Randomizing women to intrauterine device type: a pilot study experience

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ACCEPTABILITY OF THE IUD AMONG WOMEN WHO OPTED OUT OF A RANDOMIZED CONTROLLED TRIAL OF INTRACESAREAN INSERTION OF THE COPPER-T 380A IN KAMPALA, UGANDA

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Objectives: The purpose of this study was to examine factors associated with the acceptability of the intrauterine device (IUD) among women who opted out of a randomized trial of intraccesarain insertion of the copper IUD.

Methods: This study is a cross-sectional, mixed-methods cohort study nested within a randomized controlled trial comparing outcomes of immediate post-placental insertion of the copper IUD to interval insertion performed 6 weeks after delivery for patients undergoing cesarean delivery at the Mulago Hospital in Kampala, Uganda. All eligible women were recruited during a three-month period. Women who chose not to participate in the randomized trial were asked to participate in the opt-out study.

Results: Of the 212 women screened, 96 enrolled, 116 opted out and 110 completed surveys. Of survey respondents, 61 (55%) expressed a positive opinion about the IUD overall, while 14 (13%) expressed a negative opinion. Forty-five (41%) had opted out because they wanted to ask their husband first, 16 (15%) said their husband did not like the IUD, 18 (16%) did not like the IUD themselves, and 12 (11%) wanted to use another method. Twenty-six women (24%) expressed concern about side effects, 16 (15%) believed the IUD causes cervical or uterine cancer, and 7 (6%) believed it causes fibroids.

Conclusions: Women are interested in immediate postpartum IUD insertion, but fear of partner disapproval is a barrier to uptake in this population. There are also many misconceptions about the safety of the IUD. Future efforts aimed at expanding access to long-acting reversible contraception in this population should include outreach to men as well as women.

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RANDOMIZING WOMEN TO INTRAUTERINE DEVICE TYPE: A PILOT STUDY EXPERIENCE

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Objectives: To assess feasibility and acceptability of randomizing women seeking an intrauterine device (IUD) for contraception to IUD type.

Methods: Women seeking an IUD for contraception were enrolled in a pilot study designed to quantify immune cell populations in the reproductive tract. Enrolled women were block randomized to the levonorgestrel IUD (LNG-IUD) or the Copper T380A (Cu-IUD) in a 1:1 ratio. Women were informed during study consent that they would have the option at the final visit to keep or remove the IUD, or to exchange the IUD at no cost for the other IUD type. The 2-month follow-up visit, study participants were asked about their satisfaction with the IUD and menstrual changes. Removal or exchange of the IUD was performed if requested.

Results: All 32 enrolled subjects returned for the two-month follow-up. Twenty-seven women (84%) were satisfied with the IUD to which they were randomized. The 5 dissatisfied women included 1 of 16 women (6%) randomized to the LNG-IUD and 4 of 16 women (25%) randomized to the Cu-IUD (p=33, Fisher exact test). All dissatisfied women cited menstrual changes as the primary reason for dissatisfaction. Two (6%) opted to exchange the IUD, 2 (6%) opted for IUD removal, and 1 (3%) opted to keep the IUD despite stated dissatisfaction. The dissatisfied woman who was randomized to the LNG-IUD opted for removal. The
overall continuation rate at 2 months was 88% with the randomized IUD and 94% with any IUD.

Conclusions: Randomization to IUD type during contraceptive research participation is feasible and acceptable to most women seeking an IUD for contraception.

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CERVICAL LIDOCAINE FOR IUD INSERTIONAL PAIN: A RANDOMIZED CONTROL TRIAL
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Objectives: Anticipated pain with intrauterine device (IUD) insertion may be a barrier to more widespread use of this highly effective method of contraception. Previous research evaluating nonsteroidal anti-inflammatory medications, paracervical block with local anesthetic, and cervical ripening agents has been disappointing. Our objective was to evaluate the efficacy of 2% lidocaine gel for pain relief with IUD insertion.

Methods: We performed a double-blind, randomized control trial of women undergoing IUD insertion at a single site. Participants were randomly assigned to 2% lidocaine gel or placebo water-based lubricant and received 3 cc’s of study gel 3 minutes prior to IUD insertion. Using a 10-point Visual Analog Scale, pain scores were assessed for anticipated pain, for pre-procedural baseline pain, after tenaculum placement and immediately following IUD insertion.

