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A prospective cohort study comparing expulsion after postplacental insertion: the levonorgestrel versus the copper intrauterine device☆,☆☆

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ABSTRACT

Objectives: To compare the expulsion rate at 6 months after postplacental insertion by intrauterine device (IUD) type.

Study design: This prospective cohort included participants with a postplacental IUD inserted after vaginal or cesarean delivery, aged 18–45 and ≥24 weeks' gestation. Study enrollment took place after IUD selection and insertion. Participants returned for a postpartum visit and received a short message service survey regarding IUD expulsion, removal, vaginal bleeding and breastfeeding weekly from weeks 0 to 5 and on weeks 12 and 24 postpartum. Multivariable logistic regression examined 6-month expulsion rate by IUD type adjusting for variables that differed between the groups at baseline and in the bivariate analyses.

Results: Of 114 participants, 75 (65.8%) chose a levonorgestrel 52-mg IUD and 39 (34.2%) chose a copper IUD; 58 (50.9%) had a vaginal delivery, and 56 (49.1%) had a cesarean delivery. Groups were similar except that copper IUD users had a higher median parity (3 vs. 2, p=.03) and a higher proportion of senior residents compared to junior residents had performed insertion (46.2% vs. 22.7%, p=.02). The expulsion rate at 6 months was similar between the levonorgestrel and copper groups (26.7% and 20.5%, respectively; p=.38). Multivariable logistic regression also demonstrated that the odds of expulsion did not differ by IUD type (adjusted odds ratio 0.98, 95% confidence interval 0.22–4.48).

Conclusion: The expulsion rate at 6 months after postplacental insertion did not differ between the levonorgestrel and copper IUD type.

Implications: Prior studies demonstrate a wide range of expulsion after postplacental insertion, and recent data suggest a higher expulsion rate for the levonorgestrel compared to the copper intrauterine device. However, many studies did not control for patient-level factors or delivery route. We found that when controlling for these confounding variables, the expulsion rate at 6 months postpartum did not differ by intrauterine device type.

1. Introduction

Postplacental intrauterine device (IUD) insertion (placement within 10 min of placental delivery) is increasingly available in the United States with evidence supporting safety, efficacy and cost-effectiveness [1–4]. Despite these benefits, one disadvantage is a higher rate of expulsion when compared to interval insertion (placement unrelated to timing of delivery, usually after 6–8 weeks postpartum).

Expulsion rates following postplacental insertion vary widely across studies, ranging from 0% to 46.7% at 3–12 months postpartum [5–21]. A recent meta-analysis found that postplacental IUD insertion had over a sevenfold higher risk of expulsion than interval insertion. Expulsion was higher for the levonorgestrel 52 mg (LNG) IUD compared to the Copper T380A (Cu) IUD and after vaginal delivery versus cesarean delivery [21]. These findings suggest that both IUD type and delivery route are

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predictors of expulsion. However, the wide range of expulsion rates across studies may reflect the inclusion of studies with differing diagnostic criteria for expulsion, varied methods of confirming expulsions and varying lengths of follow-up. In addition, the meta-analysis examined factors at a study level and could not control for confounding variables.

We aimed to compare the expulsion rate at 6 months after postplacental insertion by IUD type while controlling for clinical and demographic factors associated with expulsion. Secondarily, we aimed to compare IUD expulsion by delivery route and to compare IUD removal, breastfeeding and vaginal bleeding patterns after postplacental insertion of the LNG or Cu IUD.

2. Materials and methods

We conducted this prospective cohort study at Bellevue Hospital Center in New York City from August 2016 to January 2018. The New York University School of Medicine Institutional Review Board approved this study. We included women if they had a postplacental LNG or Cu IUD placed after vaginal or cesarean delivery and provided written informed consent in English or Spanish. We excluded women if they were aged <18 or >45 years, delivered at <24 weeks of gestation or did not have a cellular phone with short message service (SMS) capability.

