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Tara P. Cleary 4/17/12

IMMEDIATE POST-PLACENTAL INSERTION OF LNG-IUS AND COPPER T380A UNDER ULTRASOUND GUIDANCE AT A TEACHING HOSPITAL

By

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Epidemiology

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An abstract of
A thesis submitted to the Faculty of the
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Abstract

IMMEDIATE POST-PLACENTAL INSERTION OF LNG-IUS AND COPPER T380A UNDER ULTRASOUND GUIDANCE AT A TEACHING HOSPITAL

By Tara P. Cleary, M.D.

Objectives:

To determine whether risk of expulsion following ultrasound-guided post-placental IUD insertion is associated with provider level of training.

Methods:

We enrolled patients from the prenatal clinic at a teaching hospital who were planning vaginal delivery and desired a postpartum IUD. Patients selected the copper T380A IUD or Levonorgestrel IUS after comprehensive counseling. Women who underwent immediate postplacental insertion were seen in clinic at 4-6 weeks and contacted by telephone at 3 and 6 months. Insertions were performed by Obstetrics and Gynecology physicians at all training levels, PGY1 to attending, following a training session on postplacental IUD insertion technique.

Results:

Ninety-nine subjects were eligible and had successful post-placental placement. Ninety-seven insertions were performed by resident-physicians. Eighty-eight women had follow-up within the 6-month period. Overall, 17 expulsions were noted: 10 complete expulsions, all noted by the patient; and 7 partial expulsions, all noted on exam or ultrasound. All partially expelling IUDs were removed, with 5 out of 7 replaced per patient request. No significant association was found between expulsions and provider level of training though an association is suggested. Lower level physicians inserted 24 IUDs of which 2 expulsions (8.3%) were reported or diagnosed in 6 months; upper level physicians inserted 64 IUDs of which 15 expulsions (23.4%) were reported or diagnosed during follow-up. Analyses also suggest there may be an association between not receiving IV or regional anesthesia and expulsion.

Conclusion:

Postplacental IUD insertions can be safely performed within a training program under ultrasound guidance. The risk of expulsion among women who had their IUD inserted by an upper level physician were more than two times the risk of expulsion among women who had insertion performed by a lower level physician. This result was not statistically significant therefore we cannot rule out chance. Further studies are needed for this relationship and to evaluate a possible association between expulsions and lack of anesthesia.

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BACKGROUND

Worldwide, intrauterine devices (IUDs) are the most common form of reversible contraception[1]. Unlike other forms of birth control, no periodic visits or regular administration are required to maintain contraception, leading to one of the lowest typical use failure rates of all available methods. The IUD also has the highest continuation rate compared to other reversible methods and is the most cost-effective method over a five-year period [1-3]. The two devices currently available in the US are the Copper T380A (CuT380A IUD or Paragard™) and the Levonorgestrel Intrauterine System (LNG-IUS or Mirena™). The CuT380A was FDA approved in 1988. Its mechanism of action includes inhibition of speed of ovum transport, of sperm transport and viability, and damage to the ovum all to prevent fertilization. The LNG-IUS, approved in 2000, contains 52mg levonorgestrel released at a rate of 20ug per day, which additionally causes endometrial suppression and thickens cervical mucus[1].

According to the latest National Survey of Family Growth from 2006-2008, the prevalence of IUD use in the United States is approximately 3.4% with 7.4% of women reporting past use [4]. In the 1960s and 1970s the IUD's popularity in the US peaked constituting 11% of all female contraceptive users. IUD use then plummeted with reports of septic abortion and pelvic infection that were associated with the Dalkon Shield. These complications were contributed to this IUDs unique design, involving poly-filament strings, which eventually led to all but one IUD being removed from the US market by 1988. The IUD has not reclaimed the same popularity level in the US since[1].

The IUD has the lowest usage rates in North America and sub-Saharan Africa. Factors contributing to IUD use exist at the individual level, as well as levels of service delivery and providers, programs, and local and national policies. Highest rates are seen amongst female contraception users in Korea (78%), Egypt (63%), Cuba (59%) and China (49.8%) where

national family planning programs or well-funded private sectors support access to long-term reversible contraception or sterilization [5].

