



Original Article

## Immediate Postpartum Levonorgestrel IUD Versus CuT380A: Expulsion, Continuation, and Satisfaction at 12 Months—A Randomised Controlled Trial

Dr Khushboo Joshi<sup>1</sup>, Dr Swati Phalodia<sup>2</sup>, Dr Mukesh Valmiki<sup>3</sup>

<sup>1</sup>Assistant professor, S.P Medical College Bikaner Rajasthan

<sup>2</sup>Senior Professor, S P Medical college Bikaner Rajasthan

<sup>3</sup>Senior Specialist, Gangashaher Satellite Dispensary Bikaner Rajasthan

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### Corresponding Author:

**Dr Khushboo Joshi**

Assistant professor, S.P Medical  
College Bikaner Rajasthan

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### ABSTRACT

**Background:** Immediate postpartum intrauterine device (IUD) insertion improves access to long-acting reversible contraception, but expulsion and bleeding-related discontinuation can affect long-term use.

**Objective:** To compare expulsion, continuation, and satisfaction at 12 months following immediate postpartum insertion of LNG-IUD versus CuT380A.

**Methods:** This single-centre, open-label, randomised controlled trial was conducted at Gangashahar Government Satellite Hospital, Bikaner, Rajasthan. Postpartum women opting for intrauterine contraception were randomised 1:1 to immediate postpartum LNG-IUD (n=50) or CuT380A (n=50). Follow-up was planned at 6 weeks, 6 months, and 12 months. Primary outcomes were any expulsion (complete + partial) by 12 months, continuation at 12 months, and satisfaction at 12 months. Bleeding pattern and adverse events were also assessed. Analyses followed the intention-to-treat principle.

**Results:** Of 152 women assessed, 100 were randomised (50 per group). Twelve-month outcome data were available for 49/50 (98%) in each group. Any expulsion occurred in 16.0% (8/50) in the LNG-IUD group versus 24.0% (12/50) in the CuT380A group (RR 0.67, 95% CI 0.30–1.49). Most expulsions occurred by 6 weeks (LNG-IUD 75.0%; CuT380A 66.7% of expulsions). Continuation at 12 months was 70.0% (35/50) versus 66.0% (33/50) (RR 1.06, 95% CI 0.81–1.39). Among continuers, high satisfaction (score 4–5/5) was reported by 85.7% (30/35) versus 78.8% (26/33) (RR 1.09, 95% CI 0.87–1.36). At 12 months, amenorrhea was more common with LNG-IUD (30.6%) than CuT380A (2.0%), while heavy bleeding was less frequent (6.1% vs 22.4%). Suspected infection/endometritis occurred in 4.0% in each group; no perforations or pregnancies were recorded.

**Conclusion:** Immediate postpartum LNG-IUD and CuT380A showed similar 12-month continuation, with expulsions occurring predominantly in the first 6 weeks. LNG-IUD demonstrated a more favourable bleeding profile and high satisfaction among continuers. Strengthening fundal placement technique and ensuring early follow-up may optimise postpartum IUD outcomes in public-sector settings.

**Keywords:** postpartum contraception; LNG-IUD; CuT380A; expulsion; continuation; satisfaction; randomized controlled trial.

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### INTRODUCTION

The immediate postpartum period is a high-impact window for initiating effective contraception because women are already in contact with the health system and may have limited ability to return for interval family planning visits. Postpartum intrauterine contraception (PPIUD) offers long-acting, user-independent protection and can help reduce short interpregnancy intervals, which are clinically associated with adverse maternal and perinatal outcomes.

Immediate postpartum IUD insertion is safe and highly effective, but programmatic scale-up is often limited by concerns around expulsion, early discontinuation, and variable experiences with bleeding and cramping. In a recent systematic literature review, expulsions were noted to occur predominantly in the early outpatient period with wide variability across settings, while serious complications (infection/perforation) remained uncommon and pregnancies were rare and usually occurred after discontinuation rather than device failure [1-4]

Evidence from public-sector and LMIC program settings demonstrates that postpartum IUD services can achieve high acceptability and satisfaction when counselling and follow-up are integrated. In Zambia, a large observational program reported favourable continuation and very high satisfaction, with expulsion rates that were considered acceptable for postpartum insertion programs [1]. Similarly, expulsion and satisfaction data from peri-urban Lusaka showed encouraging satisfaction alongside measurable expulsion rates, reinforcing the importance of insertion technique and follow-up in postpartum cohorts [2-3].

