3-1-2018

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Reni Soon
Swedish Medical Center, Seattle, WA

Katie McGuire
Swedish Medical Center, Seattle, WA

Jennifer Salcedo
Swedish Medical Center, Seattle, WA

Bliss Kaneshiro
Swedish Medical Center, Seattle, WA

Immediate Versus Delayed Insertion of the Levonorgestrel Intrauterine Device in Postpartum Adolescents: A Randomized Pilot Study

Reni Soon MD, MPH; Katie McGuire MD;, Jennifer Salcedo MD, MPH, MPP; and Bliss Kaneshiro MD, MPH

Abstract

This pilot study assessed the feasibility of conducting a larger randomized controlled trial comparing the proportion of adolescents using a levonorgestrel intrauterine device (LNG IUD) at six months postpartum when it is inserted immediately after vaginal delivery (within 10 minutes after placental expulsion) compared to insertion four to six weeks postpartum. Pregnant adolescents (14 to 19 years) who desired a LNG IUD for postpartum contraception were randomized to insertion of the LNG IUD either within 10 minutes of delivery of the placenta or at 4-6 weeks postpartum. Study follow-up visits were conducted at 4-6 weeks postpartum, 10 weeks postpartum, and 6 months postpartum. From November 2013 to June 2015, eleven adolescents were randomized - six participants to the immediate postpartum LNG IUD insertion group, and five to the delayed insertion group. All six women in the immediate insertion group had successful immediate postpartum insertion; two of five women in the delayed insertion group had an IUD inserted. At six months postpartum, four of six women in the immediate insertion group had a LNG IUD in place; of the five women in the delayed group, three did not have a LNG IUD in place and two were pregnant. The study was discontinued after 19 months because of suboptimal enrollment. Though insertion of a LNG IUD immediately after delivery is an appropriate option for some adolescents, a larger prospective study comparing immediate to delayed LNG IUD insertion is unlikely to be feasible at our institution.

Keywords

long-acting reversible contraception (LARC), adolescent contraception, postpartum contraception, intrauterine device (IUD)

Abbreviations

LARC – Long-acting reversible contraception
IUD – intrauterine device
LNG – levonorgestrel
OCPs – oral contraceptive pills
DMPA – Depot medroxyprogesterone acetate
UH – University of Hawai'i
OB/GYN – Obstetrics and gynecology

Introduction

Immediate postpartum insertion of long acting reversible contraception (LARC) is increasingly recognized as a useful approach to reduce unintended pregnancies.[1] Among adolescents, 75% of pregnancies are unintended[2] and one in five adolescent mothers becomes pregnant again within 12 months of delivery.[3] In Hawai'i, 17% of all births among women age 15 to 19 years are repeat births.[4] To avoid increasing the socioeconomic hardship,[5-8] and pregnancy complications[9] associated with repeat adolescent births, access to immediate postpartum contraception is particularly important in this population.

LARC methods, including the copper and levonorgestrel (LNG) intrauterine devices (IUDs) and the contraceptive implant, are described as first-line contraceptives for adolescents and adults by the American College of Obstetricians and Gynecologists.[10] LARC methods require little action on the part of the patient after insertion, resulting in typical-use effectiveness of 99.8% in the first year of use.[11,12] Women using the oral contraceptive pill, patch, and ring are 22 times more likely to become pregnant in the first year of use compared with women using a LARC method.[13]

Programs most successful at reducing rapid repeat adolescent pregnancy have generally included promotion of LARC methods.[3,14,15] Immediate postpartum IUD insertion, defined as insertion of an IUD within ten minutes of placental delivery, has been studied in adult women. Insertion in this setting is convenient for the patient and the provider, bypasses many of the barriers that are present when women wait the standard four to six weeks following delivery for IUD insertion, and ensures that the woman is not pregnant at the time of insertion. An increasing number of studies have investigated immediate postpartum insertion of the LNG IUD,[16-20] but most lack randomization and fail to provide adequate information on adolescents. Not only do adolescents disproportionately experience unintended pregnancy, but they also may be differently affected by factors like expulsion rates and the desire for reinsertion of the device compared to adults. Furthermore, adolescent mothers typically face more barriers to care following discharge from the hospital.[21]

The aim of this pilot study was to determine the feasibility of conducting a large randomized controlled trial comparing the proportion of adolescents using a LNG IUD at 6 months postpartum when it is placed within 10 minutes of delivery of the placenta following vaginal delivery (immediate insertion) versus four to six weeks postpartum (delayed insertion). We also aimed to identify methodological challenges and the percent attrition in both study groups. Additional outcomes included patient satisfaction, expulsion, bleeding patterns, and breastfeeding rates.