Additionally, numerous countries routinely offer immediate post-placental insertions (within ten minutes of placental delivery) to further aid in IUD utilization. Advantages of postplacental IUDs include: (1) immediate access to contraception (2) easier contraception education while hospitalized, (3) no possibility of pregnancy at the time of insertion, (4) fewer complaints of bleeding and pain than with interval insertion, (5) potentially lower costs, (6) easier insertion and (7) increased utilization rates [6].

A Cochrane Review update in 2010 evaluated 9 randomized controlled trials of postpartum IUD insertion and found that while this timing appears safe and effective, spontaneous expulsion rates appear to be higher with postpartum insertions compared to interval insertions (more than 6-8 weeks after delivery) [7]. Only one randomized trial has directly compared immediate postplacental insertion with interval insertion and this was done using LNG-IUS. Expulsion rates were reported as 24% with postplacental insertion compared with 4.4% with interval insertion [8]. Additionally, one study demonstrated that hand insertion of CuT380A had similar expulsion rates as instrument-guided insertion [9]. All other trials evaluated in the review involved IUDs that are no longer commercially available.

While randomized controlled trials are limited, several observational studies have also demonstrated that immediate postplacental insertion of IUDs is safe and effective. Immediate postplacental placement is therefore supported by the U.S. Medical Eligibility Criteria for Contraceptive Use and the American College of Obstetrics and Gynecology[10, 11]. These studies have reported no increase in perforation or infection rates, while reporting an increase in expulsion rates compared to those of interval insertion in the literature [9, 12-14].

Still, an increased risk of expulsion may be outweighed by an increase in access to highly effective reversible contraception in cases where significant barriers exist. One study that randomized post-abortal patients to delayed versus immediate IUD insertion found that 42% of the women in the delayed group failed to return for their IUD [15]. A retrospective chart review of 1627 postpartum women at the University of New Mexico found that of the 114 women who desired an IUD postpartum for whom follow-up information was available, only 60% had the IUD placed. The most common reasons for non-placement were choosing an alternate method, failure to come back for the postpartum visit, discouragement by provider, and early repeat pregnancy[16].

Timing of postpartum IUD placement has also been investigated. A prospective study of 268 women in Turkey using the CuT380A IUD compared immediate postplacental (within ten minutes of placental delivery) and early postpartum IUD insertion (between ten minutes and 72 hours) with interval IUD insertion (after six weeks). There was no statistical significance between the groups for uterine perforation and infection, although there was a significant difference in complete and partial expulsions according to the timing of insertion. At one year, the complete expulsion rate was highest in the early postpartum group (18.6%) compared to both the immediate postplacental group (14.3%) and the interval group (3.8%). Partial expulsions at one year were seen in 51.2% of the early postpartum group while 22.6% and 3.1% of the women in the immediate postplacental and interval groups, respectively, experienced this complication. All differences for both complete and partial expulsions were found to be significant at one year [12].

A study investigating two early postpartum IUD programs in Africa found similar results with the CuT380A. Both programs in Kenya and Mali demonstrated higher expulsion rates for early postpartum placement (5% and 25%) compared to immediate insertion (1% and 14%

respectively) though only the difference in Mali was significant. Thus, both these studies in Africa and Turkey suggest immediate postplacental timing may be superior to the early postpartum period to achieve lower expulsion rates.

It has also been suggested that expulsion rates are associated with the experience of the provider as one study demonstrated variation across several different institutions[17]. Another early study on postplacental insertion by found that one out of twelve insertions by attending physicians resulted in expulsion, compared to twenty of 35 placements by resident physicians. Furthermore, a training session stressing high fundal insertion improved the expulsion rates of the residents to thirteen out of sixty-seven placements—a statistically significant improvement [18]. The CuT380A IUD was used in an African study comparing immediate and late postplacental (between 10 minutes and 72 hours after placental delivery) insertions using both hand and inserter placements. The study confirmed that the CuT380A IUD has decreased expulsion rates compared to other IUDs when placed immediately postplacental, and also showed that the service provider had the strongest association with expulsions (Morrison reference). Another study found expulsions decreased from 26% in the first 50 placements to 8% in the last 50 placements by the same providers, further suggesting that expulsions can be decreased significantly with training [19].