Indian data also support postpartum IUCD feasibility and acceptability in routine clinical practice. A comparative study reported better acceptability, continuation, and satisfaction with immediate postpartum IUCD insertion compared with delayed insertion, highlighting the service-delivery advantage of offering the method during the delivery admission itself [2]. In addition, innovations aimed at improving high fundal placement—such as a dedicated postpartum IUD inserter—have shown promising pilot experience in Indian public hospitals, supporting safer, standardised insertion and potentially improving user experience and outcomes [5].

International guidance increasingly emphasises institutionalising postpartum family planning within maternity services. The FIGO position statement on postpartum intrauterine devices advocates integrating PPIUD into routine obstetric care through provider training, high-quality counselling, and systems for follow-up—components that are particularly relevant to busy government facilities [6].

Despite expanding postpartum IUCD services, direct comparative clinical evidence for immediate postpartum LNG-IUD versus CuT380A in Indian public-sector settings remains limited, and method-specific bleeding patterns may materially influence continuation and satisfaction over time. This randomised controlled trial at Gangashahar Government Satellite Hospital, Bikaner (Rajasthan) was designed to compare expulsion, continuation, and satisfaction at 12 months following immediate postpartum insertion of LNG-IUD versus CuT380A.

## AIM

To compare immediate postpartum LNG-IUD versus CuT380A at 12 months in terms of expulsion, continuation, and satisfaction.

## OBJECTIVES

1. To compare IUD expulsion (complete + partial) within 12 months after immediate postpartum insertion of LNG-IUD versus CuT380A.
2. To compare continuation rates at 12 months between the two groups.
3. To compare patient satisfaction at 12 months between the two groups.
4. To compare bleeding patterns and pain/cramping symptoms during follow-up in both groups.
5. To compare safety outcomes (infection/endometritis, missing strings/malposition, uterine perforation, and pregnancy) over 12 months.
6. To document reasons for discontinuation/removal and identify predictors of expulsion or discontinuation.

## METHODS

### Study design and setting

This was a single-centre, open-label, parallel-group randomised controlled trial conducted in the Department of Obstetrics & Gynaecology at Gangashahar Government Satellite Hospital, Bikaner, Rajasthan, India. Participants were enrolled during the delivery admission and followed for 12 months after insertion.

### Participants

Postpartum women delivering at the study hospital who desired intrauterine contraception were screened and counselled for immediate postpartum IUD insertion. Written informed consent was obtained before randomisation.

### Eligibility criteria

#### Inclusion criteria

- Women aged 18–45 years delivering (vaginal or cesarean) at the study hospital
- Willing for immediate postpartum IUD insertion and follow-up for 12 months
- Eligible for IUD as per standard medical eligibility criteria

### Exclusion criteria

- Clinical suspicion/diagnosis of chorioamnionitis, puerperal sepsis, or active genital tract infection
- Uncontrolled postpartum hemorrhage or uterine atony requiring ongoing intervention
- Prolonged rupture of membranes with infection concern (as per institutional protocol)
- Known uterine anomaly or significant fibroid distorting the uterine cavity
- Known hypersensitivity/contraindication to either device (LNG-IUD or copper IUD)
- Any other condition judged by the treating clinician to make immediate insertion unsafe

### Sample size

A total of 100 participants were randomised (50 per group). The sample size was planned as a pragmatic departmental RCT to compare clinically important differences in expulsion, continuation, and satisfaction over 12 months.

### Randomisation and allocation concealment

Participants were randomised in a 1:1 ratio to LNG-IUD or CuT380A using a computer-generated random sequence. Allocation was concealed using sequentially numbered, opaque, sealed envelopes opened only after consent and confirmation of eligibility. Due to the nature of the intervention, blinding of participants and providers was not feasible.

### Interventions

Participants received either:

- Immediate postpartum LNG-IUD, or
- Immediate postpartum CuT380A

**Timing of insertion:** Post-placental insertion was performed within 10 minutes of placental delivery (preferred) and up to within 48 hours postpartum as per institutional postpartum insertion protocol; timing was recorded for each participant.

### Insertion technique:

- **After vaginal delivery:** High fundal placement was performed using sterile technique (e.g., long forceps/manual technique as per training), ensuring fundal positioning.
- **During cesarean delivery:** The device was placed at the uterine fundus through the uterine incision before closure, with strings directed towards the cervix (not deliberately pulled through).

All insertions were performed by trained obstetricians/residents as per departmental protocol. Standard post-insertion counselling was provided, including warning signs (expulsion, fever, foul discharge, excessive bleeding, severe pain) and the follow-up schedule.

