



Original research article

Impact of training level on postplacental levonorgestrel 52 mg intrauterine device expulsion^{☆,☆☆}

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ABSTRACT

Objective: To determine the association between provider training level and postplacental intrauterine device (IUD) outcomes following insertion instruction by email only.

Study design: We conducted a single-center chart review of demographics, insertion and clinical outcomes within 6 months of delivery for 116 patients who underwent postplacental levonorgestrel 52 mg IUD placement from October 1, 2016, to March 31, 2017.

Results: We confirmed IUD retention, removal or expulsion in 87 of 116 (75.0%) patients by 6 months after delivery. Complete expulsion or removal for malposition occurred in 20 (23.0%) patients and more frequently after vaginal than cesarean delivery (30.2% vs. 4.2%, OR 9.93 [95% CI 1.25–78.96]) and when a postgraduate year (PGY) 1 physician placed the IUD compared to a PGY 2–4 or attending physician (37.5% vs. 14.5%, OR 3.52 [95% CI 1.25–9.94]).

Conclusion: Postplacental levonorgestrel 52 mg IUD expulsion rates are associated with provider training level as well as delivery route, though the individual association of each of these factors is difficult to ascertain given the high degree of collinearity between these two variables in our study.

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1. Introduction

Intrauterine device (IUD) insertion immediately postpartum is safe, convenient, desired by patients and expands access to long-acting reversible contraception (LARC) [1]. However, the impact of provider training level on postplacental IUD (PPIUD) outcomes is not clearly known [2,3]. Jatlaoui et al. [2] found no difference in expulsion rates when comparing insertion by lower- (postgraduate [PGY] 1/2) and senior-level (PGY 3/4) residents, though the study was underpowered to detect a meaningful difference. Furthermore, PPIUD expulsion specifically following placement by PGY 1 physicians, who perform the majority of vaginal deliveries in many training programs and may have less experience in similar clinical skills such as manual removal of the placenta or uterine bimanual massage for hemorrhage, has not been previously reported. Therefore, we conducted a retrospective analysis of a PPIUD initiative at our academic county hospital to explore the clinical and demographic factors associated with PPIUD expulsion, including

provider training level completing the placement. We anticipated a higher risk of expulsion for those providers with less training.

2. Material and methods

We performed a retrospective cohort analysis of data collected within a prospective PPIUD initiative conducted at an academic county hospital in Cleveland, OH, for deliveries between October 1, 2016, and March 31, 2017. The MetroHealth Medical Center institutional review board approved the study. We introduced the PPIUD initiative via an email to residents and faculty describing inclusion and exclusion criteria, counseling, insertion techniques and follow-up for PPIUD placement (Appendix 1) [4]. One author (K.S.A.) had experience with PPIUD placement during residency training; no other providers had past training or experience. In patients who desired and consented to placement, the resident physician completing the delivery (with direct attending physician supervision) or the attending physician (if no trainee was available for delivery) inserted the IUD within 10 min of placental delivery. We exclusively used a single IUD, the levonorgestrel 52 mg IUD (Liletta®, Medicines360, San Francisco, CA, USA), to eliminate potential outcome differences based on IUD type and due to lower cost.

We reviewed billing reports for all women who had a delivery during the study time frame to identify patients who had a PPIUD placement and confirmed IUD distribution with pharmacy logs. We reviewed delivery records and clinical course from the electronic

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medical record through 6 months after delivery. We abstracted demographic data; training status of the provider who inserted the PPIUD; and outcomes including expulsion or removal within 6 months, need for additional imaging to locate the IUD and reason for IUD removal. We defined expulsion by either (a) patient report of expulsion as recorded in the electronic medical record or (b) confirmatory imaging with ultrasound or x-ray if the clinician noted no threads at a postpartum examination. We did not explicitly define malposition for study purposes and abstracted the reason for removal based on documentation.

We present results for only women who had confirmation of retention, removal or expulsion of the levonorgestrel 52 mg IUD within 6 months of delivery. We compared rates of expulsion and removal for malposition according to clinical and demographic characteristics by χ^2 or Wilcoxon rank sum test, as appropriate, as well as odds ratios with use of the Haldane–Anscombe correction when necessary. We calculated variance inflation factors (VIFs) of all significant associations with expulsion to assess collinearity. All analyses were two-tailed. We used R software (version 3.4.0) for data analysis [5] and considered a *p* value <.05 as statistically significant.

3. Results

During the 6-month study timeframe, 1506 deliveries occurred with 116 (7.7%) having a PPIUD insertion (Table 1). Physicians placed the IUD manually (*n*=101, 87.1%), with a ring forceps (*n*=8, 6.9%) or with the inserter (*n*=6, 5.2%); only two (1.7%) procedures included ultrasound guidance.