Materials and Methods

This prospective, randomized pilot study was conducted at Kapi'olani Medical Center for Women and Children in Honolulu, Hawai'i, which is the primary training site for the University of

Hawai'i (UH) John A. Burns School of Medicine Department of Obstetrics and Gynecology (OB/GYN) residency program. We enrolled pregnant adolescents (14 to 19 years old) who planned to use a LNG-IUD after delivery and randomized participants to immediate postpartum or delayed insertion of the LNG-IUD. We excluded women with an allergy to the LNG-IUD; chlamydia or gonorrhea during pregnancy without a negative test-of-cure result; an anomaly distorting the uterine cavity; current cervical cancer; a desire for a repeat pregnancy within one year; plans to move from Oahu less than six months after delivery; a planned cesarean delivery; or a delivery at less than 34 weeks gestation. This study received approval from the Western Institutional Review Board.

Potential participants were identified either at their presentation to the labor and delivery suite or at their prenatal visits at the UH resident or faculty practice clinics. Potential participants were approached about the study at 24 weeks gestation or greater, and were assured that their care would not be affected whether they chose to participate in the study or not. If an antepartum patient expressed interest in enrolling, a notation was made in her chart. Patients were then screened for eligibility and enrolled in the study at the time of presentation to the labor and delivery suite. After consent was obtained, participants completed a demographic and medical information questionnaire. Study personnel placed one of the sequentially numbered, opaque sealed envelopes with the participant's allocation assignment in the delivery room. A statistician not involved with the conduct of the study used a true random number generator to develop the 1:1 randomization scheme using block sizes of six. Subsequent exclusion criteria included: chorioamnionitis, postpartum hemorrhage, unanticipated cesarean delivery, and delivery at a time when a study investigator was unavailable. To limit post-randomization exclusions, the envelope with the participant's allocation assignment was opened after delivery. If exclusion criteria were met after consent, the unopened envelope with the study allocation assignment was returned to the stack of envelopes to maintain sequential numbering.

Patients randomized to immediate insertion had their procedure performed within ten minutes of delivery of the placenta by study investigators or UH OB/GYN residents under the direct supervision of study investigators. Insertions were performed using a technique similar to that described by O'Hanley, et al,[22] and Hayes, et al.[16] After placental expulsion and uterine massage, the IUD was removed from the inserter and placed by hand at the uterine fundus. The other hand palpated the fundus abdominally to ensure that the hand inserting the IUD was at the fundus. If placement by hand was not possible due to patient discomfort, ring forceps were used to insert the IUD using a technique described by Speroff and Mishell[23] and employed in the study by Dahlke, et al.[18] Strings were trimmed three centimeters from the external os. While ultrasound was not a routine part of the study protocol, use was left to the discretion of the treating physicians. Participants randomized to delayed insertion had the LNG IUD placed four to six weeks following delivery using the standard technique by their obstetrician (residents with faculty supervision or faculty).

Study visits were scheduled at four to six weeks, ten weeks, and six months postpartum. Participants were given a $5 online gift card at each study visit as compensation for their time. A study coordinator scheduled the four to six week follow up visit prior to hospital discharge. At each study visit, a pelvic exam was performed and if the IUD strings were not visible, an ultrasound was performed to confirm intrauterine position. If the IUD was visible in the cervix, it was considered an expulsion and was removed. Any patient who experienced an expulsion during the six-month study period was counseled about all contraceptive options and was given the option of insertion of another LNG IUD at no cost. Participants were also asked about bleeding, cramping, fever, pain, sexual activity, and breastfeeding. Participants rated their satisfaction with the LNG IUD on a 10-cm Visual Analog Scale, anchored at 0 being very unsatisfied and 10 being very satisfied. Participants who wished to have the LNG IUD removed could return at any time during the 6-month postpartum study period to do so at no cost.

Three phone calls were made to participants who did not return for their follow up visits. If a participant declined an in-person visit, phone follow-up was done and participants were asked all the questions that would have been asked in an in-person visit, as well as additional questions to assess the likelihood of IUD expulsion. The patient's medical record was reviewed to determine if she sought care related to the IUD or had a postpartum complication.