### Follow-up and data collection

Participants were followed at 6 weeks, 6 months, and 12 months post-insertion through outpatient visits (or telephonic contact with in-person evaluation when clinically indicated). At each follow-up, data were collected on:

- Device status (in situ/expelled/removed)
- Symptoms (bleeding pattern, pain/cramping)
- Adverse events (fever, foul discharge, suspected infection, hospitalisation)
- String visibility and need for evaluation (speculum exam/ultrasound if required)
- Satisfaction assessment at 12 months

If strings were not visible or expulsion was suspected, pelvic examination and/or ultrasound were done as per clinical need to confirm device position. Women with expulsion or requested removal were managed according to standard clinical practice and counselled for alternative contraception.

### Outcomes and operational definitions

#### Expulsion:

- Complete expulsion: device completely expelled from the uterus.
  - Partial expulsion: device partially expelled or displaced (e.g., visible in cervix/vagina) requiring removal.
- The primary expulsion outcome was any expulsion (complete + partial) within 12 months.

Continuation at 12 months: Device in situ and participant continuing use at the 12-month assessment (or confirmed within the 12-month window if visit delayed).

Satisfaction: Assessed at 12 months using a 5-point Likert scale (1=very dissatisfied to 5=very satisfied). Satisfaction was analysed as both mean/median score and proportion “satisfied/very satisfied” (scores 4–5).

Safety outcomes: Suspected pelvic infection/endometritis, missing strings, malposition (confirmed clinically/ultrasound), uterine perforation, and pregnancy.

### Statistical analysis

Data were analysed using standard statistical software SPSS version 26. Continuous variables were summarised as mean (SD) or median (IQR), depending on distribution; categorical variables as frequency (%). Group comparisons for categorical outcomes (expulsion, continuation, satisfaction categories, adverse events) used the Chi-square or Fisher's exact test. Continuous outcomes (e.g., satisfaction score, pain score) used t-test or Mann–Whitney U test as appropriate. Effect estimates were reported as risk ratio (RR) or risk difference with 95% confidence intervals. The primary analysis followed the intention-to-treat principle; sensitivity analyses (per-protocol) were performed where relevant. Missing outcome data were reported, and if minimal, handled with complete-case analysis; if substantive, appropriate imputation/sensitivity methods were considered.

### Ethics and trial conduct

The study was conducted after approval from the Institutional Ethics Committee and in accordance with ethical standards for human research. Participants provided written informed consent, confidentiality was maintained, and women could withdraw at any time without affecting clinical care. Adverse events were documented and managed in accordance with institutional protocols.

## RESULTS

### 1. Participant flow (CONSORT)

During the study period, 152 postpartum women delivering at Gangashahar Government Satellite Hospital, Bikaner, were assessed for eligibility for immediate postpartum intrauterine contraception. Fifty-two women were excluded before randomization: 18 did not meet eligibility criteria (most commonly suspected/confirmed genital tract infection/chorioamnionitis, ongoing postpartum hemorrhage/uterine atony requiring active management, or other medical contraindications), 27 declined participation after counseling (preference for another method or family/partner reasons), and 7 were excluded for other reasons (e.g., inability to ensure follow-up/contact details not available or withdrawal before allocation). The remaining 100 women were randomised in a 1:1 ratio to LNG-IUD (n=50) or CuT380A (n=50), and all received the allocated intervention during the delivery admission.

Follow-up to 12 months was high. At 12 months, outcome data were available for 49/50 (98%) participants in each group; one woman in each arm was lost to follow-up (unreachable/relocated). The intention-to-treat (ITT) analysis included all randomised women (n=100), with missing 12-month outcomes documented as loss to follow-up (Figure 1).