Results: Two hundred women were randomized and 199 completed the study. Pain scores among women receiving lidocaine and placebo gel were similar both at tenaculum placement (lidocaine and placebo: median score 4, range 0–10; p=0.15) and with insertion (lidocaine: median score 5, range 1–10; placebo: median score 6, range 0–10; p=0.16), regardless of parity. We had no serious adverse events with the use of 2% lidocaine.

Conclusions: Neither topical nor intracervical 2% lidocaine gel prior to IUD insertion decreases pain scores.

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REASONS FOR INTRAUTERINE DEVICE REMOVAL: A COMPARISON OF ADULTS AND ADOLESCENTS
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Objectives: To determine if bleeding and/or cramping is a more common reason for intrauterine device (IUD) removal in adolescents than in adult women.

Methods: In this retrospective cohort study, the charts were reviewed of women who underwent IUD removal at an academic medical center between July 1, 2004, and December 1, 2011, including charts of adolescents (N=172) and a comparison group of adults (N=183). Demographic characteristics, type of IUD and reason for removal were abstracted. Analysis included all women with an identifiable IUD type (LNG IUS or CuT380A, total N=340). Differences were compared by chi-square for categorical variables.

Results: The most common reasons for removal in adolescents were bleeding and/or cramping (47%), desired pregnancy (16%) and incorrect location (16%). In adults, the most common reasons were bleeding and/or cramping (49%), desired pregnancy (23%), and completed IUD lifespan (11%). The percentage of adolescents who had an IUD removed for bleeding and/or cramping was not different from that of adults (p=0.07). Of 165 adolescents, 112 discontinued the LNG IUS (68%) and 53 discontinued the CuT380A (32%). In the adult population, 112 discontinued the LNG IUS (64%) and 63 discontinued the CuT380A (36%). The percentage of adolescents who discontinued an IUD for bleeding and cramping was not different from that of adult women for the LNG IUS (p=0.06) or for the CuT380A IUD (p=0.72).

Conclusions: Among women presenting for IUD removal, adolescents were not more likely to discontinue either the LNG IUS or CuT380A for bleeding and cramping.

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PREDICTORS OF IUD INITIATION IN ADOLESCENTS
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Objectives: To understand knowledge, attitudes, and beliefs regarding intrauterine devices (IUDs) among adolescents initiating contraception and determine factors associated with receiving an IUD.

Methods: We recruited 12–24-year-old new patients at Children’s Hospital Colorado Family Planning Clinic. Participants completed pre-visit CASI surveys regarding demographics, pregnancy attitudes, contraceptive information sources and preferences. Participants received standard clinical care, including QuickStart contraceptive initiation. Post-visit CASI surveys assessed perceived provider influence. IUD initiators were compared with users of short-acting methods.

Results: A total of 393 participants completed surveys to date. During the visit, 33.4% received IUDs, 37.7% the implant, 15.2% oral contraceptive pills, 5.9% depot medroxyprogesterone acetate, 4.1% the vaginal ring, 0.8% the patch and 2.9% another or no method. Choosing IUDs versus short-acting methods was associated with age ≥20 years, white race and ≥12th-grade education. Gravidity, parity and sexual activity were not associated with IUD uptake. Those who received IUDs were more likely than other participants to have had high pre-visit IUD acceptability scores (89.6% vs. 22.1%, p<0.001) and to know someone who used an IUD (83.3% vs. 61.3%; p=0.002). IUD choosers were more likely to have a friend who liked her IUD (78.3% vs. 52.9%; p=0.008) and more likely to say that they were influenced by factors prior to the visit rather than by information obtained at the visit (68.2% vs. 55.9%; p=0.057). In multivariable analysis including demographic and social-exposure factors, having a friend who liked her IUD and being white predicted IUD choice.

Conclusions: At this Title X adolescent family planning clinic, factors prior to the clinic visit are more likely than information obtained at the clinic to influence adolescents to choose an IUD; future research will focus on effective pre-visit social and educational messaging about this highly effective method.

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LONG-ACTING REVERSIBLE CONTRACEPTIVE SERVICES FOR TEENS AND YOUNG ADULTS IN PUBLICLY FUNDED FAMILY PLANNING FACILITIES IN THE US
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Objectives: Increased use of long-acting reversible contraception (LARC) methods among teens and young adults has the potential to significantly reduce unintended pregnancy among these women. Objectives were to describe youth-friendly LARC services available to teens and young adults at US publicly funded family planning facilities.

Methods: Between April and September 2011, clinic directors at a nationally representative sample of 1206 publicly funded facilities that provide family planning services were surveyed; 584 (52%) responded.