Although the CuT380A IUD has been well investigated, only two studies have evaluated postplacental LNG-IUS insertion after vaginal delivery. Both studies utilized ultrasound at the time of placement and a limited number of providers. Hayes et al reported an expulsion rate of 10% in a pilot study of ten insertions while, as previously stated, Chen et al reported 24% in a randomized trial [8, 18]. We hypothesize that ultrasound-guided post-placental insertion of IUDs in a teaching hospital by physicians in training is associated with similar rates of IUD expulsion as those found in the literature. We also hypothesize that the risk of expulsion will be lower if

placed by upper level residents (third year and above) compared to lower level residents (first or second year). The primary outcome assessed will be the risk of expulsion based on provider training level. Secondary outcomes will also be assessed: IUD continuation, infection, bleeding complications, and pregnancy. Additional outcomes will include perceived ease of placement and complications during placement (e.g. perforation).

METHODS

Overview

This prospective case series was conducted between March 2009 and September 2011 at Grady Memorial Hospital in Atlanta, Georgia following approval by the Emory University Institutional Review Board and Grady Review Oversight Committee. Prenatal patients from Grady prenatal clinics expressing a desire for an IUD postpartum were recruited for IUD insertion immediately following placental delivery. Inclusion criteria were as follows: age greater than or equal to 18, receiving prenatal care at Grady Memorial Hospital, requesting an IUD as their primary method of postpartum contraception, anticipating a vaginal delivery at Grady Memorial Hospital, able to read and/or understand English or Spanish, be able and willing to give informed consent in English or Spanish, able and willing to follow-up over a six-month period. Exclusion criteria at the time of placement included: Contraindications to IUD placement per U.S. medical eligibility criteria [11], fever (greater than 38.0 ° C) in labor, rupture of membranes for greater than 24 hours prior to delivery, need for cesarean section, postpartum hemorrhage with estimated blood loss greater than 500mL requiring intervention beyond bimanual massage, history of STI in current pregnancy and leaving the hospital area within 6 months.

Participants who were unable or unwilling to reaffirm their informed consent for IUD insertion for reasons of distress in labor or otherwise were ineligible for postplacental IUD placement. Those who were unable or unwilling to consent to study participation at any time were offered IUD insertion at their routine postpartum visit.

Baseline patient assessment

History taking, physical examination, and contraception education was completed as a part of routine prenatal care. After the patient indicated that she wanted an IUD for postpartum contraception and wished to participate in the study, she received informed consent for IUD use and study participation prior to study enrollment. After eligibility screening, subjects completed a brief questionnaire regarding factors that may influence either IUD expulsion or infection, including a history of sexually transmitted infections and menstrual history as well as demographic information. Having received routine contraceptive counseling with her prenatal care, subjects were given the option of either the LNG-IUS or the CuT380A IUD.

Training

An initial training session was conducted in March 2009 for all Emory Gynecology and Obstetrics residents by a study investigator who participated in the pilot study for postplacental insertion of the LNG-IUS[20]. This investigator has conducted numerous IUD training sessions for providers, including CME approved sessions. Additional training sessions were conducted in July 2009 and July 2010. The training sessions were standardized to accomplish the following: review counseling and consent before IUD insertion and use, review standard insertion technique for both IUD types, and learn the protocol for use of the standard insertion technique in the setting of postplacental IUD insertion (including abdominal ultrasound guidance). The vast majority of the residents participating in the study had already learned standard IUD insertion as well as use of abdominal ultrasound.

Baseline intervention

Upon presentation and admission to the Labor and Delivery Unit for routine labor care, consents were reviewed and subjects' willingness to participate and desired type of IUD was reaffirmed. After vaginal and placental delivery, eligibility criteria were again reviewed. For all

eligible subjects, an IUD was inserted within 10 minutes of delivery of the placenta (though up to 30 minutes was permitted) under sterile conditions. All insertions were performed under ultrasound guidance using the LNG-IUS pre-packaged inserter and ring forceps for CuT380A IUD. If the IUD could not be placed with the inserter or ring forceps, hand insertion was attempted. The ultrasound assisted to confirm fundal placement. The IUD strings were cut at the level of the external os. Data collection for placement included: provider name and training level who performed the insertion, anesthesia (epidural, local, none), and the time of both placental delivery and IUD placement.