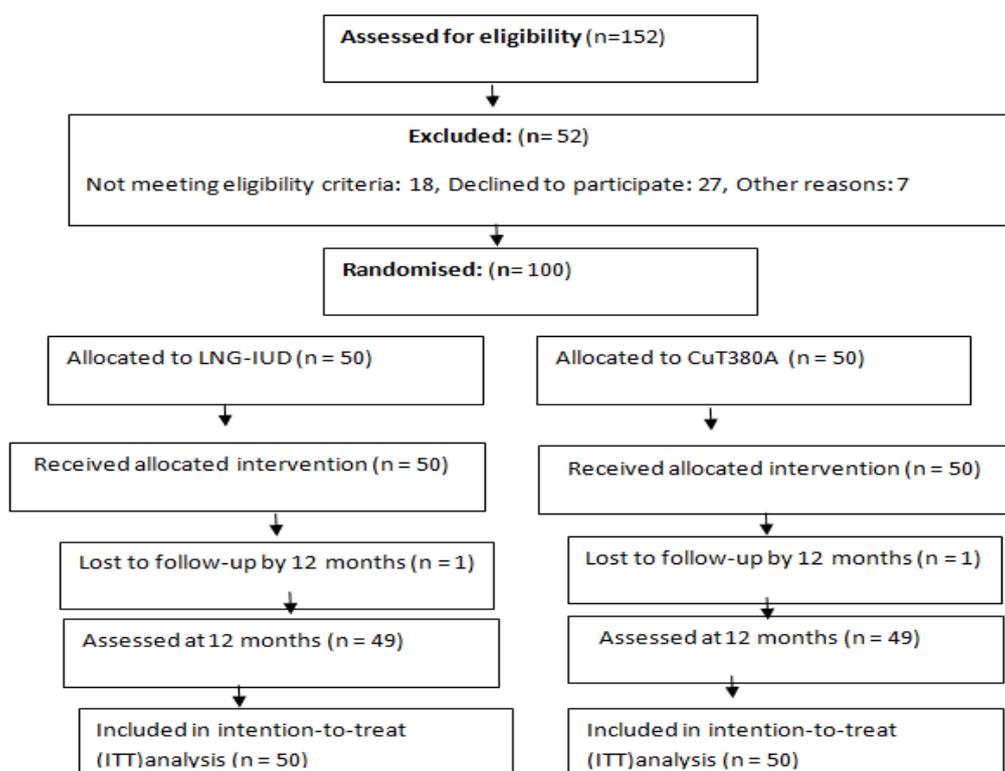


Figure 1 (CONSORT flow diagram)

## 2. Baseline demographic and clinical characteristics

Baseline demographic, obstetric, and clinical characteristics were comparable between the two groups (Table 1). The mean age was  $24.9 \pm 3.9$  years in the LNG-IUD group and  $25.5 \pm 3.4$  years in the CuT380A group ( $p=0.412$ ). Parity distribution was similar across groups (median parity 2 [IQR 1–2] in both arms). The mode of delivery was balanced, with 62.0% vaginal births and 38.0% cesarean births in each group. Mean baseline haemoglobin was  $10.94 \pm 0.89$  g/dL in the LNG-IUD group and  $11.03 \pm 0.85$  g/dL in the CuT380A group ( $p=0.635$ ). The timing of insertion was also comparable, with a median insertion time of 9 (IQR 6–11) minutes in the LNG-IUD arm versus 8 (IQR 6–12) minutes in the CuT380A arm ( $p=0.956$ ).

**Table 1. Baseline characteristics of participants by randomised group (n=100)**

Characteristic	LNG-IUD (n=50)	CuT380A (n=50)	p-value
Age (years), mean $\pm$ SD	$24.9 \pm 3.9$	$25.5 \pm 3.4$	0.412
Parity, median (IQR)	2 (1–2)	2 (1–2)	—
Mode of delivery, n (%)			
• Vaginal	31 (62.0)	31 (62.0)	1.000
• Caesarean	19 (38.0)	19 (38.0)	
Haemoglobin (g/dL), mean $\pm$ SD	$10.94 \pm 0.89$	$11.03 \pm 0.85$	0.635
Insertion time (minutes), median (IQR)	9 (6–11)	8 (6–12)	0.956

Values are presented as mean  $\pm$  SD, median (IQR), or n (%), as appropriate. p-values reflect between-group comparisons for the listed variables where applied.

## 3. Primary outcomes at 12 months (intention-to-treat)

At 12 months, any expulsion (complete + partial) occurred in 16.0% (8/50) of participants in the LNG-IUD group compared with 24.0% (12/50) in the CuT380A group (RR 0.67, 95% CI 0.30–1.49;  $p=0.454$ ). Continuation at 12 months (device in situ and continuing use) was 70.0% (35/50) in the LNG-IUD group and 66.0% (33/50) in the CuT380A group (RR 1.06, 95% CI 0.81–1.39;  $p=0.830$ ).

Among women continuing the assigned method at 12 months, high satisfaction (score 4–5/5) was reported by 85.7% (30/35) in the LNG-IUD group and 78.8% (26/33) in the CuT380A group (RR 1.09, 95% CI 0.87–1.36;  $p=0.534$ ). Mean satisfaction scores among continuers were  $4.06 \pm 0.59$  versus  $3.94 \pm 0.70$  ( $p=0.459$ ). Primary outcomes are summarised in Table 2.