2.1. Insertion technique

Prior to starting the study, all residents, faculty and certified nurse midwives received training on postplacental IUD insertion technique by a family planning faculty member according to institutional protocol. We repeated training at the start of each academic year for the incoming residents and for any new providers. Providers inserted the IUD with ring forceps for both vaginal and cesarean deliveries. The supervising provider determined if the use of ultrasound guidance was necessary. After vaginal delivery, the provider cut the IUD strings flush with the external cervical os. After cesarean delivery, the provider directed the uncut IUD strings towards the lower uterine segment but not through the cervix.

2.2. Recruitment and enrollment

A study investigator approached all eligible women on the postpartum unit after delivery and IUD insertion was complete. The choice to have a postplacental IUD (including the type of device) and the mode of delivery had been determined prior to recruitment. All women had received either an LNG 52-mg IUD (Liletta®; Medicines360, San Francisco, CA, USA) or Copper T380A IUD (ParaGard®; CooperSurgical, Trumbull, CT, USA) based on patient preference. After written informed consent, a study investigator administered an electronic survey on an encrypted tablet to collect baseline contact and sociodemographic information. Participants received remuneration for their participation.

2.3. Data collection

A study investigator collected baseline clinical and demographic data via chart review and electronic survey prior to patient discharge. After discharge, we contacted participants for the first 5 weeks postpartum and also at 12 weeks and 24 weeks postpartum. We used Mosio ®, a mobile service which specializes in secure clinical data collection, to administer the SMS surveys. Surveys included four questions regarding IUD expulsion, IUD removal, breastfeeding and bleeding (Appendix A). We gave participants a pictorial blood loss assessment tool to aid in choosing their bleeding pattern (Appendix B). We used a translation service to translate all SMS text and handouts into Spanish. If we did not receive a response, the service sent a second and third text message 12 and 24 h later. If a participant did not respond after three text messages, we called participants on the provided alternate contact numbers. We considered a participant lost to follow-up if we did not receive a response after three failed phone call attempts and 2 weeks of failure to contact them by phone or SMS. We considered a participant to have a known 6-month expulsion status if they responded to the 6-month SMS survey or had a confirmed expulsion or removal prior to the 6-month follow-up SMS survey.

Participants returned for a 6-week postpartum visit with their obstetric provider and a study investigator attended each visit. The provider performed a speculum examination, and if IUD strings were not visible, transvaginal ultrasound (TVUS) was performed at the time of the visit to confirm IUD location. We defined complete expulsion as no evidence of an IUD inside the uterus by TVUS plus a clinical history consistent with expulsion, or patient report of expulsion with visualization of the IUD. We performed an abdominal radiograph if a patient did not report a clinical history of expulsion and no IUD was seen in the uterus by TVUS. We defined partial expulsion as an IUD protruding from the cervical os or TVUS showing the distal end of the IUD below the internal os of the cervix. We offered replacement of the IUD or an alternate method of contraception if the IUD was completely or partially expelled. We defined a recognized expulsion as an expulsion that a women reported (based on symptoms or visualization of the IUD) that was confirmed by TVUS.

2.4. Sample size calculation

We anticipated an expulsion rate of 27% [8] and 7% [6] for the LNG and Cu IUD, respectively. To detect this difference at 80% power, with a 0.05 two-sided alpha, we required 114 patients for final analysis. We accounted for an expected unequal IUD selection proportion based on institutional data. We expected that approximately 65% of the sample would choose the LNG IUD and 35% would choose the Cu IUD, requiring analysis of 75 in the LNG group and 39 in the Cu IUD group. Anticipating that approximately 10% of participants would decline to enroll and approximately 15% would be lost to follow-up, we aimed to screen 145 patients and enroll 136 participants.

