

Importance of the delivery-to-insertion interval in immediate postpartum intrauterine device insertion: A secondary analysis

Klaira Lerma^{1,2,*} | Renita Bhamrah³ | Sharad Singh³ | Paul D. Blumenthal^{1,2}

¹Stanford Program for International Reproductive Education and Services, Division of Family Planning Services and Research, Department of Obstetrics and Gynecology, School of Medicine, Stanford University, Stanford, CA, USA

²Population Services International, Washington, DC, USA

³Population Services International, New Delhi, India

*Correspondence

Klaira Lerma, 300 Pasteur Drive, HG332 Stanford, CA 94305, USA.
Email: klerma@stanford.edu

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Abstract

Objective: To evaluate the delivery-to-insertion interval for copper postpartum intrauterine devices (PPIUDs).

Methods: Secondary analysis of two related studies at five academic sites in India from March 2015 to July 2016. IUDs were inserted within 48 hours of vaginal delivery. Women (n=560) were grouped by whether they underwent postplacental (≤ 10 minutes) or immediate (> 10 minutes) insertion. Outcomes were complete expulsion at the 6–8-week follow-up (primary), and IUD-to-fundus distance, as assessed by postinsertion ultrasound (secondary).

Results: Overall, 93 (16.6%) women received a postplacental PPIUD and 467 (83.4%) received an immediate PPIUD. Complete expulsion at follow-up was 3.2% (n=3) in the postplacental and 7.5% (n=35) in the immediate postpartum group ($P=0.176$; difference in proportions, 4.3%; 95% confidence interval, -2.0 to 8.1). Distance from the fundus did not differ between the two groups ($P=0.107$); high fundal placement (≤ 10 mm from the internal endometrial verge) was achieved for most women.

Conclusion: The present data challenge previous guidance on the timing of PPIUD insertion. The 10-minute insertion window is a barrier to uptake and should be reassessed for inclusion in service delivery guidelines. A flexible interval would accommodate the multiple post-delivery tasks of providers and increase access to PPIUD.

KEYWORDS

Copper IUD; Intrauterine contraceptive device; Intrauterine device; IUCD; Postpartum IUD; Postplacental IUD

1 | INTRODUCTION

Despite significant effort to provide women with contraception, there remains a global disparity in access to family planning services among women in the first year following delivery, with levels of unmet need during this period as high as 70%.¹ Reducing this unmet need has the potential to decrease maternal and child morbidity and mortality.^{2,3} Decades of clinical research and demonstration projects have provided evidence that postpartum intrauterine devices (PPIUDs) are convenient and safe, and their utilization continues to increase globally.^{4–19}

At most facilities in both low- and high-resource countries, an optimal time for IUD insertion is immediately after delivery.¹² In most low-resource countries, women are discharged rapidly after delivery and seldom return for a postpartum visit. In India, for example, an average of 30% of women do not return for a postpartum visit (based on 2015–2016 data), and consequently may not receive the contraception that they desire.²⁰

With regard to PPIUD insertion, several protocols, training curricula, and professional guidelines^{21,22} emphasize insertion of the PPIUD within 10 minutes of placental delivery, a procedure generally termed “postplacental insertion.” The emphasis of this 10-minute window may be traced

to a study by Chi et al.⁷ in 1989 that focused on “the expulsion problem.” Despite the data limitations of a retrospective, multi-country, multi-IUD study, Chi et al.⁷ concluded that immediate postplacental insertion in the first 10 minutes after placental delivery should be prioritized.⁷

That conclusion has influenced subsequent study protocols and practices regarding PPIUD for decades, resulting in the restrictive parameters of several trials and the programmatic “rule” of insertion within this 10-minute window. In terms of providing guidance for current practice, however, the data on which such guidelines are based are problematic. They were obtained using devices that are no longer available and insertion techniques that are no longer utilized. Furthermore, this emphasis has become a barrier to women getting their desired contraception in numerous labor and delivery settings. In some cases, if providers are unable to insert the device in the 10-minute interval, the IUD is not provided.

At least some provider reluctance to insert an IUD in the postpartum period stems from concerns about the purported higher expulsion rate associated with insertion in the immediate postpartum period (>10 minutes to 48 hours after placental delivery).⁷ However, given changes in IUDs, insertion techniques, and provider experience with both PPIUD and post-abortion IUD insertion subsequent to the study of Chi et al.,⁷ the 10-minute interval as a strategy to reduce expulsion may no longer be applicable.