Table 1

Demographic characteristics of all women undergoing postplacental levonorgestrel 52 mg IUD placement and of those with confirmation of IUD retention, removal or expulsion at 6 months postdelivery

	All placements <i>n</i> =116	Placements with confirmation <i>n</i> =87	<i>p</i> value
Age (years)	26 (22–30)	27 (23–30)	.46
Parity	2 (1–3)	2 (1–3)	.52
BMI (kg/m ²)	32 (27–38)	32 (27–39)	.46
Race			.85
Asian	1 (0.9)	1 (1.1)	
Black	50 (43.1)	37 (42.5)	
Hispanic	15 (12.9)	15 (17.2)	
White	47 (40.5)	32 (36.8)	
Other/unknown	3 (2.6)	1 (1.1)	
Insurance			.65
Medicaid	99 (85.3)	70 (80.5)	
Private	12 (10.3)	12 (13.8)	
None	5 (4.3)	5 (5.7)	
Education level			.92
Grade 12 or less without graduating	40 (34.5)	25 (28.7)	
High school diploma or GED	38 (32.8)	29 (33.3)	
Some college	22 (19.0)	18 (20.7)	
Bachelor's degree	8 (6.9)	7 (8.0)	
Graduate degree	5 (4.3)	5 (5.7)	
Unknown	3 (2.6)	1 (1.1)	
Married			.53
Yes	18 (15.5)	17 (19.5)	
No	97 (83.6)	70 (80.5)	
Unknown	1 (0.9)	0 (0)	
Gestational age at delivery (weeks)	39 (37–39)	39 (37–39)	.88
Delivery route			.89
Vaginal	83 (71.6)	63 (72.4)	
Cesarean	33 (28.4)	24 (27.6)	
Provider training level			.96
PGY 1	42 (36.2)	32 (36.8)	
PGY 2–4	62 (53.4)	47 (54.0)	
Attending	12 (10.3)	8 (9.2)	

Data presented as *n* (%) or median (interquartile range). BMI, body mass index.

Within 6 months of delivery, 87 (75.0%) patients had a documented follow-up assessment with outcomes of retention, removal or expulsion reported in Table 2. Twenty (23.0%) patients had complete expulsion or IUD removal for malposition. Thirteen (76.5%) expulsions occurred within the first 30 days.

Factors associated with expulsion and removal for malposition are reported in Table 3. Inserter training level was associated with expulsion or removal for malposition across all levels of training (*p*=.002). Regression modeling of the two significant factors (delivery route and provider training level) demonstrated a high degree of collinearity (VIF 15.0 for delivery route and 9.5 for training level), and therefore, multivariable regression was not performed. In the subgroup of those patients with vaginal deliveries, the association between training level and expulsion or removal for malposition was no longer significant (36.7% expulsion when placed by a PGY 1 physician vs. 24.2% expulsion when placed by a PGY 2–4 or attending physician, *p*=.42).

4. Discussion

We found a combined complete expulsion and removal for malposition rate of 23.0% after initiation of a postplacental levonorgestrel 52 mg IUD placement program at our urban teaching hospital. This rate is similar to or lower than that reported in previously published prospective studies [6–10]. The two risk factors associated with expulsion or removal for malposition identified in our study were vaginal delivery and placement by a PGY 1 physician despite direct attending physician supervision during PPIUD insertion. Possible explanations for the former include lack of advanced cervical dilation for scheduled cesarean deliveries, ease of placing the IUD correctly at the uterine fundus due to ability to palpate the fundus directly and excellent anesthesia at time of cesarean delivery. In contrast to our findings, one contemporary study has shown no significant difference in expulsion rate between vaginal and cesarean deliveries [10], whereas a different study had similar findings to ours [11]. A systematic review also concluded that expulsion was more common after vaginal rather than cesarean delivery but included both immediate (within 10 min of placental delivery) and early (greater than 10 min to less than 4 weeks) in the comparison [12]. However, given the small number of cesareans performed in active labor, we are unable to draw conclusions for laboring women undergoing cesarean delivery.

Previous studies that have evaluated the correlation between provider training level and IUD expulsion have been underpowered to detect a difference or have not studied the resident trainee population specifically [2,3]. The higher expulsion rate of IUDs placed by PGY 1

Table 2

Outcomes for women with confirmation of levonorgestrel 52 mg IUD retention, removal or expulsion^{a, b}

	Placements with confirmation <i>n</i> =87
Postpartum infection	4 (4.6)
IUD removed	6 (6.9)
Indication for IUD removal	
Malposition without pain	2 (2.3)
Malposition with pain	1 (1.1)
Pain only	2 (2.3)
Bleeding	1 (1.1)
Breastmilk supply concern	1 (1.1)
Postpartum visit within 90 days of discharge	83 (95.4)
Expulsion within 6 months of discharge ^a	17 (19.5)
Postpartum IUD threads not visible on exam	24 ^b (27.6)
Ultrasound examination ordered	13 (14.9)
Examination completed	11 (12.6)

Data presented as *n* (%).