2.5. Data analysis

We computed descriptive statistics and tested for normality. We summarized demographic and clinical characteristics in counts and proportions for categorical variables. We summarized continuous variables by mean and standard deviation if normally distributed or median and interquartile range if skewed. We compared characteristics between the LNG and the Cu IUD by using Fisher's Exact Test for categorical variables or Wilcoxon's rank sum test for continuous variables. We performed a multivariable logistic regression to quantify the association between the primary outcome of expulsion and IUD type while controlling for potential confounding variables including those that were significantly different ($p<.05$) between groups at baseline (parity, inserting provider level) and in bivariate analyses (delivery route, age, gestational age, postpartum hemorrhage, bleeding and breastfeeding status at 6 weeks postpartum, use of uterotonics and use of ultrasound guidance). We also included an interaction term in the multivariable logistic regression model to allow for the interaction between IUD type and delivery route on the primary outcome of expulsion. We considered breastfeeding and bleeding status as a priori exploratory outcomes and performed a generalized linear mixed effects models with a logit link function to assess their effect on expulsion over multiple time points throughout the study (at weeks 0, 1–5, 12 and 24 weeks postpartum). We imputed five participants' missing values for these variables based on the most common response for each respective variable (light/moderate bleeding and both breast and bottle feeding). We performed a sensitivity analyses assuming that participants who were lost to follow-up either all expelled the IUD or all retained the IUD. A p value <.05 was

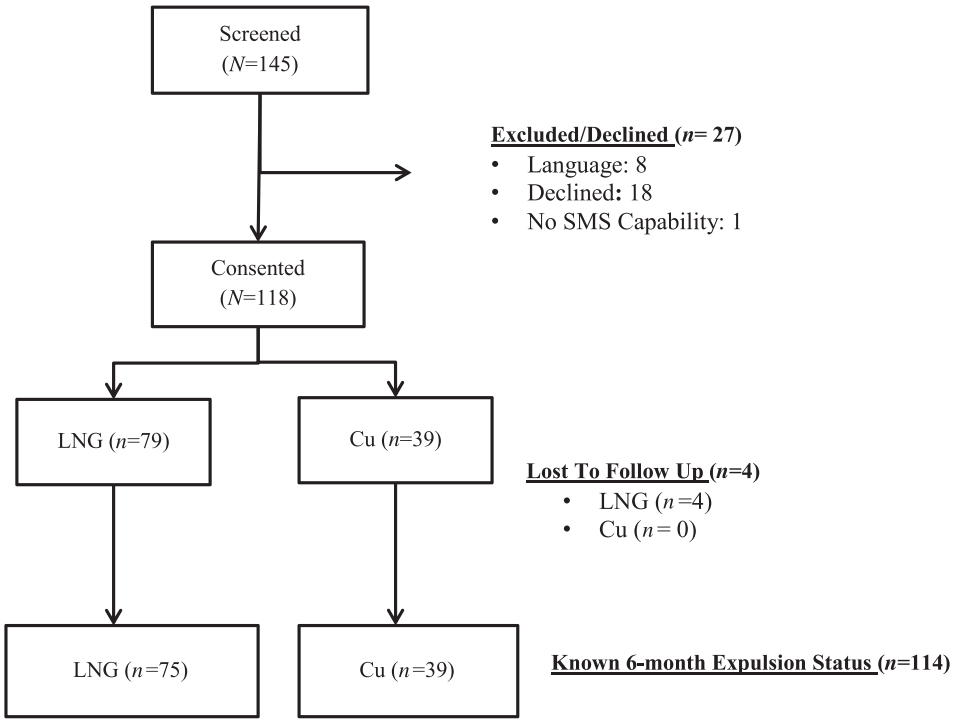

Fig. 1. Study enrollment and follow-up of participants choosing postplacental insertion of the LNG or Cu IUD in prospective cohort at a public hospital in New York City, August 2016 to January 2018.

considered to be statistically significant. We performed all analyses in SAS 9.4 (SAS Institute Inc., Cary, NC, USA).

3. Results

3.1. Participant characteristics

Fig. 1 summarizes participant enrollment and follow-up. Of the 114 women enrolled, 91 (79.8%) returned for a postpartum visit. Of these, 46 (50.5%) had visible strings on speculum examination, and the remainder 45 (49.5%) had a TVUS to confirm presence or absence of the IUD.

Table 1 summarizes baseline sociodemographic and clinical characteristics. Of the 114 women enrolled, 75 (65.8%) had selected an LNG IUD and 39 (34.2%) had selected a Cu IUD (Table 1). Fifty-eight (50.9%) had a vaginal delivery and 56 (49.1%) had a cesarean delivery. Groups were similar except that Cu IUD users had a higher median parity (3 vs. 2, p=.03) and a higher proportion of senior residents (18/39 or 46.2%) compared to junior residents (17/75 or 22.7%) had performed insertion (p=.02).