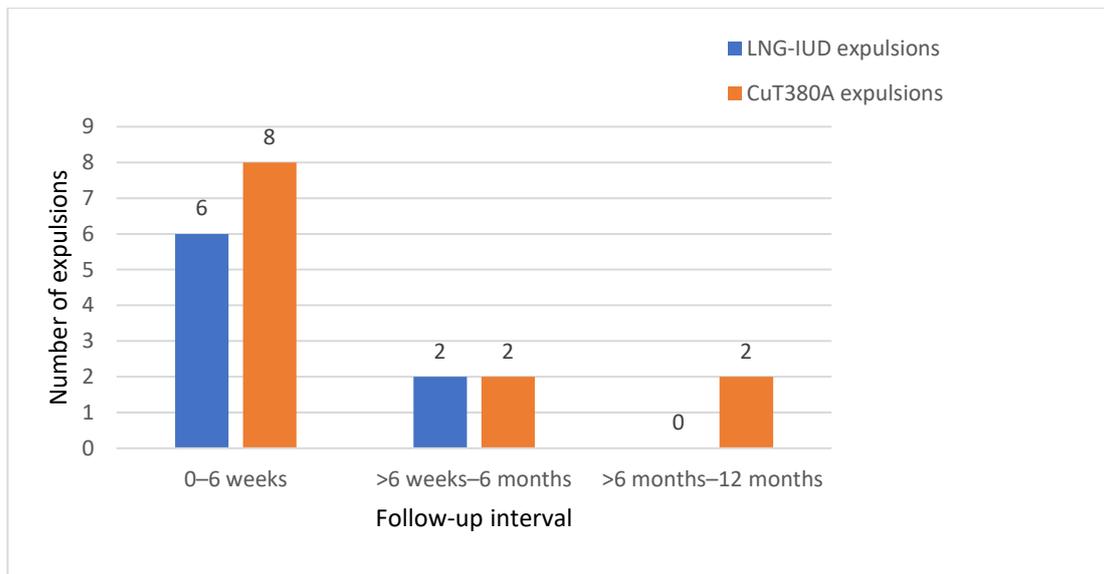
**Table 2. Primary outcomes at 12 months (intention-to-treat analysis)**

Outcome	LNG-IUD	CuT380A	Effect estimate	p-value
Any expulsion (complete + partial) by 12 months, n/N (%)	8/50 (16.0)	12/50 (24.0)	RR 0.67 (95% CI 0.30–1.49)	0.454
Continuation at 12 months (in situ), n/N (%)	35/50 (70.0)	33/50 (66.0)	RR 1.06 (95% CI 0.81–1.39)	0.830
High satisfaction (score 4–5/5) among continuers at 12 months, n/N (%)	30/35 (85.7)	26/33 (78.8)	RR 1.09 (95% CI 0.87–1.36)	0.534
Satisfaction score among continuers (1–5), mean $\pm$ SD	$4.06 \pm 0.59$ (n=35)	$3.94 \pm 0.70$ (n=33)	Mean difference 0.12	0.459

RR = risk ratio; CI = confidence interval. Satisfaction outcomes are reported among women continuing the assigned method at 12 months.

## 4. Timing of expulsions by follow-up interval

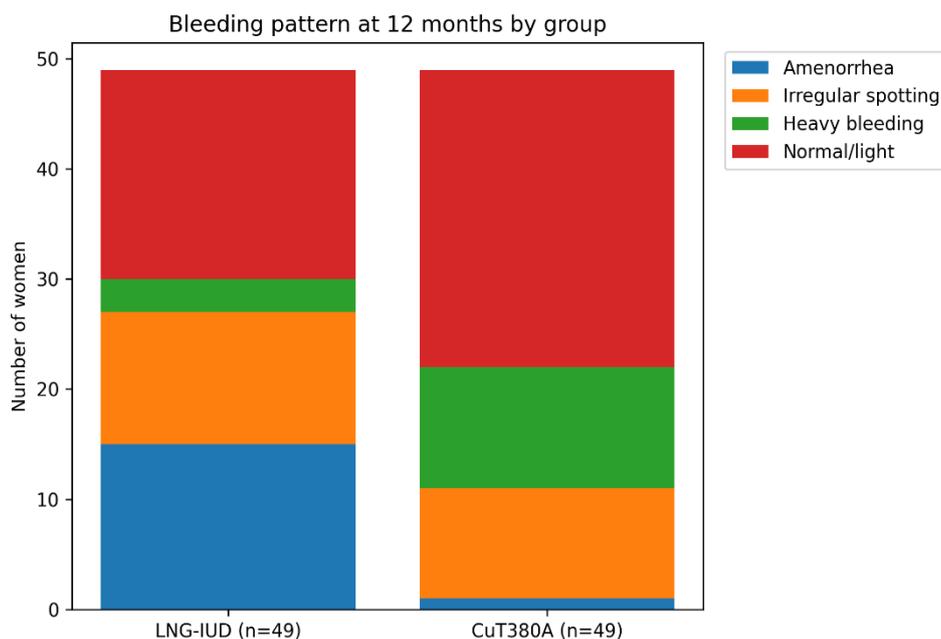
Expulsions were concentrated in the early postpartum period (Figure 2). In the LNG-IUD group, 6 of 8 expulsions (75.0%) occurred within 0–6 weeks, while 2 (25.0%) occurred between >6 weeks and 6 months, and none occurred after 6 months. In the CuT380A group, 8 of 12 expulsions (66.7%) occurred within 0–6 weeks, 2 (16.7%) occurred between >6 weeks and 6 months, and 2 (16.7%) occurred between >6 months and 12 months. Overall, the first 6 weeks accounted for the majority of expulsions in both groups, supporting the clinical importance of early postpartum follow-up.



