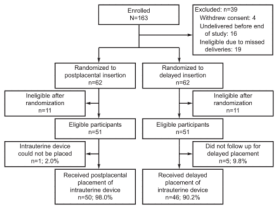


**Fig. 1.**
Study flow.
Chen. Postplacental or Delayed IUD After Vaginal Delivery. Obstet Gynecol 2010.

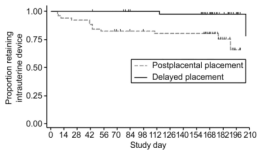


**Fig. 2.**

Time to intrauterine device expulsion. Hash marks indicate last contact for patients lost to follow-up or at study completion.

Chen. Postplacental or Delayed IUD After Vaginal Delivery. Obstet Gynecol 2010.

## Table 1

Demographics of Final Group Assignments for Levonorgestrel-Releasing Intrauterine Device Insertion*

| | Postplacental (n=51) | Delayed (n=51) | Ineligible (n=41) | *P* |
|---|---|---|---|---|
| Age (y) | 25.4±5.3 | 24.7±5.2 | 25.9±6.5 | .74 |
| Gravidity | | | | |
| 1 | 20 (39.2) | 12 (23.5) | 12 (29.3) | .09 |
| 2 | 9 (17.7) | 12 (23.5) | 12 (29.3) | |
| 3 | 13 (25.5) | 12 (23.5) | 3 (7.3) | |
| 4 or more | 9 (17.7) | 15 (29.4) | 14 (34.2) | |
| Parity | | | | |
| 0 | 22 (43.1) | 20 (39.2) | 15 (36.6) | .19 |
| 1 | 15 (29.4) | 15 (29.4) | 16 (39.0) | |
| 2 | 12 (23.5) | 6 (11.8) | 6 (14.6) | |
| 3 or more | 2 (3.9) | 10 (19.6) | 4 (9.8) | |
| Race | | | | |
| White | 31 (60.8) | 20 (39.2) | 22 (53.7) | .23 |
| African American | 18 (35.3) | 27 (52.9) | 18 (43.9) | |
| Other | 2 (3.9) | 4 (7.8) | 1 (2.4) | |
| Hispanic | 3 (5.9) | 2 (3.9) | 1 (2.4) | .88 |
| Obstetric–gynecologic care | | | | |
| Resident clinic | 38 (74.5) | 42 (82.4) | 25 (61.0) | .14 |
| Private obstetrician | 9 (17.7) | 7 (13.7) | 14 (34.2) | |
| Midwife | 4 (7.8) | 2 (3.9) | 2 (4.9) | |
| Marital status | | | | |
| Single | 39 (76.5) | 38 (74.5) | 26 (63.4) | .54 |
| Married | 11 (21.6) | 12 (23.5) | 12 (29.3) | |
| Divorced or separated | 1 (2.0) | 1 (2.0) | 3 (7.3) | |
| Insurance | | | | |
| Government | 34 (66.7) | 41 (80.4) | 32 (78.0) | .23 |
| Private | 17 (33.3) | 10 (19.6) | 9 (22.0) | |

SD, standard deviation.

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

* Percentages may not add up to 100 as a result of rounding.

**Table 2**

Results of Multivariable Cox Regression for Intrauterine Device Expulsion

| Variable | Hazard Ratio (95% CI) | *P* |
|---|---|---|
| Delayed IUD insertion | 0.08 (0.01–0.63) | .016 |
| Age | 1.0 (0.89–1.13) | .99 |
| Primiparous | 0.84 (0.25–2.83) | .78 |
| African-American race | 0.28 (0.05–1.43) | .13 |

CI, confidence interval; IUD, intrauterine device.

**Table 3**

Intrauterine Device Placement, Expulsion, and 6-Month Use

| Group | Postplacental (n=51) | Delayed (n=51) | Percent Difference (95% CI) | *P* | Number Needed to Treat* |
|---|---|---|---|---|---|
| Received IUD per protocol | 50/51 (98.0) | 46/51 (90.2) | 7.8 (−1.2 to 16.8) | .2 | 12.7 |
| Expelled IUD | 12/50 (24.0) | 2/46 (4.4) | 19.6 (6.4 to 32.9) | .008 | 5.1 |
| LTFU at 6 mo | 5/51 (9.8) | 7/51 (13.7) | −3.9 (−16.4 to 8.6) | .76 | — |
| Use at 6 mo† | | | | | |
| LTFU counted as failures | 43/51 (84.3) | 39/51 (76.5) | 7.8 (−7.5 to 23.2) | .32 | 12.7 |
| LTFU counted as continued use | 48/51 (94.1) | 45/51 (88.2) | 5.9 (−5.1 to 16.8) | .49 | 17.0 |
| LTFU removed from data | 43/46 (93.5) | 39/44 (88.6) | 4.9 (−6.9 to 16.6) | .48 | 21 |

CI, confidence interval; IUD, intrauterine device; LTFU, lost to follow-up.

Data are n (%) unless otherwise specified.

*Number of postplacental insertions to have one more event occur compared with delayed insertion.

†Based on accounting for LTFU in different ways.

**Table 4**

Results of Multivariable Logistic Regression for 6-Month Intrauterine Device Use

| Variable | Odds Ratio (95% CI) | *P* |
|---|---|---|
| Delayed IUD insertion | 0.80 (0.19–3.41) | .77 |
| Age | 1.11 (0.94–1.31) | .23 |
| Primiparous | 1.72 (0.36–8.11) | .49 |
| African-American race | 1.17 (0.25–5.48) | .84 |

CI, confidence interval; IUD, intrauterine device.

**Table 5**

Contraceptive Method at 6 Months by Modified Intention to Treat (no., %)*

| | Postplacental (n=51) | Delayed (n=51) | Ineligible (n=41) | *P* |
|---|---|---|---|---|
| LNG IUD | 43 (84.3%) | 39 (76.5%) | 11 (26.8%) | <.001 |
| Combined contraceptives | 2 (3.9%) | 2 (3.9%) | 4 (9.8%) | .47 |
| DMPA | 0 (0%) | 1 (2.0%) | 3 (7.3%) | .10 |
| Condoms | 0 (0%) | 1 (2.0%) | 5 (12.2%) | .01 |
| None | 0 (0%) | 0 (0%) | 4 (9.8%) | .006 |
| Abstinence | 1 (2.0%) | 1 (2.0%) | 0 (0%) | >.99 |
| Sterilization | 0 (0%) | 0 (0%) | 1 (2.4%) | .29 |
| Lost to follow-up | 5 (9.8%) | 7 (13.7%) | 12 (29.3%) | .04 |
| Pregnant† | 0 (0%) | 0 (0%) | 1 (2.4%) | .29 |

LNG IUD, levonorgestrel-releasing intrauterine device; DMPA, depot medroxyprogesterone acetate.

*Percentages may not add up to 100% as a result of rounding.

†Of two women known to be pregnant, one was contacted at 6 months and one was lost to follow-up.