^a Expulsion defined as either (a) patient report of expulsion as recorded in the electronic medical record or (b) confirmatory imaging with ultrasound or x-ray if no threads were noted at the time of postpartum examination.

^b Fourteen had expulsions by patient report or ultrasound examination.

Table 3
Factors associated with postplacental levonorgestrel 52 mg IUD outcome^a

	n	Confirmed IUD expulsion/removal for malposition n=20	OR (95% CI)
Parity			0.36 (0.09–1.36)
Primiparous	25	3 (12.0)	
Multiparous	62	17 (27.4)	
Delivery route			9.93 (1.25–78.96)
Vaginal	63	19 (30.2)	
Cesarean ^a	24	1 (4.2)	
Gestational age at delivery			12.10 (0.69–211.80)
Preterm (<37 weeks)	15	0	
Term (≥37 weeks)	72	20 (27.8)	
BMI (kg/m ²)			3.66 (1.11–12.09)
<30	36	4 (11.1)	
30	51	16 (31.4)	
Provider training level			3.52 (1.25–9.94)
Attending or PGY 2–4	55	8 (14.5)	
PGY 1	32	12 (37.5)	
Placement method			--
Manual	78	17 (21.8)	
Inserter	3	0	
Ring	5	2 (40.0)	
Unknown	1	1 (100.0)	
Infection	4	0	0.34 (0.02–6.67)
Ultrasound used at time of placement	2	1 (50.0)	3.47 (0.21–58.18)

Data presented as n (%).

OR, odds ratio; CI, confidence interval.

^a All scheduled cesarean deliveries except one woman in the confirmed group in active labor.

physicians after email-only instruction suggests that a formal education program with simulation training (as recommended by the American College of Obstetricians and Gynecologists [13]) targeted to those with less clinical experience in similar intrauterine manipulation might improve expulsion rates for these providers. Importantly, however, there was a high degree of collinearity between the two significantly associated factors of delivery route and provider training level. Furthermore, the association between provider training level and expulsion was not significant in the subgroup of vaginal deliveries, though this study was underpowered to detect a difference for this comparison. Thus, further study is necessary to analyze the relationship between these two factors and PPIUD expulsion.

Our study has limitations including ability to confirm retention or expulsion in only 75% of our cohort, reliance on email-only instruction, and lack of standardized definition or management plan for malposition. As a single IUD was used in the study, our findings may not be generalizable to other IUDs. Moving forward, further analysis of whether expulsion rate varies by provider training level after traditional simulation-based insertion education is warranted.

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Appendix 1. Immediate Postpartum Long-Acting Reversible Contraception (LARC)

Post-placental intrauterine device (IUD) insertion is a safe, convenient, and effective option for postpartum contraception. “Post-placental” refers to insertion within 10–15 minutes of placental delivery either after vaginal or cesarean delivery.

Post-placental IUD insertion has several benefits. It provides immediate contraception — this is of critical importance in women with decreased access to care as the postpartum visit is a significant barrier to postpartum contraceptive use. Optimal timing of the subsequent

pregnancy is related to improved maternal and neonatal outcomes. Post-placental IUD insertion has not been associated with increased infection, uterine perforation, postpartum bleeding, or uterine subinvolution and does not interfere with breastfeeding. Continuation rates are relatively high (87.6% and 76.3%, at 6 and 12 months, respectively)

However, it is important to note that the expulsion rate is higher (approximately 12% in the first postpartum year) after immediate postpartum insertion compared to 3%–5% with insertion 4 to 8 weeks later. This rate of expulsion dramatically increases with length of time between placental delivery and IUD insertion, therefore insertion should ideally be performed within 10 minutes of placental delivery. Given this short window of time between delivery and IUD insertion, it is important that every eligible patient be approached and counseled regarding post-placental IUD insertion *prior to delivery*.

The attending physician supervising the insertion must be credentialed to insert IUDs by MHMC.

1. Eligibility

a. Inclusion Criteria

- i. Any patient desiring long-acting reversible contraception (LARC) who meets U.S. CDC Medical Eligibility Criteria Category 1 or 2

b. Exclusion Criteria

- i. Presence of suspected intrauterine infection/chorioamnionitis or unexplained fever during labor
- ii. Uterine anomaly
- iii. Unresolved postpartum hemorrhage
Uterotonics can be used in standard fashion and atony should be treated as clinically indicated prior to IUD insertion. If severe postpartum bleeding is ongoing after ten minutes of placental delivery, or recurrent uterine atony occurs prior to IUD insertion, the operator should consider not inserting the IUD and alternate plans for contraception should be made.
- iv. Retained placenta requiring dilation and curettage
- v. Inadequate (ring forceps insertion) or no (manual insertion) regional analgesia at the time of delivery.