**Figure 2. Timing of expulsions by follow-up interval and device type**

### 5. Bleeding pattern and symptom profile

Bleeding patterns at 12 months differed between the two groups (Figure 3). Amenorrhea was more frequent in the LNG-IUD group (15/49 [30.6%]) compared with the CuT380A group (1/49 [2.0%],  $p < 0.001$ ). In contrast, heavy bleeding was more commonly reported with CuT380A (11/49 [22.4%]) than with LNG-IUD (3/49 [6.1%],  $p = 0.040$ ). Irregular spotting was reported by 12/49 (24.5%) in the LNG-IUD group and 10/49 (20.4%) in the CuT380A group. Overall, the distribution of bleeding patterns at 12 months was significantly different between groups ( $p < 0.001$ ). Pain/cramping scores at 12 months were low and comparable ( $1.53 \pm 1.07$  vs  $1.71 \pm 1.11$ ,  $p = 0.401$ ).



### 6. Safety outcomes and adverse events

Safety outcomes were comparable between the two groups (Table 3). Suspected pelvic infection/endometritis occurred in 2/50 (4.0%) participants in each arm ( $p = 1.000$ ). Missing strings at early follow-up were noted in 8/50 (16.0%) in the LNG-IUD group and 4/50 (8.0%) in the CuT380A group ( $p = 0.357$ ); these cases were evaluated as per protocol (clinical examination  $\pm$  ultrasound as indicated). No uterine perforations and no pregnancies were recorded during the 12-month follow-up.

**Table 3. Adverse events and safety outcomes (n=100)**

Safety outcome	LNG-IUD (n=50)	CuT380A (n=50)	p-value
Suspected infection/endometritis, n (%)	2 (4.0)	2 (4.0)	1.000
Missing strings (early follow-up), n (%)	8 (16.0)	4 (8.0)	0.357
Uterine perforation, n (%)	0 (0.0)	0 (0.0)	—
Pregnancy during follow-up, n (%)	0 (0.0)	0 (0.0)	—

*P-values are from Chi-square or Fisher's exact test as appropriate. "—" indicates a p-value is not applicable due to zero events in both groups.*

### 7. Discontinuation and reasons for removal

By 12 months, discontinuation (expulsion or removal) occurred in 14/50 (28.0%) participants in the LNG-IUD group and 16/50 (32.0%) in the CuT380A group ( $p=0.828$ ). Expulsion was the predominant contributor to discontinuation in both groups (8/50 [16.0%] vs 12/50 [24.0%]). Removals (excluding expulsions) occurred in 6/50 (12.0%) LNG-IUD users and 4/50 (8.0%) CuT380A users ( $p=0.741$ ). The most common removal indication was bleeding/spotting (LNG-IUD 3/50 [6.0%]; CuT380A 2/50 [4.0%]), followed by pain/cramping (both 1/50 [2.0%]). Other removal reasons were infrequent (Table 4).

**Table 4. Reasons for discontinuation/removal by 12 months (n=100)**

Outcome/reason	LNG-IUD (n=50)	CuT380A (n=50)	p-value
<b>Any discontinuation</b> (expulsion or removal), n (%)	14 (28.0)	16 (32.0)	0.828
<b>Expulsion</b> (complete + partial), n (%)	8 (16.0)	12 (24.0)	0.454
<b>Removal (any reason)</b> , n (%)	6 (12.0)	4 (8.0)	0.741
• Removal due to bleeding/spotting, n (%)	3 (6.0)	2 (4.0)	1.000
• Removal due to pain/cramping, n (%)	1 (2.0)	1 (2.0)	1.000
• Removal due to other reasons, n (%)	2 (4.0)	1 (2.0)	1.000

