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Satisfaction with Intrauterine Device Insertion Procedure among Adolescent and Young Adult Women in a Clinical Trial

Aletha Y. Akers, MD, MPH,

Assistant Professor of Obstetrics and Gynecology; Craig Dalsimer Division of Adolescent Medicine, Children's Hospital of Philadelphia; 3401 Civic Center Boulevard, Main Building, Suite 11NW10; Philadelphia, PA 19104; Phone: 215-590-6864

Jennifer Harding, MPA,

Research Director; Children's Hospital of Philadelphia Research Institute, PolicyLab, Roberts Center for Pediatric Research, 2716 South Street, 10225, Philadelphia, PA 19146; Phone: 267-426-1214

Lisa K. Perriera, MD, MPH,

Associate Professor of Obstetrics and Gynecology, Ryan Residency Program Director; Thomas Jefferson University; 833 Chestnut St. First Floor; Philadelphia, PA 19107; Phone: 215-955-5577

Courtney Schreiber, MD, MPH,

Associate Professor of Obstetrics and Gynecology; Hospital of the University of Pennsylvania; 3400 Spruce Street, 1000 Courtyard; Philadelphia, PA 19104; Phone: 215-615-6531

J. Felipe Garcia-Espana, PhD, and

Senior Research Biostatistician; Children's Hospital of Philadelphia Research Institute; Roberts Center for Pediatric Research, 2716 South Street, 9241, Philadelphia, PA 19146; Phone: 267-426-1140

Sarita Sonalkar, MD, MPH

Assistant Professor of Obstetrics and Gynecology; Hospital of the University of Pennsylvania; 3400 Spruce Street, 1000 Courtyard; Philadelphia, PA 19104; Phone: 215-615-5234

Abstract

OBJECTIVE—To evaluate satisfaction with intrauterine device (IUD) insertion procedures among adolescent and young adult women.

METHODS—This secondary analysis of data from a multisite, single-blind, sham-controlled randomized trial of women having a levonorgestrel 13.5 mg IUD inserted enrolled participants from March 2015 through July 2016 at 3 family planning clinics in Philadelphia, Pennsylvania. Eligible women were 14 to 22 years, nulliparous, not pregnant, and English speaking. Randomization was via computer generated allocation in block sizes of 4 to a 1% lidocaine paracervical or sham block. Only patients were blinded. Satisfaction was measured with 3-items that assessed overall satisfaction with the procedure, whether participants would recommend the

Correspondence to: Aletha Y. Akers.

IUD to friend, and the perception that the IUD was worth the discomfort. Predictors included demographics, sexual and reproductive history, pain following IUD insertion, and treatment group.

RESULTS—Ninety-five women enrolled; 93 (97.9%) were included in the analysis. Forty-five (47.4%) were white, 34 (36.0%) were black, 62 (66.0%) privately insured, and 75 (79.0%) previously used contraception. Most (n=71, 76.8%) reported high overall satisfaction with the procedure, 62 (67.4%) would recommend an IUD to a friend, and 77 (83.2%) perceived the IUD was worth the discomfort. The odds of reporting high overall satisfaction were lower among adolescents compared to young adults (OR 0.07, 95% CI: 0.008, 0.68); those who never had a gynecologic exam compared to those who had (OR 0.26; 95% CI: 0.069, 0.99); and decreased as pain score increased (OR 0.96; 95% CI: 0.94, 0.99). Higher pain scores were negatively correlated with the odds of recommending an IUD to a friend and perceiving the IUD was worth the discomfort.

CONCLUSION—Adolescent and young adult women report high levels of satisfaction following the IUD insertion procedure. Young age, lack of experience with gynecologic exams, and high pain were inversely related to satisfaction.

Clinical Trial Registration—ClinicalTrials.gov, https://clinicaltrials.gov, NCT02352714.

INTRODUCTION

Although intrauterine devices (IUDs) have been available in the U.S. for decades, utilization rates remain low among adolescent and young adult women. Only 4% use IUDs compared to 12% of women over age 20 years.[2–4] The contraceptives most commonly used by young women (pills, patch, and ring) are twenty times less effective than IUDs.[5,6] Given the high rate of unintended pregnancies in this population, improving IUD use is important.[5,6] Barriers to IUD utilization including lack of knowledge, negative personal attitudes, negative social norms, and limited IUD access, particularly in pediatric care settings.[7–9] Interventions have focused on improving access, promoting patient-centered counseling, and promoting long-acting methods.[10,11]

An understudied aspect of IUD utilization is women's perceptions of the IUD insertion procedure. For young women, concern about discomfort during the insertion procedure is a major barrier to IUD use. Improving our understanding of young women's experiences during the procedure may aid with counseling and service delivery, help address pre-procedure anxiety, identify modifiable aspects of the procedure, and improve IUD uptake.[7–9,12] Studies assessing young women's satisfaction with the IUD measure satisfaction six to 12 months after device placement; we are not aware of any studies assessing young women's satisfaction immediately following IUD insertion.[13–15] In the current study, we examine satisfaction with the IUD insertion procedure and predictors of satisfaction among adolescent and young adult women participating in a randomized clinical trial that examined the effectiveness of a 1% lidocaine paracervical nerve block on pain reported during IUD insertion compared to a sham block.

MATERIALS AND METHODS

Study Design

This was a secondary analysis of data from a multisite, single-blind, sham-controlled randomized trial conducted at three clinics in Philadelphia, Pennsylvania from March 2015 to July 2016 that involved one study visit. The CONSORT guidelines were followed to design and report the trial; full details regarding the trial are repored elsewhere.[16] The protocol is available by request. Institutional Review Board (IRB) approval was obtained from the Children's Hospital of Philadelphia (CHOP, which was the IRB of record), Hospital of the University of Pennsylvania, and Thomas Jefferson University, all of which performed study visits. Approval was also obtained from AccessMatters, which funds Title X clinics in southeastern Pennsylvania, which allowed study recruitment flyers to be posted in Title X clinics that refer adolescents to CHOP for IUD insertions. The trial was registered with Clinical trials.gov (NCT# NCT02352714).

Recruitment, Eligibility and Consent

Women presenting to a study site requesting a hormonal IUD were asked by a clinician if they were interested in talking with research staff about the study. Interested women seeking reproductive health services at a non-enrolling study site who saw a recruitment flyer called the study coordinator who described the study and scheduled a study visit. Patients were eligible for inclusion if they were between ages 14 to 22 years, nulliparous, not pregnant currently, not pregnant in the prior 6 weeks, interested in the Skyla IUD (levonorgestrel 13.5mg IUD), and English speaking. The cut-off of 22 years, rather than 24 years, was chosen to minimize the number of older, young adult women. Patients were excluded if they did not meet medical eligibility criteria for an IUD;[17] had a contraindication to taking amino-amide anesthetics or non-steroidal anti-inflammatory agents; were unwilling to be randomized; were at high risk for pregnancy; used narcotics or benzodiazepine in the prior 24 hours; previously used an IUD; or had a prior unsuccessful IUD insertion. Women could enroll at a later date if inclusion criteria were not initially met. Written informed consent was obtained from all participants, regardless of age, since females 13 and older in Pennsylvania can legally consent for reproductive services and research studies regarding reproductive services, and because requiring parental permission for study participation would have compromised confidentiality.

Trial Procedures and Treatment Group Description

Participants completed a questionnaire assessing demographic characteristics and their medical and reproductive history. Prior to randomization, participants received 800 mg of ibuprofen orally at least 20 minutes prior to the procedure to reduce post-procedure pain.[18] Randomization was performed by a research coordinator in the Research Data Capture (REDCap) software in block sizes of 4 with stratification by age (14 – 17 or 18 – 22 years), race, and recruitment site after completion of the demographic questionnaire. Only patients were blinded to group assignment. The lidocaine block group received 1 mL of 1% lidocaine at the tenaculum site and 4.5 mL at 4 o'clock and 8 o'clock at the cervicovaginal junction. For the sham block, pressure was applied to these same three sites with the unbroken, wood end of a cotton-tipped applicator to depress the vaginal epithelium 1 mm. There was a 3-

minute delay after administering the lidocaine and sham block before IUD insertion to allow onset of action for the lidocaine. IUD insertion followed the manufacturer's instructions, including sounding the uterus before inserting the IUD. All devices were inserted by an experienced provider who was an attending physician or a family planning fellow.

After IUD insertion, clinicians completed a questionnaire assessing procedural details (uterine size and depth, need for dilation or ultrasound guidance, and adverse events). One item assessed provider-rated patient anxiety by asking if the patient's general affect seemed "pleasant and appropriately engaging" or "anxious". Following IUD insertion, a post-procedure questionnaire was administered to participants by a research coordinator to rate their satisfaction with and discomfort during the procedure.

Participants who completed all study activities received $50 for their time. Devices were provided free of charge by the study funder. Participants' insurance was billed for the clinical procedure fee. Clinicians were not compensated for performing the IUD insertion nor for completing the questionnaire.

Outcomes

Satisfaction with the IUD insertion procedure was measured using three single-item satisfaction measures adapted from items commonly used to assess satisfaction with various dimensions of clinical care. Overall satisfaction was assessed with an item that asked, "*How would you rate your overall satisfaction with your IUD placement?*" Response options ranged from "very dissatisfied" (1) to "very satisfied" (5). Participants were classified as satisfied if they responded "Very satisfied". The second item asked if participants would "*recommend an IUD to a friend*". Response options included, "Definitely yes", "Probably yes", "Neutral", "Probably not", "Definitely not", and "Don't know, No opinion". Participants were classified as satisfied if they responded "Definitely yes". The third item asked if getting the IUD "*was worth the discomfort*". Response options were "Yes", "No" or "Unsure". Higher scores denoted greater satisfaction, higher IUD recommendation, or the belief that the procedure was worthwhile, respectively.

Covariates

Demographic variables included age, race, Hispanic ethnicity, marital status, insurance status, and education level. Sexual and reproductive history variables included age at menarche and whether participants had ever been sexually active, pregnant, used hormonal birth control, had a gynecologic exam, or were currently using birth control. As part of the medical history, participants completed the 4-item Patient Health Questionnaire-4 (PHQ-4), which consists of a 2-item depression scale and a 2-item anxiety scale. Scores > 3 suggest clinical depression or anxiety, respectively.[19] The single-item provider-rated anxiety variable was dichotomous (yes or no). Pain at IUD insertion was recorded using a 100 mm visual analog scale (VAS). Participants touched a line anchored from "no pain" (0 mm) to "worst pain in my life" (100 mm) using an iPad at seven time points: baseline (prior to placement in lithotomy), immediately after speculum placement, tenaculum placement, block administration, uterine sounding, IUD insertion, and 5-minutes after speculum removal. The pain score reported immediately after IUD insertion, which was the primary outcome for the

parent study, was included in the models. Treatment group assignment (paracervical block versus sham block group) was also included.

Analysis

Between-group differences in the baseline characteristics for the treatment groups were compared using chi-square test for proportions, Fisher's exact test for small numbers, and Wilcoxon rank-sum tests for continuous data that were not normally distributed.

Each of the three outcome variables were ordinal and highly skewed, with more than two-thirds of participants selecting the highest response category reflecting high overall satisfaction with the procedure, high likelihood of recommending an IUD to a friend, and a strong belief that the IUD was worth the discomfort. All three outcomes were therefore dichotomized to compare the highest response category to all the other response categories combined. Separate logistic regression models were run for each of the 3 dependent variables.

Predictor variables with small sample sizes (< 10% of respondents per cell) were excluded from analysis (i.e., Hispanic ethnicity, marital status, ever sexually active, prior pregnancy, self-reported depression and anxiety, and provider rating of participant's anxiety). The variable assessing whether participants had 'ever used birth control' was excluded as it was highly correlated with the variable assessing 'current birth control use', which was included. Age was dichotomized to assess whether younger age (14 to 17 years) or older age (18 to 22 years) was a significant predictor of each outcome. Race was dichotomized as White vs non-White. Education level was continuous with higher levels reflecting more education. Number of prior gynecologic exams and pain scores following IUD insertion were used as predictors of each outcome as well. ORs and 95% CIs estimates in the multivariable models were robust to the number of predictors selected.

Two-tailed p-values less than .05 were considered significant. Analyses were completed with SAS software, version 9.3 (SAS Institute).

RESULTS

Of the 95 participants who enrolled in the trial, 93 were included in the outcome analysis. One was dropped due to missing insurance data and the other due to missing pain score at IUD insertion. Participant characteristics are shown in Table 1. The mean age of the sample was 19.4 ± 2.1. Almost half were white (47.4%) and a third were black (36.0%). Most were ages 18 to 22 years (80.0%), never married (95.8%), had at least some college education (67.4%), and were privately insured (66.0%). Most also reported having had sex at least once (91.6%) and prior contraceptive use (79.0%); few reported current contraceptive use (43.2%) or a prior pregnancy (4.2%). Two-thirds (69.5%) reported having a prior gynecologic exam; the types of gynecologic exams varied, with 59.0% reporting a prior visual inspection of the vulva, 51.6% reported a prior bimanual exam, 44.2% reported a prior speculum exam, and 30.5% reported a prior pap smear.

Participants were equally distributed among the treatment groups with 47 randomized to the paracervical block group and 48 to the sham group (Figure 1). The baseline characteristics were similar in both groups, except those in the paracervical block group were less likely to be current contraceptive users compared to those in the sham group (31.9% versus 54.2%, p=0.03). The median pain score (± interquartile range [IQR]) reported immediately following IUD insertion for the sample was 63.5±53, with lower scores in the lidocaine paracervical block group compared to the sham block group (30.0±52, versus 71.5±23.5, p<0.0001)

Overall Satisfaction with IUD insertion

Most participants reported being “very satisfied” with their IUS insertion procedure (n=73, 76.8%), with 14 (14.7%) being “somewhat satisfied”, 6 (6.3%) were “neutral”, 1 (1.1%) were “somewhat dissatisfied”, and 1 (1.1%) were very dissatisfied. There were no differences in satisfaction between the lidocaine block group compared to the sham group (91.5% versus 91.7%, p=0.30).

As shown in Table 2, the odds of reporting higher overall satisfaction were lower among younger adolescents compared to older adolescents (OR 0.07; 95% Confidence Interval (CI): 0.008, 0.68); among those who had never had a gynecologic exam compared to those who had (OR 0.26; 95% CI: 0.069, 0.99); and decreased as the pain score following IUD insertion increased (OR 0.96; 95% CI: 0.94, 0.99).

Would Recommend an IUD to a Friend

When asked if they would recommend an IUD to a friend, 64 (67.4%) said “definitely yes”, 20 (21.1%) “probably yes”, 6 (6.3%) were neutral, 3 (3.2%) “probably low”, and 2 (2.1%) “definitely no”. There were no differences in recommending an IUD insertion to a friend among the lidocaine block group compared to the sham group, (91.5% versus 85.4%, p=0.45). As shown in Table 2, the odds of recommending an IUD to a friend decreased as the pain score following IUD insertion increased (OR 0.96, 95% CI: 0.941–0.986). Odds of recommending an IUD to a friend were lower among those who had never had a gynecologic exam compared to those who had, but this did not reach statistical significance (OR 0.32; 95% CI: 0.10, 1.01).

IUD was Worth the Discomfort

Most participants endorsed that getting the IUD was “worth the level of discomfort” (n=79, 83.2%), none reported that it was “not worth the level of discomfort” and 16 (16.8%) were “unsure at this time”. There were no differences between the lidocaine block group compared to the sham group (44.2% versus 39.0%, p=0.11). As shown in Table 2, the odds of reporting that getting the IUD was worth the discomfort decreased as the pain score following IUD insertion increased (OR 0.96, 95% CI: 0.93–0.99).

DISCUSSION

Utilization of IUDs is low among adolescents and young adult women, in part due to fears regarding discomfort during the insertion process.[7,8,12] In this secondary data analysis study,

we examined three dimensions of satisfaction with the IUD insertion procedure among adolescent and young adult women. We found that the majority of young women reported high satisfaction with the IUD insertion procedure. Eight of ten women reported high overall satisfaction with the procedure and believed the procedure was worth the discomfort they experienced. Seven of 10 would recommend an IUD to a friend. Higher pain during IUD insertion was the only variable associated with lower odds of satisfaction with the procedure on all 3 satisfaction measures.

Patient satisfaction is an important aspect of evaluating the quality of healthcare services, [20,21] with pain management increasingly recognized as being highly correlated with satisfaction.[20] Few studies have examined associations between pain management and patient satisfaction with procedures performed in outpatient clinic settings. This study therefore fills an important gap.

Our finding that higher pain during the IUD insertion procedure was the only variable consistently associated with reduced odds of satisfaction with the IUD insertion procedure suggests that pain-reduction interventions may be important for young women. Moreover, the finding that younger adolescents and those with no prior gynecologic exam were less likely to be satisfied with the IUD insertion procedure suggests that patients with these characteristics, in particular, may derive benefit from routine use of a paracervical block, other interventions designed to enhance procedure tolerance, or the opportunity to undergo IUD placement under sedation. In the current study, a 10 mL paracervical block with 1% lidocaine was used. Future studies should consider examining the effectiveness of other pain control interventions that are currently understudied in this population, including the 4-site paracervical block, lidocaine spray or gel applied to the cervix prior to placing a paracervical block, or using a higher dose of a lidocaine paracervical block.

We found no differences in patient satisfaction in the sham block group and paracervical block group despite the sham group reporting significantly more pain with the procedure. Similar to our study, prior randomized controlled trials assessing the effectiveness of various pain medications in reducing pain during IUD insertion have consistently noted high rates of satisfaction with the IUD insertion procedure, regardless of the pain control regimen used. [22–24] None of these studies, including our current study, assessed how motivated women were to have an IUD placed. Patients who are highly motivated to get an IUD may report high satisfaction due to receiving the contraceptive method of their choice, despite experiencing pain during the insertion procedure. Assessing young women’s motivations for using an IUD is an under-explored area that may be important for better understanding the relationship between patient satisfaction and reported pain.

There are a number of limitations in the current study. Although there are 4 hormonal IUDs on the market, we examined satisfaction with insertion of only the 13.5 mg levonorgestrel 13.5 mg IUD; these findings may not extend to other types of IUDs. We only examined satisfaction immediately following the IUD insertion, but patient satisfaction might change over time. In particular, participants’ perception that going through the IUD insertion process was worth the discomfort and their willingness to recommend an IUD to a friend might change depending on their experience with the method over time. Another key

limitation was that our study was powered to assess pain control, not patient satisfaction. It is possible that had we powered the study to assess patient satisfaction, we may have seen different results. Young age (age 14 – 17 years) was noted to be associated with decreased overall satisfaction, but the small size of this group (less than a quarter of analyzed participants) likely limited subgroup analyses by age. Finally, there are some predictors that may influence patient satisfaction that we could not analyze due to too few of our subjects reporting those predictors. If we had a larger sample size, predictors such as anxiety or depression may have influenced patient satisfaction.

CONCLUSION

Adolescents and young women report high overall satisfaction with the IUD insertion procedure, whether or not they receive a paracervical block. Although younger age, lack of experience with a gynecologic exam, and higher pain were inversely associated with satisfaction, most young women consider receiving an IUD to be worth the discomfort. Future research should evaluate satisfaction with the IUD over a longer time period, as well as other interventions to improve the IUD insertion experience for younger adolescents.

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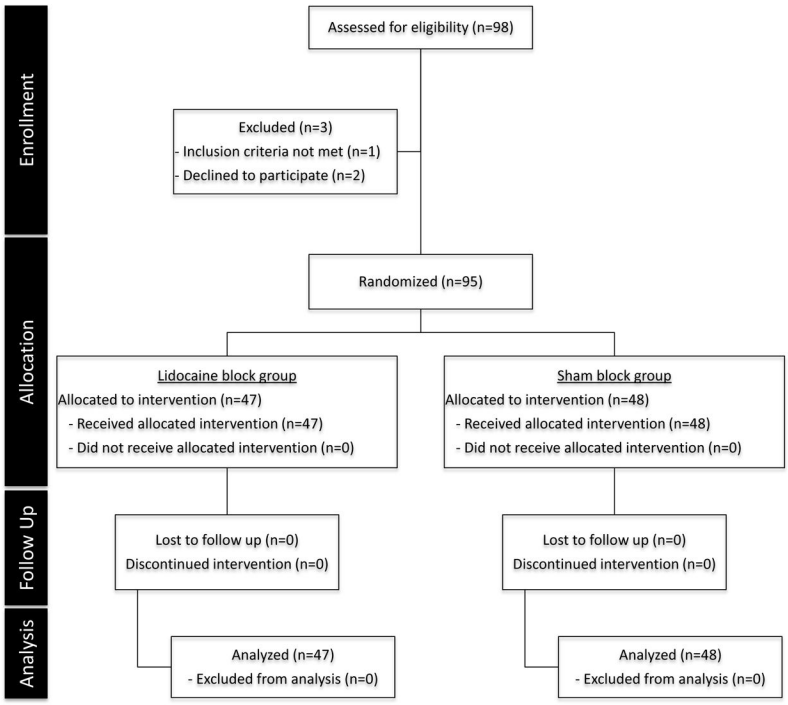

Figure 1.

Table 1

Characteristics of Participants, by treatment group (N=95)

Covariates	Total Sample (N=95) *n (%)*	Block Group (N= 47) *n (%)*	Sham Group (N= 48) *n (%)*
Mean age in years ± SD[1]	19.4±2.1	19.3±2.1	19.5±2.1
Age group			
Ages 14 – 17 years	19 (20.0)	10 (18.8)	9 (18.8)
Ages 18 – 22 years	76 (80.0)	37 (78.7)	39 (81.3)
Primary Race			
White	45 (47.4)	15 (31.9)	19 (39.6)
Black	34 (36.0)	23 (48.9)	22 (45.8)
Other	16 (16.8)	9 (19.2)	7 (14.6)
% Non-Hispanic	86 (90.5)	42 (89.4)	44 (91.7)
Marital Status			
Never married, not living with partner	91 (95.8)	46 (97.9)	45 (93.8)
Never married, living with partner	3 (3.2)	1 (2.1)	2 (4.2)
Married, living with partner	1 (1.1)	0 (0.0)	1 (2.1)
Education			
Less than high school degree	22 (23.2)	11 (23.4)	11 (22.9)
High school degree or equivalent	9 (9.5)	5 (10.6)	4 (8.3)
Some college or higher	64 (67.4)	31 (66.0)	33 (68.8)
Insurance			
None	1 (1.1)	0	1 (2.1)
Public insurance	29 (30.9)	15 (32.6)	14 (29.2)
Private insurance	62 (66.0)	30 (65.2)	32 (66.7)
None or other	2 (2.1)	1 (2.2)	1 (2.1)
Age at menarche in years ±SD	11.9±1.6	11.7±1.7	12.1±1.5
Ever sexually active	87 (91.6)	44 (93.6)	43 (89.6)
Prior pregnancy	4 (4.2)	2 (4.3)	2 (4.2)
Ever used hormonal birth control	75 (79.0)	37 (78.7)	38 (79.2)
Currently using hormonal birth control	41 (43.2)	15 (31.9)	26 (54.2)
Prior gynecologic exam	66 (69.5)	34 (72.3)	32 (66.7)
Median number of prior gynecologic exams ±IQR[2]	2.0±3.0	2.0±3.0	2.0±3.0
% Clinically anxiety	2 (2.1)	1 (2.1)	1 (2.1)
% Clinically depressed	2 (2.1)	2 (4.26)	0 (0.0)
% Provider-rated participant anxiety	9 (9.5)	5 (10.6)	4 (8.3)