Follow-up visits

Subjects returned for a 4-8-week follow-up visit in conjunction with routine postpartum visits. Follow-up questionnaires were also administered by study staff regarding satisfaction with the IUD, and symptoms of expulsion or infection. Pelvic exams were performed to check for bleeding, any evidence of infection and to visualize IUD strings and trim strings if necessary. Transvaginal ultrasound was performed to ensure IUD intrauterine placement and to measure the distance of the IUD from the fundus. Follow-up questionnaires were repeated at three and six months via telephone interview. If any follow-up contact was missed, subjects were contacted via telephone twice, then by certified mail, preserving patient confidentiality, to reschedule the visit or request subjects call study team. Subjects were considered lost to follow-up if they had not had at least one follow-up contact within the allotted study time (6 months postpartum).

Sample size and rationale

The specific aim of this study was to demonstrate that a clinical protocol for post-placental IUD insertion can be safely and effectively utilized in a teaching hospital by prospectively observing a group of women who receive an IUD postplacentally from a trained

physician. Every woman who entered the prenatal clinic of Grady Memorial Hospital and who desired an IUD for postpartum contraception was assessed for study eligibility. However, of the 3800 women who deliver at Grady annually, we anticipated fewer women, approximately 10%, would actually desire a post-placental IUD. The study sample was a convenience sample as it was estimated that we would be able to recruit 200 women in the two-year enrollment period of the study.

Data analysis

Analysis of baseline data

Age, race, education, employment, income, number of prior births, insurance status, future fertility desires and relationship status as baseline characteristics are summarized with descriptive statistics. Measures for continuous variables include means and standard deviations. Categorical variables are expressed with frequencies. Descriptive analyses were also stratified by type of IUD (LNG versus CuT380A) to identify potential differences in women choosing one IUD over the other.

Primary and secondary analyses

The primary objective of this thesis is to assess the risk of expulsion based on provider training level and whether this risk differs significantly among provider levels. Secondary outcomes that will also be assessed include infection, pregnancy, perforations and any other notable complications. An expulsion was defined as either complete or partial. A partial expulsion was defined as an IUD visible or palpable at the external cervical os or transvaginal ultrasound showing the distal tip of the IUD entering into the cervical canal. A complete expulsion was defined as no IUD inside the uterus and a history consistent with expulsion.

Statistical analysis was performed using SAS 9.3 (Cary, NC). Primary analysis sought to identify risk factors for expulsion including the exposure of interest, insertion provider level, among women who had follow-up within six months. Bivariate analysis was performed using Fisher's Exact test to compare categorical variables and the Student's t-test was used to compare continuous variables between the IUD expulsions and non-expulsions. Covariates for bivariate analysis included age, race, number of prior births, anesthesia, insertion time interval after placental delivery, IUD type, insertion provider level, provider assessment of insertion presence of infection at postpartum visit, and IUD distance from fundus on ultrasound at postpartum visit. Confounding was assessed for age, race, number of prior births, anesthesia, insertion time interval after placental delivery, IUD type and presence of infection at postpartum visit. Stratified analysis was then performed by the exposure of interest, the level of provider experience (PGY1 and PGY2 versus PGY3 and above) to identify a difference in expulsion risk among the same covariates listed for confounding assessment. Finally, multivariate analysis was performed with logistic regression using age, insertion provider level, number of prior births, anesthesia insertion time interval after placental delivery and IUD type.

RESULTS

Between March 2009 and March 2011, 175 women were enrolled in the study and 99 underwent postplacental IUD insertion. Those who were excluded either withdrew consent or were ineligible according to U.S. Medical Eligibility Criteria[11]. All 99 attempts at insertion were successful. Of the 99 women who had an IUD placed, 69 women selected LNG-IUS while 30 chose the CuT380A IUD. Eighty-eight women completed one follow-up contact within six months. Demographic information was not significantly different between women choosing LNG-IUS and women choosing CuT380A (Table I). Those women who had follow-up were also similar to the entire group who underwent postplacental insertion. The demographic characteristics represent the population of female patients at Grady Memorial Hospital; the majority of women are black, unemployed, single who have completed a GED or high school education and have Medicaid coverage.