Overall SMS survey response rates were high (>70% at each study time point), with the response rate ranging from 79% to 87% from postpartum week 1 through 12 and with a nadir of 71% at postpartum week 24. The majority of respondents reported being completely satisfied (53.6%) or somewhat satisfied (34.5%) with the SMS survey as a means to collect data.

3.2. Primary outcome

Confirmed expulsions numbered 28/114 (24.5%) by 6 months postpartum. We confirmed 20/28 (71.4%) of expulsions at the postpartum visit and 8/28 (28.6%) by participant self-report (SMS followed by confirmation phone call). Of the 28 confirmed expulsions, 21 (75%) were complete, 7 (25%) were partial, and 22 (78.6%) of women recognized when their IUD expelled. The median time to expulsion was 23 days [interquartile range (IQR): 7– 52.5], which was similar for both the LNG and Cu IUD group (26.5 and 23 days, respectively).

The expulsion rate at 6 months (Table 2) was similar between the levonorgestrel and copper groups (20/28 or 26.7% and 8/39 or 20.5%, respectively; p=.38). Multivariable logistic regression (Table 3) also demonstrated that the odds of expulsion did not differ by IUD type [adjusted odds ratio (aOR) 0.98, 95% confidence interval (CI) 0.22–4.48]. A sensitivity analysis assuming that all four participants who were lost to follow-up expelled their IUD demonstrated that the expulsion rate at 6 months postpartum did not differ between the LNG and Cu IUD groups (24/79 or 30.4% and 8/39 or 20.5%, respectively; p=.80). Similarly, assuming all four participants who were lost to follow-up retained their IUD, the expulsion rate at 6 months postpartum did not differ between the LNG and Cu IUD groups (20/79 or 25.3% and 8/39 or 20.5%, respectively; p=.76).

3.3. Secondary outcomes

The expulsion rate at 6 months postpartum (Table 2) was higher after vaginal delivery than after cesarean delivery (25/58 or 43.1% vs. 3/36 or 5.4%, respectively; p<.001). Multivariable logistic regression (Table 3) also demonstrated that the odds of expulsion of remained higher after vaginal delivery when compared with cesarean delivery (aOR 10.10, 95% CI 1.71–59.84). In addition, women who had an LNG IUD placed after vaginal delivery had a higher odds of expulsion than women who had an LNG placed after cesarean delivery (aOR: 9.87, 95% CI 1.29–75.36). We did not find this difference in expulsion by delivery route for the Cu IUD, and there were no other significant predictors of expulsion.

Table 1
Demographic and clinical characteristics of participants choosing postplacental insertion of the LNG or Cu IUD in prospective cohort at a public hospital in New York City, August 2016 to January 2018 (N=114)

	LNG IUD (n=75)	Cu IUD (n=39)	p value
Sociodemographic characteristics			
Age (in years), mean ± SD	30.3±5.2	31.5±6.2	.28
Race			.15
Hispanic	40 (53.3%)	25 (64.1%)	
Black	21 (28.0%)	5 (12.8%)	
Asian	8 (10.7%)	4 (10.3%)	
White	4 (5.3%)	3 (7.7%)	
Other	2 (2.7%)	2 (5.1%)	
Insurance			1.00
None	1 (1.3%)	0 (0%)	
Public	71 (94.7%)	38 (97.4%)	
Private	3 (4.0%)	1 (2.6%)	
Marital status			.56
Single	29 (38.7%)	14 (35.9%)	
Married/cohabitating	40 (53.3%)	24 (61.5%)	
Separated/divorced/other	6 (8%)	1 (2.6%)	
Education			.15
<8th grade	7 (9.5%)	8 (20.5%)	
Some high school/high school graduate	27 (36.5%)	17 (43.6%)	
Some college/college graduate	37 (50.0%)	12 (30.8%)	
Beyond college	3 (4.1%)	2 (5.1%)	
Clinical characteristics			
Delivery type			.13
Vaginal delivery	42 (56.0%)	16 (41.0%)	
Cesarean delivery	33 (44.0%)	23 (59.0%)	
Parity	2 (1, 3)	3 (2, 4)	.03
Gestational age	39 (37.4, 39.2)	39 (37.2, 39.5)	.66
Pre-pregnancy BMI	27.9 (24.1, 32.4)	31.2 (26.9, 33.6)	.08
Labor induced	29 (38.7%)	14 (35.9%)	.77
Use of uterotonics	16 (21.3%)	12 (30.8%)	.27
Use of ultrasound guidance	4 (5.3%)	4 (10.3%)	.44
Provider level			.02
Junior resident (PGY1/PGY2)	56 (74.7%)	19 (48.7%)	
Senior resident (PGY3/PGY4)	17 (22.7%)	18 (46.2%)	
Attending/midwife	2 (2.7%)	2 (5.1%)	
Postpartum hemorrhage	16 (21.3%)	10 (25.6%)	.63

