Original Report

Intrauterine Device Insertion Procedure Duration in Adolescent and Young Adult Women

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A B S T R A C T

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 vs sham paracervical nerve block for pain control during levonorgestrel 13.5 mg IUD insertion. Adolescent and young adult women ages 14-22 years were recruited from 3 outpatient academic sites in Philadelphia, Pennsylvania.

Interventions and Main Outcome Measures: Pain scores were recorded at 7 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 (19/95, 20%) were ages 14-17 and 76 (76/95, 80%) were ages 18-22 years. The median procedure duration (seconds ± interquartile range) was longer for adolescents than for young adults (555 ± 428 seconds vs 383 ± 196 seconds; $P = .008$). After adjusting for study site, the difference in expected median procedure duration between age groups was not significant ($P = .3832$).

Conclusion: The difference in 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 on the basis of age alone.

Key Words: 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 because this population frequently chooses less effective contraceptive options (eg, 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 2011-2015 showed that by age 15 years, 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 showed 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 to support these concerns.

In this secondary data analysis, we sought to determine the difference in IUD insertion procedure duration in adolescents compared with that in young adult women and to

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This study is registered at Clinicaltrials.gov (NCT02352714).

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identify factors that might 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 was a secondary analysis of data from a multisite, single-blind, sham-controlled, randomized clinical trial conducted at 3 academic clinics in Philadelphia, Pennsylvania, from March 2015 to July 2016. A detailed description of the methods has been previously published.[6] The primary study examined the effectiveness of a 1% lidocaine paracervical block compared with a sham block in reducing patient-reported pain during insertion of the levonorgestrel 13.5 mg IUD (protocol available by request). Institutional review board approval was obtained from the Children's Hospital of Philadelphia (CHOP; institutional review board 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 1 was a pediatric gynecology practice (CHOP). The trial is registered at Clinical trials.gov (NCT02352714).

English-speaking, nulliparous women, ages 14-22 years, who requested 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, because young women age 13 and older in Pennsylvania can legally consent for reproductive services.

Participants completed a questionnaire on demographic characteristics and their medical and reproductive history. The IUD insertion procedure followed the manufacturer's instructions and all devices were inserted by an experienced obstetrics and gynecology 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 analogue scale at 7 points during the procedure. The specific time points included: (1) baseline (after placement in the supine position but before 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.

Data on 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 2 age groups: adolescents (ages 14-17 years) and young adult women (ages 18-22 years). Differences in the baseline characteristics between the age and treatment groups were compared using the χ^2 test for proportions, Fisher 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 2 age groups. A Cox proportional hazards regression model that included all baseline variables with a P value of .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 vs 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 used 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 2 age groups. Analyses were performed according to the intention-to-treat principle. P values of .05 or less were considered to indicate statistical significance. All statistical analyses were performed using SAS, version 9.4 (SAS Institute Inc, 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 (42/95, 44%) and a third were black (34/95, 36%). The study groups were unequal with young adult women ages 18-22 years comprising 80% (76/95) of the study population. Ninety-two percent of participants (87/95) reported having sex at least once, however, only 44% (42/95) had ever had a gynecological exam with a speculum. The participants were unevenly distributed across the study sites. Almost half were enrolled at HUP (45/95, 47%) or CHOP (43/95, 45%), and only 7% (7/95) were recruited from JEFF. In terms of patient-reported anxiety and depression, rates in our population were low with 87% (83/95) of participants scoring negatively on the PHQ-4 questionnaire. The previously described demographic characteristics are summarized in Table 1. Median reported pain scores were not significantly different between adolescents and young adult women. The median visual analogue scale score for adolescents was 70 mm and for young adult women it was 61 mm ($P = .4392$).

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 $\pm$ interquartile range) was longer in

Table 1
Demographic Characteristics According to Age Group

Characteristic	Ages 14-17, n (% of Total)	Ages 18-22, n (% of Total)	Total, n (%)	*P*
Location				**.004**
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				**.0001**
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				.76*
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)	.20
Ever had a speculum exam	5 (5.3)	37 (39.0)	42 (44.2)	.12
PHQ-4 Score†				.06
Positive	5 (5.3)	7 (7.4)	12 (12.6)	
Negative	14 (14.7)	69 (72.6)	83 (87.3)	

CHOP, Children's Hospital of Philadelphia; HUP, Hospital of the University of Pennsylvania; JEFF, Thomas Jefferson University; PHQ-4, Patient Health Questionnaire for Depression and Anxiety.
All *P* values are derived from Fisher exact test, except as noted. Significant *P* values are shown in bold.
* χ^2 test.
† Responses with a score of greater than 3 were recorded as positive results.

adolescents compared with that in young adult women (555 ± 428 seconds vs 383 ± 196 seconds; $P = .008$). 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 with that at JEFF and HUP (581 ± 375 seconds, 362 ± 49 seconds, and 360 ± 60 seconds, respectively; $P < .0001$). A sensitivity analysis was performed in which the estimated median procedure duration was compared between the pediatric and adult sites for the group young adult women only, and the procedural times remained significantly longer at the pediatric site ($P < .0001$). When controlling for study site, the expected median procedure duration, adjusted by age group, was only 41 seconds longer in adolescents compared with that in young adult women (472 seconds vs 431 seconds; $P = .3832$). 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 shown 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 showed a statistically significant difference in survival curves ($P = .0283$). After adjusting for study site and age group in a proportional hazards model, the hazard ratio for age group was not statistically significant (hazard ratio for age ≤17 years, 1.040; 95% confidence interval, 0.584-1.851).