The mean time to insertion was 7 minutes (SD 4.6 minutes) (Table 2). Most insertions (72.7%) were performed by a PGY3 level resident or above and performed under epidural anesthesia (63.6%). Bivariate analysis did not reveal any statistically significant differences between any covariates and expulsion as seen in Table 2. Interestingly the IUDs placed by lower level physicians had a lower risk of expulsion versus those IUDs placed by upper level physicians, however this difference was not statistically significant. Additionally, it is suggested that a history of zero or a history of three or more prior births as well as use of anesthesia (epidural or IV pain medication) may have a protective association with expulsion. The risk of expulsion among women with no anesthesia was two times the risk among women who received epidural or IV anesthesia though this was not found to be significant. No meaningful relationship between expulsion risk and provider assessment was found and thus provider assessment was dropped from further analysis.

Seventeen expulsions (19.3%) occurred among 88 women who had follow-up within six months. Sixty-five women (65.6%) presented for a 4-6 week follow-up visit with exam. Of those who returned, 7 were diagnosed with a partial expulsion with IUD visible in the cervical canal and thus the IUD was removed. Five of those women chose to have another IUD placed. Complete expulsions totaled 10 among the 88 subjects (11.4%) with follow-up. All subjects saw the IUD after expulsion, eight returned for follow-up visit where IUD was not seen on US and the remaining two did not return for visit. The only removals that occurred were for partial expulsions. No pregnancies or perforations were reported during follow-up. Seven subjects were empirically treated for cervicitis or PID at the postpartum visit. No IUDs were removed for infection. Four additional subjects reported infection during follow-up calls. One was treated for trichomoniasis, one was diagnosed with HSV and two were not sure what their diagnosis was and they were seen at clinics outside of the study. None of the eleven participants identified as having an infection were also identified as having an expulsion at any point during follow-up. Since all complete expulsions occurred prior to follow-up and all partial expulsions were diagnosed at follow-up visit, ultrasound measurement of IUD placement was not used as a predictor in analysis.

Two of the expulsions occurred among the 24 IUDs (8.3%) placed by lower level physicians while the remainder of expulsions occurred among upper level physicians (23.4%). Though a difference can be seen, it was not found to be statistically significant and may be due to chance.

Although power is limited by the small number of adverse outcomes, a multivariate analysis was performed to determine if any factors were strongly correlated with the outcome. Associations between factors and the exposure (provider level) were also assessed. No factors could be determined to be associated with either the exposure of provider level (Table 3), or the

outcome of expulsion (Table 5). Multivariate analysis using a full model including age, timing, use of any anesthesia, number of prior births and IUD type was performed and compared to a reduced model only containing the exposure of interest, provider level. No meaningful difference was found for the null odds ratio of 0.29 (95% CI 0.06-1.44) for the full model compared to the reduced model (OR 0.3; 95% CI 0.06-1.41) as seen in Table 5. Adjusting therefore for these other factors does not meaningfully change the crude effect estimate for provider level.

Stratified analysis further examined the relationship between anesthesia and provider level as well as number of prior births and provider level. No statistically significant effect modification was found which might be due to small cell size and therefore not enough power to detect a difference among the stratified groups. The final table, Table 6, includes a collinearity matrix with no condition indices (CI) approaching 30 indicating no collinearity exists between covariates and the exposure of provider level.

DISCUSSION

While we hypothesized that expulsions would be higher among women who had IUDs placed by lower level physicians, our findings suggest that placement by a lower level physician may be protective. Though not significant, the number of expulsions was meaningfully higher in the group of IUDs placed by upper level physicians (23.4%) compared to those placed by lower level physicians (8.3%). The number of expulsions was also higher in women who did not receive any anesthesia and in women who have had 1 or 2 prior births, though these differences were not statistically significant. We examined whether patients may have been selected according to their parity or anesthesia use for insertion by a particular provider level, however we did not find any associations between these predictors. Upper level residents placed a similar proportion of IUDs in women who did not receive anesthesia as those who did receive anesthesia; they also placed a similar proportion of IUDs among the different categories for prior births (Table 3).

It is possible that lower level physicians received more supervision by upper level physicians including an attending physician during insertion. The coaching during the insertion may have improved technique to achieve high fundal placement leading to a decrease in expulsions. Upper level physicians, meanwhile, may not have received the same attention during insertion. Given their increased responsibilities and patient load, upper level physicians may have rushed insertions. Information regarding the insertion setting including provider participants present, the provider who performed ultrasound, the distance of initial IUD placement from the fundus and whether an attending physician was present for insertion was not collected. Larger studies with strict insertion protocols randomized by provider level may further elucidate these relationships.