In addition, guidelines recommending insertion in the first 10 minutes after delivery causes confusion among mid-level and non-specialist providers and may have become a barrier to practice. Furthermore, with a shift toward task-sharing to increase access to care, deliveries are less likely to be attended by an obstetrician. Although some providers approach recommendations with flexibility and independent judgement, many rigidly adhere to guidelines in practice, ultimately limiting PPIUD provision.

In a recent systematic review and meta-analysis, Jatlaoui et al.²³ compared expulsion rates among women with PPIUD insertion in the first 10 minutes, those with insertion from 11 minutes to 4 weeks postpartum, and those with insertion after 4 weeks postpartum.²³ However, those intervals do not specifically consider either insertions that occur after 10 minutes but with the mother still in the delivery room (delivery room insertions) or immediate postpartum insertions (≤ 48 hours after delivery).

To explore the relevance of IUD insertion within the first 10 minutes after placental delivery, the aim of the present study was to assess the effect of delivery-to-insertion interval on fundal location of PPIUDs and subsequent complete expulsion under the hypothesis that insertion timing does not have a significant effect on complete expulsion or continuation of IUD use.

2 | MATERIALS AND METHODS

The present secondary analysis was based on pooled data from a pilot study (enrollment from March 10 to May 30, 2015) and a randomized trial (enrollment September 27, 2015 to July 09, 2016) conducted among women undergoing postpartum insertion of a CuT-380A IUD in five

centers in India. The study data were provided in a de-identified, non-coded manner that was therefore not deemed human subject research, and were exempt from ethical review. The original studies were approved by the Drug Controller General of India, and ethics committee approval was obtained from all study sites (Bangalore Medical College and Research Institute, King George's Medical University, S.M.S. Medical College and Attached Hospitals, VMMC and Safdarjung Hospital, and Lady Hardinge Medical College and Associated Hospitals). Both studies were registered with the Clinical Trial Registry of India and were overseen by a data and safety monitoring board. All participants provided informed consent.

The original studies were carried out in the same five academic institutions with the same providers, and are described elsewhere.^{15,19} In brief, before study implementation, all resident-level providers received standardized training in PPIUD insertion. The pilot study investigated the use of a dedicated PPIUD inserter (PPIUD Inserter[®]; Pregna International, Mumbai, India),¹⁵ and the randomized trial compared the same dedicated PPIUD inserter to forceps insertion (using modified Kelly placental forceps) of the IUD in the immediate postpartum period.¹⁹ Therefore, all women in the present analysis had the PPIUD inserted either with the dedicated PPIUD inserter or with modified Kelly forceps. Because no significant statistical or clinical differences in fundal placement or complete expulsion were found between the two methods of insertion,¹⁹ the total sample from the two studies was pooled for the present analysis.

The inclusion criteria for each study were the WHO medical eligibility criteria for PPIUD,²⁴ insertion within 48 hours of delivery, and provision of informed consent. The exclusion criteria were rupture of membranes occurring 18 hours or more before delivery, diagnosis of chorioamnionitis at time of delivery, unresolved postpartum hemorrhage, and cesarean delivery.

The only insertion-timing guidance that providers were given was that insertion had to occur within 48 hours of delivery (the time when women were discharged from the hospital), making this a pragmatic study. The time of delivery and time of insertion were documented by facility staff, and the delivery-to-insertion interval was calculated and recorded. Participants underwent immediate postinsertion abdominal ultrasound to measure the distance from the uterine fundus (or endometrial verge) to the top of the device in millimeters. Women completed a pain questionnaire before and after insertion on a 3-point Likert scale (unbearable, bearable, none) developed by local investigators.

Women attended a follow-up visit at 6–8 weeks after delivery, where a string check and speculum exam were carried out. In cases of partial expulsion (asymptomatic, but with part of the IUD in the cervix), the device was removed and the woman received counseling on replacement, alternatives, or no contraception. In cases of missing strings, an ultrasound or X-ray was performed to locate the IUD. Due to logistic issues, some women attended the follow-up visit at a partner facility, where their IUD status was assessed by the same methodology and was reported to the study staff by clinical personnel at the partner facility.

For the present secondary analysis, women were assigned to one of two groups based on the delivery-to-insertion interval: postplacental insertion (≤ 10 minutes of placental delivery), or immediate postpartum insertion (>10 minutes after placental delivery). The retrospective cohort analysis was not powered.