The sample size of this pilot study was estimated to determine feasibility of a larger study. We used principles outlined by Hertzog[24] to estimate that a sample size of 30 participants, 15 in each group, would be needed to adequately describe recruitment, post-enrollment exclusion, and attrition to determine the feasibility of a larger study. With this sample size and an observed 15% attrition rate we could be 68% confident that our estimates would be accurate within 8 percentage points.

The study was discontinued prior to meeting our sample size goal due to suboptimal enrollment. We had planned to compare the proportion of participants who continued to use the LNG IUD at six months with Chi-square or Fisher's exact tests. Patients who experienced an expulsion but had an IUD reinserted would have been classified as using an IUD, and we were planning to analyze using intention-to-treat principles. However, because the study had to be discontinued, the participants and their follow-up are described.

Results

From November 2013 to June 2015, 18 women verbally agreed to participate. Seven women were excluded prior to randomization – three women had a cesarean section, one developed chorioamnionitis, one delivered at less than 34 weeks gestation, one declined insertion of an IUD, and for one participant the reason for exclusion was not recorded. Of the eleven women remaining, six were randomized to immediate insertion and five to delayed insertion.

Patient demographic factors are described in Table 1. The mean age of participants was 18.4 years. Six participants had been previously pregnant, and three had experienced a prior delivery. Five of the participants had never used a form of contraception; four had used condoms; and four had used a short-term hormonal contraceptive.

All of the participants and their course through the study are detailed in Table 2 and Figure 1. Of the six participants randomized to immediate IUD insertion, all six had successful insertion of their IUDs immediately postpartum (100% insertion), and four (67%) had the IUD in place at six months postpartum. One participant in the immediate insertion group had an IUD expulsion prior to her 4-6 week follow-up visit and did not desire IUD replacement. She was unable to be reached for the 10-week follow-up and 6-month follow-up visits. The other participant randomized to immediate insertion requested removal of her IUD at her 10-week visit because of some discomfort she attributed to the IUD and requested a contraceptive injection. She could not be reached for her 6-month follow-up.

Of the five participants randomized to delayed IUD insertion at follow-up, only two had an IUD inserted (40% insertion). At six months, one of the two had had her IUD removed a month after insertion and was pregnant; the other was unable to be reached. Of the three participants randomized to delayed insertion who never had an IUD inserted, one of them presented to the labor and delivery suite eleven months postpartum with a term pregnancy, and two declined IUD insertion at their follow-up visits. At six months postpartum, three of the five participants randomized to delayed IUD insertion did not have IUDs in place and two of the three were pregnant.

Some of the participants followed up at outside facilities instead of the resident clinic where study visits were conducted. Of the 18 follow-up visits among the immediate insertion participants, 14 were completed (78%); of the 15 follow-up visits among delayed insertion participants, six (40%) were completed, but two were completed over the phone and two were completed at an outside facility. Because of this, we have data on contraceptive method at the time of the visit but do not have data for most participants on bleeding patterns, breastfeeding, sexual activity or contraceptive method satisfaction. Therefore we are unable to comment on any differences in these outcomes between groups. Of the six participants who had follow-up visits in the resident clinic, five were in the immediate insertion group. Four of these five expressed a preference for IUD insertion immediately postpartum over delayed insertion and rated their experience as "very satisfied." One participant who had an immediate insertion and had an IUD expulsion prior to her 4-6 week visit stated she would prefer delayed IUD insertion over immediate. One participant in the delayed insertion group, and the only one from that group who followed-up in the resident clinic and therefore the only one who was asked the question, stated she did not have a preference for immediate or delayed IUD insertion.

Table 1. Participant Characteristics

Characteristic	Immediate Postpartum Group (n=6)	Delayed Group (n=5)
Mean age (years ± SD)	18.33 ± 1.03	18.40 ± 0.89
Race*		
Non-Hispanic white	1 (17%)	1 (20%)
Non-Hispanic black	1 (17%)	0 (0%)
Asian	1 (17%)	1 (20%)
Native Hawaiian/Pacific Islander	4 (67%)	4 (80%)
Previously used contraception**	3 (50%)	3 (60%)
Previously used IUD or implant	0 (0%)	0 (0%)
Previously pregnant	1 (17%)	5 (100%)
Previous delivery	0 (0%)	3 (60%)

*Participants could identify more than one race
**Contraceptive methods asked about: IUD, implant, injection, oral contraceptive, patch, ring, condoms

Discussion

Although we found that a larger randomized controlled trial comparing immediate to delayed postpartum LNG IUD insertion among adolescents is not feasible at our institution, we describe a small cohort of adolescent women in Honolulu who appear to have benefitted from immediate postpartum IUD insertion. Of the women randomized to immediate insertion, four of the six had an IUD in place at six months postpartum. Four of the six women expressed a preference of immediate insertion over delayed insertion and were "very satisfied" with their experience. Of the five women randomized to delayed insertion, three of them did not have an IUD in place at six months postpartum and two of the women had again become pregnant. Our findings are consistent with other studies in adult women showing that many women who have immediate postpartum insertions of a LNG IUD are using an IUD at six months postpartum.[18-20] Most of these studies also report high patient satisfaction with immediate postpartum placement.