Discussion

In this study, we compared the duration of the IUD insertion procedure in adolescent and young adult women. We found that the 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 on pain control options for IUD insertion have compared

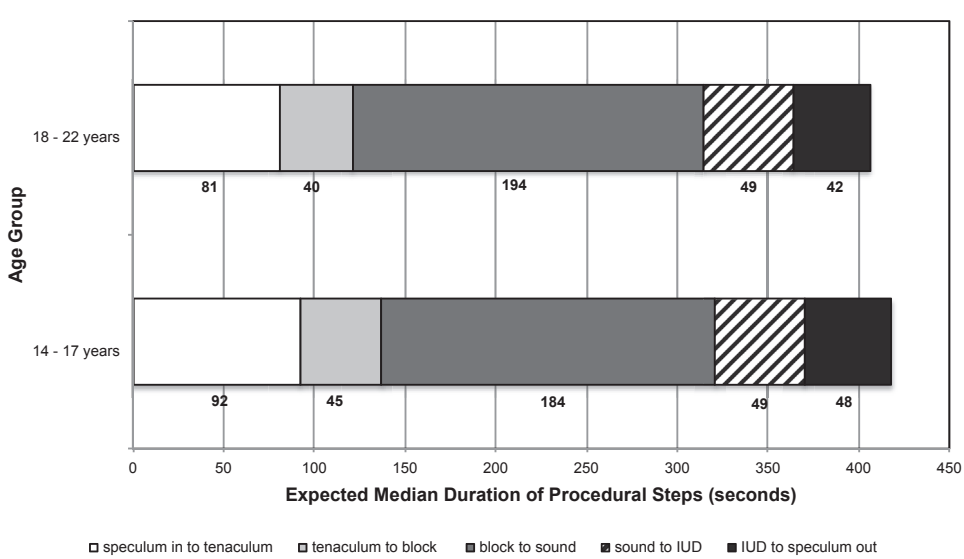

Fig. 1. Expected median duration for intrauterine device (IUD) insertion procedure in adolescents and young adult women: overall procedure duration and duration of each procedural step is adjusted for study site. Of note, the sum of the expected median duration of each procedural step does not equal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

IUD insertion procedure duration between treatment groups.[8–11] Mody et al studied 1% paracervical block vs placebo for pain relief during IUD insertion among adult women and reported a nonsignificant trend toward reduced pain in the paracervical block group, but significantly longer median procedure duration in the paracervical block group (9.1 minutes vs 4.3 minutes; $P < .0001$).[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 on the basis of patient characteristics.

IUD insertion procedure duration was longest at the pediatric site, CHOP. This outcome was unexpected because there were no obvious differences in patient or provider characteristics across sites besides patient age. Specifically, there were no differences in participants' previous experience with pelvic exams, previous sexual activity, anxiety or depression scores, or pain after IUD insertion. The procedures were all performed by obstetrics and gynecology 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 might 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 procedure 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 might result in increased procedure duration. The effect 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 levonorgestrel 13.5 mg IUD. The study population was skewed in terms of age, with larger numbers of young adult women recruited compared with adolescents, because this secondary aim was not the focus of the primary study analysis. Our results might 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 previously discussed. Additionally, our study did not standardize preprocedural 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 on the duration of IUD insertion procedures in adult women compared with adolescent and young adult women might 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 according to age should empower providers who 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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References

1. Curtis KM, Tepper NK, Jatlaoui TC, et al: U.S. medical eligibility criteria for contraceptive use, 2016. MMWR Recomm Rep 2016; 65:1
2. Martinez GM, Abma JC: Sexual activity, contraceptive use, and childbearing of teenagers aged 15-19 in the United States. NCHS Data Brief 2015; 209:1
3. Abma JC, Martinez GM: Sexual activity and contraceptive use among teenagers in the United States, 2011-2015. Natl Health Stat Rep 2017; 104:1
4. Committee on Adolescent Health Care Long-Acting Reversible Contraception Working Group, The American College of Obstetricians and Gynecologists: Committee opinion no. 539: adolescents and long-acting reversible contraception: implants and intrauterine devices. Obstet Gynecol 2012; 120:983
5. Kavanaugh ML, Frohwirth L, Jerman J, et al: Long-acting reversible contraception for adolescents and young adults: patient and provider perspectives. J Pediatr Adolesc Gynecol 2013; 26:86
6. Akers AY, Steinway C, Sonalkar S, et al: Reducing pain during intrauterine device insertion: a randomized controlled trial in adolescents and young women. Obstet Gynecol 2017; 130:795
7. Kroenke K, Spitzer RL, Williams JB, et al: An ultra-brief screening scale for anxiety and depression: the PHQ-4. Psychosomatics 2009; 50:613
8. Edelman AB, Schaefer E, Olson A, et al: Effects of prophylactic misoprostol administration prior to intrauterine device insertion in nulliparous women. Contraception 2011; 84:234
9. Aksoy H, Aksoy U, Ozyurt S, et al: Lidocaine 10% spray to the cervix reduces pain during intrauterine device insertion: a double-blind randomised controlled trial. J Fam Plann Reprod Health Care 2016; 42:83
10. Allen RH, Raker C, Goyal V: Higher dose cervical 2% lidocaine gel for IUD insertion: a randomized controlled trial. Contraception 2013; 88:730
11. Ibrahim ZM, Sayed Ahmed WA: Sublingual misoprostol prior to insertion of a T380A intrauterine device in women with no previous vaginal delivery. Eur J Contracept Reprod Health Care 2013; 18:300
12. Mody SK, Kiley J, Rademaker A, et al: Pain control for intrauterine device insertion: a randomized trial of 1% lidocaine paracervical block. Contraception 2012; 86:704
13. Monahan JC: Using an age-specific nursing model to tailor care to the adolescent surgical patient. AORN J 2014; 99:733