The suggestion that non-use of anesthesia may be associated with an increased risk of expulsion is a new finding. This study was not powered to detect a difference among use or non-use of anesthesia or type of anesthesia used. However, there is a two-fold increase in the proportion of women with expulsions among those who did not receive anesthesia compared to those who did receive anesthesia. Further studies with adequate power to detect a difference are needed to determine if an association truly exists.

Women with no prior birth history or a history of 3 or more births had a lower proportion of expulsions than those women with a history of one or two births. This was not determined to be a confounder or effect modifier in analysis. There are no previous studies that confer similar findings and larger studies again would help elucidate this possible association. Biologically there does not appear to be a physiologic or anatomic reason for this relationship.

The analysis of this study is limited by small sample size and limited by the original design. This study was not powered to detect a difference in expulsions between provider level groups or between users and non-users of anesthesia and no statistically significant differences were seen; a difference among these groups is suggested however by our findings.

The most clinically significant finding of this study is that resident physicians may safely place with an overall risk of expulsion within the range of 10-24% published in the literature[7-9, 12-14, 20]. Only two IUDs were placed by the same attending physician who had prior experience with postplacental IUD insertion. All other insertions were performed by resident physicians who had no prior clinical experience with postplacental IUD insertion. A training session is sufficient to safely and effective place IUDs after placental delivery under ultrasound guidance.

Older studies have shown that expulsions are higher among providers with less experience[17-19]. None of these studies involved the currently available LNG-IUS or

CopperT380A. The two published studies looking at postplacental LNG-IUS placement did not involve resident physicians. This study demonstrates that postplacental IUD protocols may be initiated in training hospitals across the country.

While the risk of expulsion has been shown to be higher with postplacental insertion compared to interval insertion, certain patient populations may benefit more from the access and delivery of highly effective reversible contraception at the time of vaginal delivery. The study population recruited from the Grady Health System is representative of patients who have difficulties in returning for postpartum visits and receiving the IUD that they want for contraception. The study population does not represent all women and those patients who are able to obtain an IUD without difficulty at a postpartum visit should delay insertion to decrease expulsion risk.

By initiating postplacental IUD insertion protocols in residency training facilities in the US, access to long term highly effective contraception would increase for patients who have difficulty returning for a visit and receiving their desired IUD. Monitoring such programs would close the gap of knowledge regarding risk factors for expulsion of currently available IUDs and may aide in better counseling for increased risk of expulsion or to aide in proper patient selection for postplacental IUD insertion.