Suboptimal enrollment and difficulty in following up with participants precluded conduct of any of the planned analyses. While LARC use among adolescents is increasing, overall rates of use are still low and most of the increase seen has been in the use of the contraceptive implant. In an analysis of contraceptive method use among sexually active women age 15-19 years from 2011-2015, 2.8% had used an IUD (increase from 2.5% in 2006-2010) and 3.0% had used an implant (increased from 0.6% in 2006-2010).[25] Our suboptimal enrollment reflects this overall low rate of IUD use among adolescents. In addition, follow-up with our adolescent participants was challenging. Only 78% of potential follow-up visits were conducted in the immediate insertion group compared to 40% in the delayed insertion group. While it is not surprising that the participants who received the intervention were more likely to follow-up, this leads to ascertainment bias in addition to poor overall obtainment of outcome data.

Table 2. Study Participants and Follow-up

Age	Pregnancy history	Previous birth control used	4-6 wk f/u – IUD in place?	10 wk f/u – IUD in place?	6 mo f/u – IUD in place?	IUD in place at 4-6 weeks	IUD in place at 6 months	Preference for timing of IUD placement (asked at all f/u visits)
Immediate insertion group								
19	G1P0	None	No – expulsed. Did not want replacement	Unable to contact	Unable to contact	No	Unknown	Delayed
19	G1P0	OCPs	Yes	Yes	Yes	Yes	Yes	Immediate for all 3 visits
19	G2P0	None	Yes	Yes	Yes	Yes	Yes	Immediate for all 3 visits
17	G1P0	None	Yes	Unable to contact	Yes (visit was at 9 months postpartum)	Yes	Yes	Visit was at outside facility and was not asked
19	G1P0	Condoms	Yes	Yes	Yes	Yes	Yes	Immediate for all 3 visits
17	G1P0	Condoms, DMPA	Yes	Requested IUD removal; got DMPA	Unable to contact	Yes	Unknown	Immediate for 2 visits
Delayed insertion group								
18	G2P1	Condoms, OCPs	IUD inserted	Unable to contact	Unable to contact	Yes	Unknown	"Do not care"
17	G2P1	Condoms	IUD inserted at outside facility	Unable to contact	Presented to outside facility for pregnancy test (positive). Stated had IUD removed 1 month after it was placed	Yes	No	Was not asked
19	G2P0	None	Unable to contact	*Stated she received DMPA injection post-partum and was not sure what method she wanted to use	*Stated she did not have an IUD and was not sure what method she wanted to use	No	No	Was not asked
19	G3P2	DMPA	No f/u, but 11 mos later admitted to hospital in labor with another full-term pregnancy				No	Was not asked
19	G2P0	None	No. Stated she wanted the contraceptive implant but never returned	Unable to contact	Unable to contact	No	Unknown	Was not asked

*Follow-up by phone

Abbreviations: G=gravidity (number of pregnancies), P=parity (number of deliveries), DMPA=Depot medroxyprogesterone acetate (contraceptive injection), OCPs=oral contraceptive pills