TABLE 1 Baseline and insertion characteristics of the study women by timing of PPIUD insertion after delivery.^a

| Characteristic | Postplacental insertion (≤10 min) (n=93) | Immediate insertion (>10 min) (n=467) | P value |
|----------------------------------------------|------------------------------------------|---------------------------------------|---------------------|
| Age, y | 24 (19–40) | 25 (18–45) | 0.707 ^d |
| Previous delivery | 55 (59.1) | 326 (69.8) | 0.044 ^e |
| Time of contraceptive counseling | | | <0.001 ^f |
| Prenatal care | 21 (22.6) | 130 (27.8) | |
| Early labor | 68 (73.1) | 228 (48.8) | |
| Immediate postpartum | 4 (4.3) | 109 (23.4) | |
| Type of delivery | | | 0.314 ^f |
| Normal vaginal | 29 (31.2) | 183 (39.2) | |
| Normal vaginal with episiotomy | 63 (67.7) | 277 (59.3) | |
| Assisted vaginal | 1 (1.1) | 7 (1.5) | |
| Insertion technique | | | 0.447 ^e |
| Dedicated PPIUD inserter | 50 (53.8) | 271 (58.0) | |
| Modified Kelly forceps | 43 (46.2) | 196 (42.0) | |
| Distance from IUD to fundus, mm ^b | 4 (0–62) | 5 (0–130) | 0.107 ^d |
| High fundal placement ^c | 70 (76.1) | 353 (77.1) | 0.838 ^e |

Abbreviations: PPIUD, postpartum intrauterine device; IUD, intrauterine device.

^aValues are given as median (range) or number (percentage).

^bTen women did not receive an immediate postinsertion ultrasound: one in the postplacental and nine in the immediate postpartum group.

^cDefined as ≤10 mm from the internal endometrial verge.

^dBy independent samples Mann-Whitney *U* test.

^eBy Pearson χ^2 test.

^fBy Fisher exact test.

Statistical analysis was performed with SPSS version 25 (IBM, Armonk, NY, USA). Pearson χ^2 test or Fisher exact test were used, as appropriate, for categorical data. Independent samples Mann-Whitney *U* test was used for nonparametric data, and Student *t* test for continuous data. A binary logistic regression was performed to ascertain the effects of insertion timing, previous delivery, insertion technique, and fundal placement on the likelihood of complete expulsion among all study women.

3 | RESULTS

In total, 560 women were included in the secondary analysis. The average age was 25 years. Most women had the PPIUD inserted in the immediate postpartum period (n=467, 83.4%), with no difference in timing by insertion technique (dedicated inserter vs forceps) between the postplacental and the immediate postpartum groups ($P=0.447$) (Table 1, File S1).

Most women had a history of previous delivery. As compared with the postplacental group, a higher proportion of women in the immediate postpartum group had a history of previous delivery ($P=0.044$), and received contraceptive counseling after rather than before delivery ($P<0.001$). All women had a vaginal delivery, mostly without labor analgesia or anesthesia (n=558, 99.6%). The median (range) delivery-to-insertion interval was 7 minutes (2–10 minutes) in the postplacental group and 51 minutes (11 minutes to 46.25 hours) in the immediate

postpartum group ($P<0.001$). No perforations or adverse events related to PPIUD insertion were observed.

The median distance from the top of the PPIUD to the fundus on postinsertion ultrasound was similar between the two groups ($P=0.107$). The majority of IUDs were inserted with high fundal placement (defined as ≤10 mm from the fundus) in both groups ($P=0.838$) (Table 1). For most women in each group, there was no change in their perceived pain level immediately before and after insertion ($P=0.656$) (Table 2).

At the 6–8-week follow-up, most women in both the postplacental (n=77, 82.8%) and immediate postpartum (n=358, 76.7%) groups had

TABLE 2 Pain on PPIUD insertion.^a

| Outcome | Postplacental insertion (≤10 min) (n=93) | Immediate insertion (>10 min) (n=467) | P value |
|-------------------------------------------|------------------------------------------|---------------------------------------|--------------------|
| Pain between delivery and PPIUD insertion | | | 0.656 ^b |
| Increase in pain | 7 (7.5) | 32 (6.9) | |
| No change in pain | 75 (80.6) | 393 (84.2) | |
| Decrease in pain | 11 (11.8) | 42 (9.0) | |

Abbreviation: PPIUD, postpartum intrauterine device.

^aValues are given as number (percentage).

^bBy Pearson χ^2 test.

TABLE 3 Intrauterine device status at follow-up 6–8 wk postpartum.^a

| IUD status | Postplacental insertion (≤10 min) (n=93) | Immediate insertion (>10 min) (n=467) | P value ^b |
|-------------------------|------------------------------------------|---------------------------------------|----------------------|
| Retained | 77 (82.8) | 358 (76.7) | 0.305 |
| Removed | 8 (8.6) | 28 (6.0) | |
| Accidental self-removal | 0 (0) | 5 (1.1) | |
| Partial expulsion | 5 (5.4) | 41 (8.8) | |
| Complete expulsion | 3 (3.2) | 35 (7.5) | |

Abbreviation: IUD, intrauterine device.