## DISCUSSION

Our trial adds clinically relevant comparative data on immediate postpartum LNG-IUD versus CuT380A in a government maternity setting, where the dominant determinant of one-year performance remains early expulsion rather than late adverse events. We observed any expulsion in 16% of LNG-IUD users versus 24% of CuT380A users, with most expulsions occurring by 6 weeks (75% and 67% of expulsions, respectively). Despite expulsions, 12-month continuation remained substantial (70% vs 66%), and satisfaction among continuers was high (86% vs 79% reporting scores 4–5/5). These patterns reinforce the counselling message that immediate postpartum initiation can deliver strong contraceptive coverage at one year, provided women are prepared for an early expulsion window and are linked to early follow-up.

Kapp and Curtis (2009) synthesised postpartum IUD insertion evidence and concluded that immediate post-placental copper IUD insertion is generally safe, while expulsion rates are higher than interval insertion and vary widely by study conditions; importantly, their review included copper IUDs only and identified no LNG-IUD postpartum studies at the time [7]. This matters for interpretation: the overall expulsion range in postpartum programs has long been expected to be broader than interval practice, and our observed expulsion levels (mid-teens to mid-twenties) fall within the plausible spectrum when expulsions are actively ascertained, and partial expulsions are included as clinically relevant failures [7]. Mode of delivery and placement conditions are major drivers of expulsion variability, particularly because fundal placement at caesarean can be performed under direct visualisation. Levi et al. (2012), in a prospective cohort of immediate postplacental IUD insertion during caesarean delivery, reported no expulsions among women returning at 6 weeks (43/90 returned) and 80% “happy/very happy” at 6 months among those reached by phone follow-up [8]. While their follow-up completeness was limited, their “low-expulsion, high-acceptability” caesarean signal is consistent with what many intracaearean programs observe. In our trial (with a balanced mix of vaginal and caesarean births), the early clustering of expulsions supports a practical approach: optimise fundal placement and ensure a 6-week contact, because that is where most expulsion-related method failures declare themselves.

More recent LNG-IUD-specific postpartum evidence helps benchmark our LNG arm. Desai et al. (2024) analysed immediate postpartum LNG-IUD insertions and reported an overall expulsion rate of 14.4% across 647 insertions, with no significant difference by insertion technique (manual vs ring forceps vs device applicator) [9]. Our LNG-IUD expulsion (16%) is numerically close to that large-series estimate, supporting the plausibility that, when high fundal placement is consistently achieved, LNG-IUD expulsion in immediate postpartum practice can remain in the mid-teens. Where our study diverges is the point estimate suggesting higher expulsion with CuT380A than LNG-IUD; given our sample size and wide confidence interval, this difference is best interpreted as context-sensitive rather than device-intrinsic, and could reflect delivery-mix, provider technique variation during high-volume vaginal insertions, or differential detection of partial expulsions.

Copper-IUD postpartum studies from the region illustrate how expulsion estimates can shift with follow-up windows and program conditions. Das et al. (2022), evaluating postpartum CuT380A, reported an overall expulsion rate of 5.6% at 3

months and 8.4% at 6 months, and noted markedly higher expulsion in the presence of infection (e.g., 22.7% with infection vs 3.9% without) [10]. Those mid-single-digit to high-single-digit expulsions at  $\leq 6$  months are lower than our 12-month CuT380A expulsion (24%), but the difference is numerically plausible once two factors are considered: (i) expulsion accumulates over time, and (ii) measured expulsion depends heavily on how aggressively expulsions (including partial expulsions) are detected and recorded. In routine government-sector practice, where women may return for symptoms and expulsion detection is often symptom-triggered, studies with structured follow-up and explicit expulsion definitions can report higher rates than those relying on passive reporting—so the direction of “higher” versus “lower” expulsion across studies may reflect ascertainment intensity as much as performance.

Indian program experience also provides a concrete benchmark for complications and continuation. Mishra (2014) reported outcomes after postplacental and intra-caesarean CuT380A insertion with follow-up out to 6–18 months; among 434 women followed, there were 39 expulsions (~9%), bleeding complaints were common (102 cases), string problems were noted (49 cases), and overall continuation among those followed was high (352/434, ~81%) with 43 removals (~10%) [11]. That profile—bleeding and string issues being frequent “clinical touchpoints,” while serious events remain rare—resembles our safety experience (no perforations, low suspected infection) and supports a consistent counselling emphasis: women should expect that minor symptoms and string visibility issues are part of postpartum IUD care pathways, and early follow-up is where reassurance and management most improve continuation.