Categorical data are presented as n (%) with p values determined using Pearson χ^2 or Fisher's Exact Test where appropriate. Continuous variables are presented as mean±SD for normal distribution or median (IQR) for non-normal distribution.
BMI, body mass index; PGY, postgraduate year.

Participants reported seven IUD removals (five due to bleeding, one due to weight gain/hair loss and one due to desire for permanent contraception) and two complications (one perforation requiring laparoscopic removal and one endometritis diagnosed on postpartum day 1).

Table 2
Rate of expulsion at 6 months postpartum by IUD type and delivery route in prospective cohort at a public hospital in New York City, August 2016 to January 2018 (N=114).

	Total expulsion[a]	OR	95% CI	p value
By IUD type				
LNG IUD (n=75)	20 (26.7%)	1.41	0.56–3.57	.38
Cu IUD (n=39)	8 (20.5%)	Reference		
By delivery type				
Vaginal delivery (n=58)	25 (43.1%)	13.38	3.74–47.84	<.001
Cesarean delivery (n=56)	3 (5.4%)	Reference		
By IUD type and delivery route				
Vaginal and LNG IUD (n=42)	19 (45.0%)	8.67	1.80–41.80	.007
Vaginal and Cu IUD (n=16)	6 (38.0%)	6.30	1.08–36.94	.04
Cesarean and LNG IUD (n=33)	1 (3.0%)	0.33	0.03–3.85	.47
Cesarean and Cu IUD (n=23)	2 (9.0%)	Reference		

Data are presented as n (%).
[a] Total expulsion includes partial and complete expulsions.

Table 3
Multivariable logistic regression of IUD expulsion at 6 months postpartum.

Factor	aOR	95% CI	p value
IUD type			
LNG vs. Cu	0.98	0.21–4.48	.98
Delivery route			
Vaginal vs. cesarean	10.10	1.71–59.84	.01
IUD type and delivery route			
Vaginal and LNG IUD	9.87	1.29–75.36	.03
Vaginal and Cu IUD	4.92	0.54–45.17	.54
Cesarean and LNG IUD	0.48	0.04–6.30	.57
Cesarean and Cu IUD			Reference
Age	0.93	0.82–1.05	.22
Gestational age	1.08	0.77–1.53	.66
Provider level			
Junior resident (PGY1/PGY2)			Reference
Senior resident (PGY3/PGY4)	0.65	0.12–3.42	.61
Attending/midwife	3.24	0.25–41.35	.37
Parity	1.42	0.89–2.25	.14
Postpartum hemorrhage	1..28	0.25–6.59	.77
Breastfeeding status, 6 weeks postpartum			
Bottle feeding only			Reference
Breast feeding only	3.96	0.80–19.69	.09
Breast and bottle feeding	2.39	0.64–8.94	.20
Bleeding pattern, 6 weeks postpartum			
None			Reference
Moderate and/or heavy	0.86	0.12–6.43	.88
Light and/or spotting	0.61	0.18–2.10	.43
Use of uterotonics	1.67	0.48–5.84	.42
Use of ultrasound guidance	2.26	0.39–13.13	.36

We assessed subjective vaginal bleeding pattern and reported breastfeeding status to examine the effect of vaginal bleeding and breastfeeding patterns on expulsion (Table 4). The expulsion rate did not differ among bleeding types (p=.53). Women who exclusively breastfed had a lower odds of expulsion when compared to women who bottle fed only (aOR 0.47, 95% CI: 0.28–0.79) and when compared to women who combination fed (aOR: 0.58, 95% CI: 0.35–0.97).