^aValues are given as number (percentage).

^bBy Fisher exact test.

retained their IUD (Table 3). Overall, IUD status did not differ between the two groups at follow-up. A few women in each group had accidentally self-removed the device, asked for the device to be removed, or were found to have a partial expulsion on examination ($P=0.305$) (Table 3). The proportion of women with complete expulsion at 6–8-weeks postpartum did not differ statistically between the postplacental ($n=3$, 3.2%) and immediate postpartum ($n=35$, 7.5%) groups ($P=0.176$). The difference in proportions was 4.3% (95% confidence interval, -2.0 to 8.1).

In the immediate postpartum group ($n=467$), approximately 90% ($n=408$) of women had undergone IUD insertion by 3 hours after delivery. Cut-off intervals other than 10 minutes, ranging from 15 minutes to 3 hours while the mother would still be in the delivery room, were also considered. No statistically significant differences were observed in expulsion rates for any of these intervals (Fig. 1). In a stratified analysis by insertion technique (dedicated inserter or forceps), complete expulsion did not differ between the postplacental and immediate postpartum insertion groups (Table 4).

In a binary logistic regression assessing the effect of several factors on the likelihood of complete expulsion in the total group ($n=550$), including insertion timing (postplacental or immediate postpartum), previous delivery (yes or no), insertion technique (dedicated PPIUD inserter or forceps), and fundal placement (≤ 10 mm or >10 mm), the timing of insertion did not influence expulsion likelihood ($P=0.209$). Parity and insertion method were not significant factors for complete expulsion ($P=0.112$ and $P=0.475$, respectively). High fundal placement was associated with a decreased likelihood of complete expulsion ($P=0.039$).

4 | DISCUSSION

The present analysis does not support previous guidance on PPIUD insertion timing requiring insertion of the device within 10 minutes of placental delivery. Complete expulsion at follow-up was 3.2% and 7.5% in the postplacental and immediate postpartum groups, respectively ($P=0.176$). Although this non-significant statistical difference might be considered by some to have potential clinical significance, it is important to note that, if guidelines precluding insertion after 10 minutes had been followed, a substantial number of women would not have received an IUD at all (467 women or 83.4% of the sample). Failure to begin a desired method of contraception and risk of pregnancy in the postpartum period has public health significance, and is associated with far greater morbidity and mortality as compared with recognized IUD expulsion. The assessment of alternative cut-off intervals other than 10 minutes found that the difference in expulsion rate between the groups remained statistically insignificant and narrowed overtime (Fig. 1).

On the basis of immediate postinsertion ultrasound, there was no difference between the two groups in IUD distance from the fundus, a protective factor of expulsion.²⁵ Despite the importance of fundal

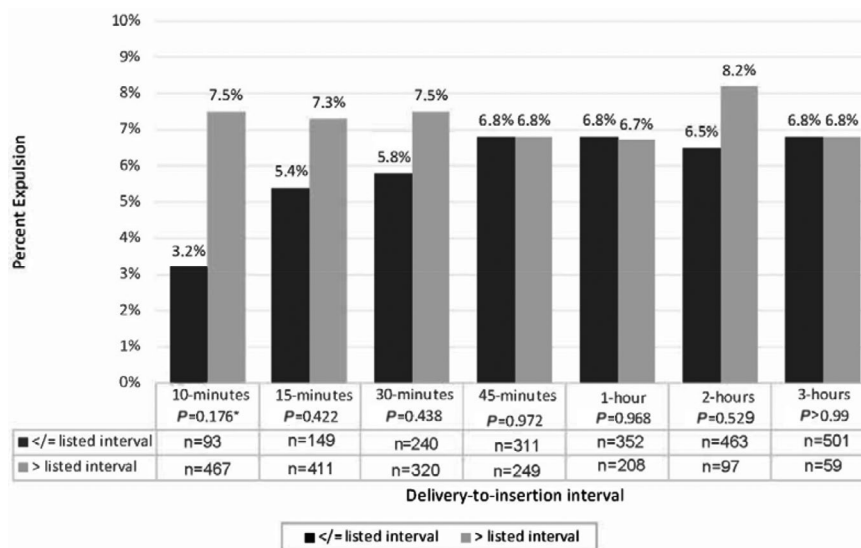


FIGURE 1 Effect of different delivery-to-insertion intervals on complete expulsion of the IUD. *Assessed by Fisher exact test; all other differences assessed by χ^2 test.

placement, we do not recommend routine ultrasound after PPIUD insertion. In the present study, ultrasound was conducted for research purposes; its utility in practice is limited and is not cost- or resource-effective, particularly in low-income settings where it is probably not accessible or feasible in most facilities where deliveries occur. In addition, there was no difference in reported pain following insertion between the two study groups—an important finding to better inform counseling for women with regard to PPIUDs.