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APPENDIX

Table 1. Characteristics of women receiving a postplacental IUD, by IUD type									
	Total Insertions *N=99*		Completed Follow-up* *N=88*		LNG-IUS (%) *N=69*		CuT380A (%) *N=30*		**p-value****
Age									**0.94**
Mean (SD)	23.7 (4.6)		23.7 (4.6)		23.7 (4.4)		23.7 (5.2)		
Race									**0.12**
Black	73	73.7%	67	76.1%	53	76.8%	20	66.7%	
Asian	1	1.0%	0	0.0%	0	0.0%	1	3.3%	
Hispanic	19	19.2%	16	18.2%	11	15.9%	8	26.7%	
Unspecified	6	6.1%	5	5.7%	5	7.2%	0	0.0%	
School									**0.74**
Less than 8y	6	6.1%	5	5.7%	3	4.3%	3	10.0%	
Some HS	23	23.2%	19	21.6%	16	23.2%	7	23.3%	
HS/GED	43	43.4%	40	45.5%	31	44.9%	12	40.0%	
Some College	17	17.2%	15	17.0%	12	17.4%	5	10.0%	
Other	10	10.1%	9	10.2%	7	10.1%	3	10.0%	
Employment									**0.50**
Unemployed	64	64.6%	57	64.8%	41	59.4%	23	76.7%	
Full-time	13	13.1%	12	13.6%	10	14.5%	3	10.0%	
Part-time	12	12.1%	10	11.4%	10	14.5%	2	6.7%	
Unspecified	10	10.1%	4	4.5%	8	11.6%	2	6.7%	
Annual Income									**0.99**
< $10,000	50	50.5%	43	48.9%	35	50.7%	15	50.0%	
$10-30,000	26	26.3%	24	27.3%	18	26.1%	8	26.7%	
> $30,000	2	2.0%	2	2.3%	2	2.9%	0	0.0%	
Unspecified	21	21.2%	19	21.6%	14	20.3%	7	23.3%	
Prior births									**0.98**
0	17	17.2%	14	15.9%	12	17.4%	5	16.7%	
1	34	34.3%	31	35.2%	23	33.3%	11	36.7%	
2	22	22.2%	19	21.6%	16	23.2%	6	20.0%	
3 or greater	25	25.3%	24	27.3%	18	26.1%	7	23.3%	
Unspecified	1	1.0%	0	0.0%	0	0.0%	1	3.3%	
Insurance									**0.83**
Yes	78	78.8%	68	77.3%	54	78.3%	24	80.0%	
Medicaid	67	67.7%	61	--	45	83.3%	22	91.7%	**0.81**
Other	3	3.0%	3	--	2	3.7%	1	4.2%	
Unknown	8	8.1%	4	--	7	13.0%	1	4.2%	
No	14	14.1%	14	15.9%	9	13.0%	5	16.7%	
Unknown	7	7.1%	4	8.0%	6	8.7%	1	3.3%	
Future Fertility									**0.15**
No	57	57.6%	52	59.1%	35	50.7%	22	73.3%	
Yes	22	22.2%	19	21.6%	17	24.6%	5	16.7%	
Unsure	14	14.1%	12	13.6%	12	17.4%	2	6.7%	
Unknown	6	6.1%	5	5.7%	5	7.2%	1	3.3%	
Relationship Status									**0.77**
Single	78	78.8%	69	78.4%	53	76.8%	25	83.3%	
Married	15	15.2%	14	15.9%	11	15.9%	4	13.3%	
Unspecified	6	6.1%	5	5.7%	5	7.2%	1	3.3%	

**With at least one follow-up contact in 6 months* ** LNG-IUS vs CopperT380A

Table 2. Characteristics of participants with follow-up by Expulsion versus Non-Expulsion

Overall risk of expulsion 17/88=19.3%

Covariate	Subjects*	Expulsion		Non-Expulsion		p-value
	N=88	*N=17*		*N=71*		
Age**						
Mean (SD)	23.7 (4.6)	23.5 (5.2)		23.8 (4.5)		**0.8**
Race						**1**
Black	67	14	20.9%	53	79.1%	
Hispanic	16	3	18.8%	13	81.3%	
Unspecified	5	0	0.0%	5	100.0%	
Prior Births						**0.0292**
0	14	1	7.1%	13	92.9%	
1	31	9	29.0%	22	71.0%	
2	19	6	31.6%	13	68.4%	
3 or greater	24	1	4.2%	23	95.8%	
Anesthesia						**0.15**
None	17	6	35.3%	11	64.7%	
IV pain medicine	12	2	16.7%	10	83.3%	
Epidural	56	8	14.3%	48	85.7%	
Unspecified	3	1	33.3%	2	66.7%	
Insertion Time from placenta delivery,** min (SD)	7 (5.1)	7.5 (5.4)		5 (2.8)		**0.1007**
IUD Type						**1**
LNG-IUS	62	12	19.4%	50	80.6%	
CuT380A	26	5	19.2%	21	80.8%	
Provider Level						**0.14**
PGY1 or PGY2	24	2	8.3%	22	91.67%	
PGY3 or above	64	15	23.4%	49	76.56%	
Infection after Discharge						**0.11**
No	77	17	22.1%	60	77.9%	
Yes	11	0	0.0%	11	100.0%	
Provider Assessment						**0.9321**
Very Easy	33	8	24.2%	25	75.8%	
Somewhat Easy	25	5	20.0%	20	80.0%	
Somewhat Difficult	13	2	15.4%	11	84.6%	
Very Difficult	3	0	0.0%	3	100.0%	
Unspecified	14	2	14.3%	12	85.7%	
Measurement from Fundus on Followup Ultrasound (mm)						**<0.001**
0-20	25	3	12.0%	22	88.0%	
21-40	22	0	0.0%	22	100.0%	
41-60	4	1	25.0%	3	75.0%	
61-80	1	1	100.0%	0	0.0%	
>80	22	11	50.0%	11	50.0%	
Unspecified	14	1	7.1%	13	92.9%	