2. Documentation:

- a. The counseling process must be documented prior to delivery and include the fact that the expulsion rate is 12% in 1 year and thus, higher than the 3%–5% expulsion rate for IUDs placed 6 weeks postpartum. Counseling must also include that the IUD position cannot be confirmed until the postpartum visit when filaments are visualized (and trimmed, if necessary). Therefore, follow-up is required and abstinence until this appointment is encouraged.
- b. IPad procedure consent must be signed by the patient and physician prior to delivery.
 - i. Adolescents MUST have a parent/guardian sign the consent form
- c. A Time-Out must be performed prior to procedure with patient, nurse, and physician
- d. After insertion, a procedure note must be documented by the physician (including ultrasound guidance if appropriate) and the device lot number and expiration date must be documented in the MAR by the nurse

3. Insertion technique:

- a. Vaginal delivery
 - i. Placental delivery should occur in standard fashion. Once adequate hemostasis has been achieved, IUD insertion can begin. The IUD is placed on the sterile field. Sterile gloves are changed. IUD insertion can occur either by hand or with ring forceps.
1. If IUD insertion occurs by hand, the stem of the IUD should be grasped between the index and third fingers, inserted through the

uterine cervix and placed in the fundus. The uterine fundus should be grasped with the abdominal hand to confirm placement location, and that perforation or unexpected removal of the IUD have not occurred. The operator releases the IUD and the operator's hand is then rotated 90 degrees and removed from the uterus.

Manual IUD insertion should not be performed on women without adequate analgesia.

2. If IUD insertion occurs by ring forceps, the stem of the IUD is grasped with the forceps near the t-bar but attention should be paid to avoidance of ratcheting the forceps closed as this may damage the IUD. Entry into the uterine cavity occurs and the IUD is brought to the fundus. The ring forceps are released, rotated ninety degrees and then removed by the operator. IUD insertion by ring forceps may be appropriate for women without regional anesthesia if the operator determines that the patient has an adequate ability to tolerate placement of a vaginal speculum and manipulation of the uterine fundus prior to opening the IUD packaging and attempted IUD insertion.

- ii. If ultrasound guidance is deemed appropriate by the physician, simultaneous transabdominal ultrasound may be used to confirm fundal IUD placement.

b. Cesarean delivery

- i. Placental delivery should occur in standard fashion. Once adequate hemostasis has been achieved, with good tone noted in the body and fundus of the uterus, IUD insertion can begin. The IUD will be placed on the sterile field. Sterile gloves are changed. IUD insertion can be achieved either by hand or ring forceps technique.

Before closing of the hysterotomy, the stem of the IUD is grasped either between the second and third fingers or by ring forceps with attention to avoidance of ratcheting the forceps closed as this may damage the IUD. The IUD is introduced through the hysterotomy incision and brought to the fundus. The other hand is used to grasp the fundus, confirm fundal IUD location, and assist in holding the IUD in the fundus. The hand / ring forceps is rotated ninety degrees and removed.

The strings are tucked into – but not through – the cervical canal using a forceps. Once the strings are introduced into the cervical canal, the forceps are removed from the sterile field.

The hysterotomy is then closed in a standard fashion with attention to avoid catching the IUD filaments in the uterine suture.

c. IUD filaments

IUD filaments are commonly not visualized past the level of the external cervical os immediately after postplacental insertion, especially for a Paragard IUD.

Visualization of excessive filament length passing through the cervix immediately after insertion can be a sign of the IUD being too low, and reinsertion should be considered as expulsion rates are increased in this circumstance.

If the filaments are visualized and IUD placement is deemed adequate, the filaments can be trimmed at the level of the cervix.

The patient should be counseled that the filaments will likely need

to be trimmed at the postpartum visit once uterine involution is complete.

- d. Vaginal lacerations should be repaired in standard fashion *after* IUD Insertion
- e. Patients with unknown gonorrhea/chlamydia status at time of admission for delivery should have cultures/PCR testing sent. If positive, standard treatment can be prescribed, and should not require IUD removal.

4. Postpartum Care

- a. Patients should be counseled to employ abstinence until their postpartum visit at which point IUD position will be confirmed.
- b. Patients should undergo a speculum at their postpartum visit to confirm IUD location. There is a higher rate of IUD filaments being non-visualized after immediate postpartum insertion than after IUD insertion remote from delivery. If the IUD filaments are not visualized at the postpartum visit, a pelvic ultrasound should be obtained to confirm appropriate IUD position.
- c. The IUD filaments can be trimmed if necessary at the postpartum visit.

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