The contrast between “immediate postplacental” and broader “early postpartum” placement windows is critical for interpreting hormonal-IUD expulsion. Lichtenstein Liljeblad et al. (2022) conducted an open-label multicenter RCT of early postpartum hormonal IUD insertion within 48 hours after vaginal delivery versus standard 6–8-week placement and stopped early due to a very high expulsion rate: 23/52 (44.2%) expulsions in the early group and 0 expulsions in the standard group, despite high ongoing method use after reinsertion [12]. Their 44% expulsion rate is far above our LNG-IUD expulsion (16%), but the difference is coherent when timing and technique context are considered: “within 48 hours” postpartum after vaginal delivery can behave differently from strictly postplacental high-fundal placement and may include placements during a period of rapid cervical and uterine change. Clinically, this supports a nuanced message: early postpartum hormonal IUD placement can still yield high eventual method use, but the expulsion penalty is highly timing-dependent, and services should be explicit about this when choosing between immediate postplacental vs later postpartum insertion windows.

Bleeding differences in our trial were large and aligned with randomised comparative bleeding literature. Perelló-Capó et al. (2023) compared an LNG 13.5 mg IUD with a copper 380 mm<sup>2</sup> IUD and concluded that the LNG IUD was associated with a significant reduction in blood loss and dysmenorrhea compared with copper [13]. Our 12-month bleeding pattern parallels that direction: amenorrhea was common with LNG-IUD (~31%) and rare with CuT380A (~2%), while heavy bleeding was notably higher with CuT380A (~22%) than LNG-IUD (~6%). Numerically, those proportions are consistent with the clinical expectation that LNG devices shift users toward lighter bleeding/amenorrhea and away from heavy bleeding, whereas copper devices can increase flow in a meaningful minority—an effect that becomes particularly relevant in regions with higher baseline anaemia.

Our device-specific expulsion direction (Cu higher than LNG) contrasts with the largest pooled synthesis on postpartum expulsion by type and timing. Averbach et al. (2020) reported that, compared with interval placement, immediate postpartum placement carries a much higher expulsion risk, and that expulsion is substantially higher after vaginal delivery than caesarean (adjusted RR 4.57). They also found that among immediate postpartum placements at vaginal delivery, LNG-IUDs had a higher risk of expulsion than copper IUDs (adjusted RR 1.90) [14]. Our findings do not replicate that direction, but they remain statistically compatible with it: our RR for LNG vs copper is  $< 1$  with a wide CI, in a modest sample, and with a mixed delivery cohort in which intracerebral placement can reduce expulsions and potentially dampen type-related contrasts. This is exactly the kind of regional and methodological variation Averbach et al. emphasise: timing definitions, expulsion definitions (complete vs partial), delivery mix, provider training, and follow-up intensity can move expulsion estimates by 10–30 percentage points and can even reverse apparent “device advantages” in small trials.

Finally, our safety outcomes (low suspected infection, no perforation, no pregnancy) are consistent with guideline-focused safety reviews. Mwalwanda and Black (2013) reviewed immediate postpartum intrauterine contraception and implants and concluded that adverse effects such as pain, bleeding, infection, and perforation are generally low across studies, while expulsion is higher immediately after vaginal delivery than interval insertion but not higher after caesarean placement, and most evidence-based guidelines support immediate postpartum provision because benefits often outweigh the risks [15]. In a government hospital context like ours, that conclusion translates into actionable service priorities: (i) standardized training for high fundal placement (especially for vaginal deliveries), (ii) a scheduled early postpartum contact to detect expulsion and address missing strings, and (iii) anticipatory counselling tailored to bleeding expectations—particularly emphasizing the LNG-IUD’s higher likelihood of amenorrhea/lighter bleeding versus the copper IUD’s higher likelihood of heavier bleeding in a subset.

## Limitations

This was a single-centre, open-label trial with a modest sample size (n=100), limiting power to detect small differences in expulsion and continuation and reducing generalizability beyond similar government-hospital settings. Expulsion ascertainment could vary by follow-up attendance and symptom-driven reporting, and subgroup analyses (e.g., by delivery mode) were not adequately powered.

## CONCLUSION

Immediate postpartum LNG-IUD and CuT380A demonstrated comparable 12-month continuation, with expulsions occurring predominantly in the first 6 weeks. LNG-IUD was associated with a more favourable bleeding profile (higher amenorrhea and lower heavy bleeding) and high satisfaction among continuers. Strengthening fundal placement technique and ensuring early follow-up are key to optimising outcomes in public-sector postpartum IUD programs.

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