** With at least one follow-up contact in 6 months*

** T-test

Table 3. Characteristics of subjects with follow-up by Provider Level

Covariate	Subjects*	Lower Level Providers		Upper Level Providers	
	N=88	*N=24, 27%*		*N=64, 73%*	
Age					
18-20	24	8	33.3%	16	66.7%
21-25	39	9	23.1%	30	76.9%
26-30	17	4	23.5%	13	76.5%
31-35	6	2	33.3%	4	66.7%
>36	2	1	50.0%	1	50.0%
Race					
Black	67	19	0.3%	48	71.6%
Hispanic	16	5	31.3%	11	68.8%
Unspecified	5	0		5	
Prior Births					
0	14	4	28.6%	10	71.4%
1	31	8	25.8%	23	74.2%
2	19	5	26.3%	14	73.7%
3 or greater	24	7	29.2%	17	70.8%
Anesthesia					
None	17	5	29.4%	15	88.2%
Yes (IV or regional)	68	19	27.9%	49	72.1%
Insertion Timing					
<10 minutes	74	22	29.7%	52	70.3%
>10 minutes	14	2	14.3%	12	85.7%
IUD Type					
LNG-IUS	62	15	31.9%	47	75.8%
CuT380A	26	9	34.6%	17	65.4%
Infection after Discharge					
No	77	21	27.3%	56	72.7%
Yes	11	3	27.3%	8	72.7%

** With at least one follow-up contact in 6 months*

Table 4. Effect of Provider Level on Expulsion Stratified by Provider Level and by Other Covariates

Covariate	Subjects*	Lower Level Providers			Upper Level Providers			
	N=88	*Non-expulsion*	*Expulsion*	*%*	*Non-expulsion*	*Expulsion*	*%*	**p-value**
Age								
18-20	24	7	1	12.5%	10	6	37.5%	0.35
21-25	39	8	1	11.1%	26	4	13.3%	1
26-30	17	4	0	0.0%	10	3	23.1%	0.54
31-35	6	2	0	0.0%	3	1	7.1%	1
>36	2	1	0	0.0%	0	1	100.0%	1
Race								
Black	67	17	2	11%	36	12	25.0%	0.32
Hispanic	16	5	0	0.0%	8	3	27.3%	0.51
Unspecified	5	0	0	0.0%	5	0	0.0%	
Prior Births								
0	14	4	0	0.0%	9	1	10.0%	1
1	31	7	1	12.5%	15	8	34.8%	0.38
2	19	4	1	20.0%	9	5	35.7%	1
3 or greater	24	7	0	0.0%	16	1	5.9%	1
Anesthesia								
None	17	4	1	20.0%	9	6	40.0%	0.61
Yes	68	18	1	5.3%	40	9	18.4%	0.26
Insertion Timing								
<10 min	74	20	2	9.1%	38	14	26.9%	0.12
>10 min	14	2	0	0.0%	11	1	8.3%	1
IUD Type								
LNG-IUS	62	13	2	13.3%	37	10	21.3%	0.71
CuT380A	26	9	0	0.0%	12	5	29.4%	0.13
Infection after Discharge								
No	77	19	2	9.5%	41	15	26.8%	0.13
Yes	11	3	0	0.0%	8	0	0.0%	-

**With at least one follow-up contact in 6 months*

Table 5. Multivariate Analysis

Model	OR estimate	95% CI		p-value
Full	0.29	0.06	1.44	0.13
Reduced	0.30	0.06	1.41	0.13

Table 6. Collinearity Matrix

Obs	_VARNAM2	VDP1	VDP2	VDP3	VDP4	VDP5
1	EIGENVAL	0.0138	0.2564	0.66313	0.83037	3.23631
2	CONDINDX	15.3193	3.55277	2.20915	1.9742	1
3						
4	Intercept	0.9848	0.01168	0.00108	0.00027	0.0022
5	prov	0.0036	0.02776	0.0119	0.93737	0.01935
6	Age	0.9666	0.02949	0.00095	0.00032	0.00263
7	meds	0.1908	0.70851	0.0686	0.02135	0.0107
8	iudtype	0.0009	0.08375	0.84863	0.03758	0.02913