The strengths of the present analysis are the large sample size, standardized insertion protocol, high rate of follow-up, and demonstration of a flexible insertion interval in the immediate postpartum period. The high proportion of insertions at more than 10 minutes after placental delivery is probably reflective of real-world practice. Indeed, providers have many competing, routine tasks to maintain both maternal and child health in the immediate postpartum period that may delay PPIUD insertion. In the present sample, 19.5% (n=109) of women were counseled for family planning in the immediate postpartum period, chose to use a PPIUD, and received the device before discharge. Although contraceptive counseling in the prenatal period is always favored, this further demonstrates the potential of a flexible interval to increase access to PPIUD provision. In addition, given recent findings of a higher perforation rate among lactating women when IUDs are inserted at a postpartum visit,²⁶ insertion at the time of delivery may be a more attractive option.

A study limitation is the small proportion of women who received postplacental IUD insertion among the whole sample, resulting in an imbalance in the two groups. The expulsion rate observed for postplacental insertion was lower than the previously reported average (10% in a recent meta-analysis²³), but consistent with data from low- and middle-income countries,⁴ a potential consideration when reviewing PPIUD studies. In addition, the IUD-to-fundus distance was smaller than previously reported in the literature; however, no difference in expulsion was observed between the two groups in this study. Owing to the high episiotomy rate (61%) in the present sample, the findings may not be generalizable to all populations, but episiotomy is fairly typical in many low-resource settings. It did not affect pain scores and should not be a deterrent to PPIUD insertion.

Another limitation is the short follow-up of 6–8 weeks postpartum; however, it seems unlikely that complete expulsions occurring at more than 8 weeks postpartum, when the cervix is closed and the uterus at normal size, would be associated with insertion timing, especially given that fundal placement was similar between the two groups.

Lastly, the present study evaluated only CuT-380A devices inserted after vaginal delivery. The levonorgestrel-releasing intrauterine system (LNG-IUS) has been associated with a higher expulsion rate in the postpartum period.⁹ In settings where LNG-IUS uptake is higher than uptake of the copper IUD, understanding whether the results of the present study are generalizable to the relationship between expulsion risk and insertion timing of LNG-IUS would be valuable.

Further research is needed to better understand the mechanism of IUD expulsion. The present data support fundal placement as a predictor of expulsion. However, a previous cost-effectiveness analysis found that PPIUD is both a cost-saving and cost-effective intervention with expulsion rates of less than 38% and 56%, respectively.¹⁷ This indicates that more emphasis should be put on method continuation or uptake of method at the earliest convenience, and expulsion de-emphasized as a sentinel clinical or programmatic outcome. Risk of expulsion remains an important counseling point for all potential users of IUD, regardless of the timing of insertion.

Expanding guidelines and practice to provide women with PPIUDs while they are still in the delivery room or facility, but beyond the conventional 10-minute window following delivery, is likely to increase access to, and as a result continuation of, IUD use. Insertion timing is not likely to significantly affect subsequent expulsion rates from either a statistical or clinical perspective. Some guidelines already support this strategy.^{27–30} We therefore recommend a more flexible approach to insertion timing, emphasizing the importance of fundal placement and uptake of desired contraception while still in the delivery room or facility, and de-emphasizing the 10-minute “rule.”

AUTHOR CONTRIBUTIONS

KL conducted the literature search; led data analysis and interpretation; and managed manuscript development. RB contributed to data collection, analysis, and interpretation; and manuscript development. SS oversaw study implementation in India; contributed to study design; led data collection; and contributed to data interpretation and manuscript development. PDB conceived the project; and contributed to data analysis and interpretation, and manuscript development.

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TABLE 4 Complete expulsion of IUD stratified by insertion technique.^a

| Insertion type | Postplacental insertion (≤ 10 min) | | Immediate insertion (> 10 min) | | P value ^b |
|--------------------|------------------------------------------|-----------|-----------------------------------|-----------|----------------------|
| | Total no. | Expulsion | Total no. | Expulsion | |
| Dedicated inserter | 50 | 2 (4.0) | n=271 | 23 (8.5) | 0.531 |
| Forceps insertion | 43 | 1 (2.3) | 196 | 12 (6.1) | 0.318 |

Abbreviation: IUD, intrauterine device.

^aValues are given as number (percentage).

^bBy Fisher exact test.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

File S1. STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist.