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Intrauterine Device Insertion Procedure Duration in Adolescent and Young Adult Women

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Abstract

STUDY OBJECTIVE: Intrauterine device (IUD) utilization in the United States is low among adolescent and young adult women. Longer procedure duration has been proposed as one potential barrier to IUD insertion in this population. We hypothesized that procedure duration would be longer in adolescents compared to young adult women.

DESIGN, SETTING, AND PARTICIPANTS: This study was a secondary analysis of a randomized clinical trial comparing the effectiveness of a lidocaine versus sham paracervical nerve block for pain control during levonorgestrel 13.5 mg IUD insertion. Adolescent and young adult women ages 14 to 22 years were recruited from three outpatient academic sites in Philadelphia, PA.

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DISCLOSURE/CONFLICT OF INTEREST

Financial disclosures: Katherine O'Flynn O'Brien does not have any potential conflicts of interest. Aletha Y. Akers is a consultant for the Merck HPV advisory board, and received less than \$5000.00 in 2017 and anticipates receiving less than \$10,000 in 2018. She is a member of the Reproductive Health Professionals (ARHP) HPV Advisory Board and receives less than \$5000.00 annually (\$2,500 in 2016), did not receive money in 2017, and anticipates receiving less than \$5000.00 in 2018. She is also a speaker for the Adolescent Reproductive and Sexual Health Education Project (ARSHEP) and she receives less than \$5000.00 annually for this relationship. Lisa K. Perriera has been a consultant to Merck who trains health care providers to insert the Nexplanon contraceptive device, and receives less than \$5000.00 annually. Courtney Schreiber receives research support from Medicines360 and Contramed. She served as a consultant for Berlex Pharmaceuticals in 2016. J. Felipe Garcia-Espana does not have any potential conflicts of interest. Sarita Sonalkar has been a consultant to the World Health Organization and is supported by National Institutes of Health, Women's Reproductive Health Research (WRHR) Career Development Program (K12-HD001265–19).

INTERVENTIONS AND MAIN OUTCOME MEASURES: Pain scores were recorded at seven steps during the procedure from speculum insertion through removal. Time stamps associated with each step were used to calculate the overall procedure duration. Cumulative IUD insertion procedure duration was estimated using the Kaplan-Meier method.

RESULTS: Ninety-five women enrolled. Nineteen (20%) were ages 14 to 17 and 76 (80%) were ages 18 to 22 years. The median procedure duration (seconds $\pm$ IQR) was longer for adolescents than young adults (555 $\pm$ 428 seconds versus 383 $\pm$ 196 seconds, $p = 0.008$). After adjusting for study site, the difference in expected median procedure duration between age groups was not significant ($p=0.3832$).

CONCLUSION: The duration of IUD insertion procedures in adolescent and young adult women is not clinically or statistically significant. Providers should not withhold IUDs from appropriate adolescent and young adult women based on age alone.

CLINICAL TRIAL REGISTRATION: [Clinicaltrials.gov](https://clinicaltrials.gov) (NCT# NCT02352714)

Keywords

Intrauterine devices; young adult; adolescent; long-acting reversible contraception; gynecological surgical procedures; ambulatory surgical procedures

INTRODUCTION

Intrauterine devices (IUDs) are a highly effective, safe, reversible form of contraception appropriate for almost all reproductive age women.¹ Increasing the utilization of IUDs among adolescents and young adult women is a national public health goal as this population frequently chooses less effective contraceptive options (e.g., condoms and the withdrawal method) and has higher rates of inconsistent contraceptive use and discontinuation. These factors contribute to the large number of unintended pregnancies in this population.² Data from the most recent National Health Statistics Report spanning 2011 to 2015 demonstrates that by age fifteen, 11% of girls have had sexual intercourse.³

Despite endorsement by national medical and public health organizations, some health providers have reservations about placing IUDs in adolescents and young adult women.⁴ A qualitative study of providers and patients at 20 publicly funded clinics that provide family planning services found that health providers perceived that IUD counseling and insertion visits required more time in this population than visits with older women.⁵ To overcome this barrier, many clinics mandated separate counseling and insertion visits for this population, resulting in an increased time burden for patients and providers. However, no objective data exists supporting these concerns.

In this secondary data analysis, we sought to determine the difference in IUD insertion procedure duration in adolescents compared to young adult women and to identify factors that may contribute to longer procedure duration. We hypothesized that IUD insertion procedures would be longer in adolescents compared to young adult women.

MATERIALS AND METHODS

This study is a secondary analysis of data from a multisite, single-blind, sham-controlled, randomized clinical trial conducted at three academic clinics in Philadelphia, Pennsylvania from March 2015 to July 2016. A detailed description of the methods has been published previously.⁶ The primary study examined the effectiveness of a 1% lidocaine paracervical block compared to a sham block in reducing patient-reported pain during insertion of the levonorgestrel 13.5 mg IUD (protocol available by request). Institutional Review Board (IRB) approval was obtained from the Children's Hospital of Philadelphia (CHOP, IRB of record), the Hospital of the University of Pennsylvania (HUP), and Thomas Jefferson University (JEFF), all of which performed study visits. Two sites were primarily adult gynecology practices (HUP and JEFF) and one was a pediatric gynecology practice (CHOP). The trial was registered with [Clinicaltrials.gov](https://clinicaltrials.gov) (NCT# NCT02352714).

English – speaking, nulliparous women, ages 14 to 22 years, requesting a hormonal IUD were eligible for screening and enrollment. Women with recent or current pelvic infections or other contraindications to the levonorgestrel 13.5 mg IUD were excluded from the study. 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, as females 13 and older in Pennsylvania can legally consent for reproductive services.

Participants completed a questionnaire assessing demographic characteristics and their medical and reproductive history. IUD insertion followed the manufacturer's instructions and all devices were inserted by an experienced OBGYN provider who was either an attending physician or family planning fellow.

The duration of the IUD insertion procedure was calculated from timestamp data collected as participants rated their pain from 0 to 100 mm on a visual analog scale (VAS) at seven points during the procedure. The specific time points included 1) baseline (after placement in the supine position but prior to dorsal lithotomy positioning), and immediately after placement of the 2) speculum, 3) tenaculum, 4) block, 5) uterine sound, 6) IUD insertion, and 7) speculum removal. Clinicians were required to wait 180 seconds between administering the lidocaine or sham paracervical block and sounding the uterus. Total procedure duration was defined as time from speculum placement to speculum removal and included the 180-second waiting period.

Demographic variables collected included age, race and reproductive health history. The Patient Health Questionnaire for Depression and Anxiety (PHQ-4) score was used as a surrogate for mental health history. The PHQ-4 score consists of a 2-item depression scale and a 2-item anxiety scale. Scores > 3 suggest clinical depression or anxiety, respectively.⁷ Study-specific variables included treatment group assignment (lidocaine or sham paracervical block group) and study site.

Patients were categorized into two age groups: adolescents (ages 14 to 17 years) and young adult women (ages 18 to 22 years). Differences in the baseline characteristics between the age and treatment groups were compared using chi-squared test for proportions, Fisher's exact test for small numbers, and Wilcoxon rank-sum tests for non-normally distributed data.

Wilcoxon rank-sum tests were used to compare the difference in median procedure duration (speculum in to speculum out) between the two age groups. A Cox proportional hazards regression model that included all baseline variables with a p value of 0.05 or less was used to perform an adjusted analysis of IUD insertion procedure duration between age groups. The following covariates were assessed for inclusion in the adjusted model: age group (adolescent versus young adult women), study site, race, pain score at time of IUD insertion, and PHQ-4 score. We planned to include age group in our analysis regardless of its significance. Quantile regression with backward stepwise elimination was employed to identify covariates with a significant effect on the procedure duration. The Kaplan–Meier method was used to estimate the cumulative duration of the IUD insertion procedure and the stratified log-rank statistic to assess the difference between the two age groups. Analyses were performed according to the intention-to-treat principle. P values of 0.05 or less were considered to indicate statistical significance. All statistical analyses were performed in SAS, version 9.4 (Cary, NC).

RESULTS

Ninety-five women enrolled and were included in the analysis. The participants were divided equally between the sham and paracervical block arms. All participants had a successful IUD insertion. Almost half were white (44%) and a third were black (36%). The study groups were unequal with young adult women ages 18 to 22 years comprising 80% of the study population. Ninety-two percent of participants (n= 82) reported having sex at least once, however, only 44% had ever had a gynecological exam with a speculum. The participants were unevenly distributed across the study sites. Almost half were enrolled at HUP (47%) or CHOP (45%), and only 7% were recruited from JEFF. In terms of patient reported anxiety and depression, rates in our population were low with almost 90% of participants scoring negatively on the PHQ-4 questionnaire. The demographic characteristics described above are summarized in Table 1.

Median reported pain scores were not significantly different between adolescents and young adult women. The median VAS score for adolescents was 70 mm and for young adult women it was 61 mm (p = 0.4392).

The unadjusted median IUD insertion procedure duration for the study population was 417 seconds, or 6.95 minutes. The unadjusted median IUD insertion procedure duration (seconds $\pm$ IQR) was longer in adolescents compared to young adult women (555 $\pm$ 428 seconds versus 383 $\pm$ 196 seconds, p = 0.008). This was a difference of 172 seconds, or 2.87 minutes.

Using backward stepwise elimination with quantile regression, the only covariate associated with IUD insertion procedure duration was study site. The median insertion procedure duration was longest at CHOP compared to JEFF and HUP (581 $\pm$ 375 seconds, 362 $\pm$ 49 seconds, and 360 $\pm$ 60 seconds, respectively, p = <0.0001). A sensitivity analysis was performed which compared the estimated median procedure duration between the pediatric and adult sites for the group young adult women only, and the procedural times remained significantly longer at the pediatric site (p = <0.0001). When controlling for study site, the

expected median procedure duration, adjusted by age group, was only 41 seconds longer in adolescents compared with young adult women (472 seconds versus 431 seconds; $p = 0.3832$). This difference is clinically and statistically insignificant. The similarity between the expected median duration for the overall procedure and each procedural step between adolescents and young adult women is demonstrated graphically in Figure 1.

Using the Kaplan – Meier method to compare the overall IUD insertion procedure duration in each age group, the log rank test demonstrated a statistically significant difference in survival curves ($p = 0.0283$). After adjusting for study site and age group in a proportional hazards model, the hazard ratio for age group was not statistically significant (HR for age < 17 years: 1.040, 95% CI 0.584, 1.851).

DISCUSSION

In this study, we compared the duration of the IUD insertion procedure between adolescent and young adult women. We found that overall IUD insertion procedure duration was similar among nulliparous adolescents and young adult women. Our measure of the procedure duration was from speculum placement to speculum removal, encompassing the time needed for uterine sounding and IUD insertion (a proxy for difficulty navigating the cervix), as well as time related to psychosocial management of the pelvic exam. When accounting for study site and age group, the adjusted difference between expected median insertion procedure duration between adolescents and young adult women, 41 seconds, was statistically and clinically insignificant.

Limited information exists regarding the duration of IUD insertion procedures, regardless of patient age. A few trials exploring pain control options for IUD insertion have compared IUD insertion procedure duration between treatment groups.^{8–11} Mody et al. studied 1% paracervical block versus placebo for pain relief during IUD insertion among adult women and found a non-significant trend towards reduced pain in the paracervical block group, but significantly longer median procedure duration in the paracervical block group (9.1 minutes versus 4.3 minutes, $p < 0.0001$).¹² In that study, a standardized waiting period of 180-seconds was only observed for the paracervical block group. In comparison, our overall median IUD insertion duration in the setting of a paracervical block was faster at 6.95 minutes, which includes a 180-second waiting period after receiving either a paracervical or sham block. Importantly, none of the previously published studies compared differences in procedure duration based on patient characteristics.