[1] SD=standard deviation

[2] Interquartile range (IQR)

Table 2

Odds of reporting high overall satisfaction with the IUD procedure, recommending an IUD to a friend, and perceiving the IUD procedure was worth the pain from multivariable logistic regression (N=93)

Covariates	Overall Satisfaction Very satisfied: n=73 (76.8%) Other: n=20 (73.2%)		Recommend to Friend Definitely yes: n=64 (67.4%) Other: n=29 (32.6%)		Worth the Discomfort Yes: n=79 (83.2%) Unsure: n=14 (16.8%)	
	Crude OR	aOR	Crude OR	aOR	Crude OR	aOR
Age 14 – 17 years (ref: 18 – 22 years)	0.24 (0.08 – 0.70)	0.07 (0.008 – 0.68)	1.15 (0.38 – 3.26)	0.76 (0.12 – 4.99)	0.73 (0.21 – 2.57)	0.66 (0.07 – 6.20)
Race: Non-white (ref: White)	0.56 (0.21 – 1.49)	0.99 (0.22 – 4.49)	1.30 (0.55 – 3.07)	2.8 (0.71 – 10.58)	1.54 (0.52 – 4.57)	4.07 (0.68 – 24.34)
Education level	1.62 (1.03 – 2.53)	0.67 (0.31 – 1.48)	0.99 (0.67 – 1.42)	0.77 (0.40 – 1.49)	1.13 (0.71 – 1.79)	0.95 (0.40 – 2.12)
Insurance: Non-private (ref: Private)	0.50 (0.19 – 1.34)	1.03 (0.20 – 5.29)	1.34 (0.53 – 3.42)	1.16 (0.26 – 5.13)	1.12 (0.35 – 3.57)	0.99 (0.14 – 7.15)
Age at menarche	1.19 (0.87 – 1.61)	0.93 (0.62 – 1.39)	1.31 (0.86 – 1.48)	1.31 (0.90 – 1.91)	1.19 (0.84 – 1.67)	1.27 (0.81 – 1.99)
Current birth control user: no (ref: Yes)	1.84 (0.70 – 4.84)	1.57 (0.49 – 5.05)	0.94 (0.39 – 2.24)	0.66 (0.23 – 1.92)	1.91 (0.64 – 5.66)	1.50 (0.41 – 5.40)
Prior gynecologic exam: no (ref: Yes)	0.57 (0.21 – 1.53)	0.26 (0.07 – 0.99)	0.60 (0.24 – 1.49)	0.32 (0.10 – 1.01)	0.99 (0.31 – 3.18)	0.56 (0.14 – 2.24)
Randomization group: Block (ref: sham)	1.90 (0.71 – 5.10)	1.14 (0.33 – 4.01)	1.80 (0.75 – 4.34)	0.80 (0.26 – 2.45)	2.38 (0.76 – 7.50)	0.89 (0.22 – 3.57)
Pain at IUD insertion	0.97 (0.95 – 0.99)	0.96 (0.94 – 0.99)	0.97 (0.96 – 0.99)	0.96 (0.94 – 0.99)	0.97 (0.94 – 0.99)	0.96 (0.93 – 0.99)

Abbreviations: CI=confidence interval; OR=odds ratio; aOR= adjusted OR; ref=referent group

Covariates included in models: age group, race, education level, insurance, number of prior gynecologic exams, randomization block group, current birth control user, and pain score following IUD insertion.

Data are OR and 95% confidence intervals, unless otherwise specified