4. Discussion

In this prospective cohort study of women choosing postplacental IUD insertion, we found no difference in expulsion at 6 months between the LNG and Cu IUD when controlling for multiple confounding variables associated with expulsion.

Our findings differ with recent data from a meta-analysis which found that IUD type and delivery route were predictors of expulsion [21]. However, expulsion rates varied widely across studies, which may be due to the inability to control for sociodemographic or clinical factors. Our findings suggest that, when controlling for these patient-level variables, IUD type is not associated with increased expulsion in our postpartum population.

Table 4
Generalized linear effects model of the association between expulsion after postplacental IUD insertion over 6 months postpartum and participant bleeding and breastfeeding status

Factor	OR	95% CI	p value
Bleeding status[a]			
Light/spotting vs. none	1.49	0.74–3.01	.27
Moderate/heavy vs. light/spotting	0.81	0.47–1.39	.44
Moderate/heavy vs. none	1.20	0.66–2.17	.54
Breastfeeding status[a]			
Exclusive vs. bottle only	0.47	0.28–0.79	<.005
Exclusive vs. combination	0.58	0.35–0.97	.04
Combination vs. bottle only	0.18	0.46–1.4	.46

[a] Participant self-reported bleeding and breastfeeding status were assessed at baseline and weekly from postpartum weeks 1–5, 12 and 24.

We found a higher rate of expulsion associated with vaginal when compared to cesarean delivery. In addition, we found a higher rate of expulsion specifically for the LNG compared to the Cu IUD after vaginal delivery but not after cesarean delivery. These findings are similar to a recent prospective study by Goldthwaite et al. which found that expulsion at 12 weeks postpartum was higher among women choosing the LNG IUD compared with the Cu IUD, specifically after vaginal delivery (38.2% vs 19.5%, p=.05) [20]. While we did not have the power to detect differences in expulsion by delivery route, the agreement in findings warrants further investigation in a larger study.

Although our study was not large enough to determine differences in expulsion based on breastfeeding status, we found a protective association between exclusive breastfeeding and expulsion. Limited evidence exists on the association between breastfeeding status and expulsion after postplacental IUD insertion. Cole et al. did not find a difference in expulsion by breastfeeding status; however, this study included only older models of the copper-based IUDs, which are not available in the United States [22]. A potential biologic mechanism for an association between breastfeeding and expulsion is that exclusive breastfeeding may lead to more rapid uterine involution, which may serve as a protective factor against expulsion [23].

A limitation of this study was a differential loss to follow-up between groups (all four participants who were lost to follow-up were from the LNG group). Demographic and clinical characteristics for those with and without follow-up did not differ. Sensitivity analyses assuming that all participants who were lost to follow-up either expelled or retained their IUD did not show a difference in expulsion rate at 6 months. Therefore, this differential loss to follow-up was unlikely to introduce bias. In addition, the study did not have adequate power to detect differences based on the planned secondary analyses, and we cannot draw conclusions based on the observed relationships. Finally, the number of expulsions may have been underestimated as a string check has been shown to be a poor predictor of IUD presence, absence or abnormal position [24] and our 6-month measure of expulsion was by patient report.

A strength of this study was the use of SMS surveys to collect clinical data, allowing for accurate assessment of the time to expulsion and timely follow-up. Participants demonstrated a high response and satisfaction rate with this method of data collection over the 6-month study period. In addition, we examined expulsion of the Liletta® IUD and found comparable rates of expulsion to ranges previously reported for the Mirena® IUD [7,8,19,20]. Given the lower cost of the Liletta® IUD, these data may be useful for institutions or clinicians for which the cost of the IUD is a barrier to providing postplacental LNG IUD insertion.

Our findings add to the growing body of literature suggesting an inherent mechanical or biochemical difference between the LNG and Cu IUD that is associated with a higher rate of expulsion, specifically when placed after vaginal delivery. Knowledge of expulsion rates, breastfeeding and bleeding patterns after postplacental insertion after both delivery routes will improve counseling for women who are considering this method of contraception.

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