IUD insertion procedure duration was longest at the pediatric site, CHOP. This outcome was unexpected as there were no obvious differences in patient or provider characteristics across sites besides patient age. Specifically, there were no differences in participants' prior experience with pelvic exams, previous sexual activity, anxiety or depression scores, or pain following IUD insertion. The procedures were all performed by OBGYN faculty or senior family planning fellows with extensive experience inserting IUDs. One potential explanation for site-related differences in procedure duration is that both adult sites are family planning clinics that routinely perform outpatient intrauterine procedures, including uterine aspirations for induced abortion and miscarriage. The systems in place at those sites may

have contributed to shorter procedure duration for IUD insertions. Guidelines for creating an adolescent-centered perioperative environment recommend that the adolescent patient guide the pace of procedures. They suggest that adolescent patients be allowed to examine the operative equipment, given the opportunity to ask as many questions as needed, and to have support persons present.¹³ This approach to structuring the care experience for patients in pediatric settings may result in increased procedure duration. The impact of different clinical environments on procedure duration and patient satisfaction is an area of future research.

There are several key strengths of this study. Strengths include the use of data from a high-quality randomized controlled trial, which minimizes bias between the treatment groups, and the inclusion of only nulliparous women. Important limitations include the inclusion of women from a single city resulting in potentially limited generalizability of study results and exclusive use of the 13.5 mg levonorgestrel IUD. The study population was skewed in terms of age, with larger numbers of young adult women recruited compared to adolescents, as this secondary aim was not the focus of the primary study analysis. Our results may have been influenced by unmeasured differences affecting how the providers at the pediatric and adult sites perform the IUD insertion procedure outside of the technical procedural steps, as discussed above. Additionally, our study did not standardize pre-procedural counseling, which could potentially influence the length of a visit and subsequent procedure. A larger, multisite study with comparable proportions of adolescents and young adult women that is designed to address unanswered questions regarding the influence of clinical environment on the technical aspects of a procedure is warranted. The generalizability and application of our study results is limited by the fact that adult women were not included in the study population. Further research comparing the duration of IUD insertion procedures in adult women to adolescent and young adult women may inform decision-making regarding IUD insertion procedures for providers who care for women of all ages.

In conclusion, we found no difference in the duration of IUD insertion procedures among adolescents and young adult women. The lack of difference in procedure duration by age should empower providers that care for adolescent and young adult women to feel more comfortable uniformly offering IUDs to their patient population to increase uptake of this effective form of contraception among these patients particularly vulnerable to unintended pregnancy.

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Figure 1. Expected median duration for IUD insertion procedure in adolescents and young adult women: overall procedure duration and duration of each procedural step adjusted for study site Of note, the sum of the expected median duration of each procedural step does not equal to the expected median duration of the overall procedure.

Table 1:

Demographic Characteristics by Age Group

Characteristic	Ages 14–17 n (% of total)	Ages 18–22 n (% of total)	Total n (%)	p=
Location				<i>p=0.004</i>
HUP	4 (4.2)	41 (43.2)	45 (47.4)	
CHOP	15 (15.8)	28 (29.5)	43 (45.3)	
JEFF	0 (0)	7 (7.4)	7 (7.4)	
Race				<i>p<0.0001</i>
White	3 (3.2)	39 (41.1)	42 (44.2)	
Black	14 (14.7)	20 (21.1)	34 (35.8)	
Asian	0 (0)	13 (13.7)	13 (13.7)	
Other	2 (2.1)	4 (4.2)	6 (6.3)	
Type of block				<i>p=0.76^a</i>
Sham	9 (9.5)	39 (41.1)	48 (50.5)	
Paracervical	10 (10.5)	37 (39.0)	47 (49.5)	
Ever had sexual intercourse	16 (16.8)	71 (74.7)	87 (91.6)	p=0.20
Ever had a speculum exam	5 (5.3)	37 (39.0)	42 (44.2)	p=0.12
PHQ - 4 ^b Score ^c				p=0.06
Positive	5 (5.3)	7 (7.3)	12 (12.6)	
Negative	14 (14.7)	69 (72.6)	83 (87.3)	

All p-values are derived from Fisher's exact test, except as noted. Significant p-values are italicized.

^aChi squared test

^bPatient Health Questionnaire for Depression and Anxiety

^cResponses scoring greater than 3 were recorded as positive results.