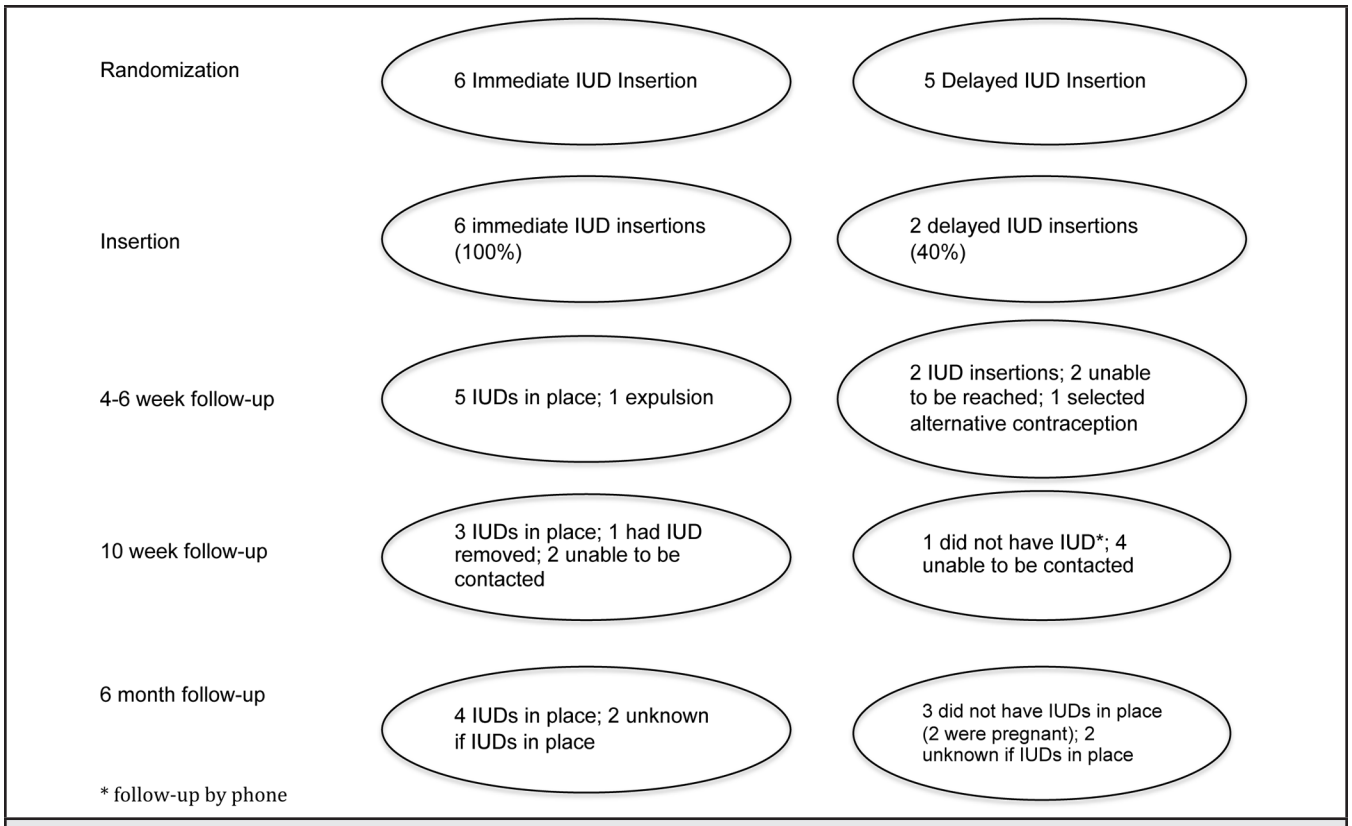

Figure 1. Study Participants and Follow-up

Despite the challenges of this study, the randomized controlled study design is critical to examining whether adolescents benefit from access to immediate postpartum IUD. While one cohort study of 82 adolescent (13-22 year-old) women who chose immediate postpartum IUD insertion found that 71% were still using an IUD at six months postpartum,[20] cohort studies are subject to selection bias. Unrecognized differences between patients who choose immediate insertion versus women who choose standard delayed insertion can affect outcomes. In addition, a healthcare provider may be more likely to recommend immediate postpartum insertion to a patient thought to be at higher risk of short interval pregnancy or poor follow-up. Ways to mitigate challenges in a study such as this may include use of a closed healthcare system, higher compensation for study visits, and alternative methods of follow-up such as text messaging or online surveys.

At our institution in Honolulu, adolescents are offered immediate postpartum IUD insertion because follow-up rates for postpartum visits are low in this group. While we found that a larger randomized controlled trial to examine this question is not feasible at our institution, we were able to describe a small group of local adolescents who benefitted from immediate postpartum IUD placement. In contrast, of the five adolescents who were randomized to delayed IUD insertion, two were pregnant again by six months after their delivery. Immediate postpartum IUD insertion may be an effective way to increase use of a highly effective contraceptive method in a group of young women at high risk for unintended pregnancy.

Conflict of Interest

None of the authors identify a conflict of interest.

Acknowledgements

The authors wish to thank Erin Yamamoto and Faapisa Soli (research assistants), the University of Hawai'i OB/GYN residents and faculty, Hawai'i Pacific Health Research Institute, Kapi'olani Medical Center for Women and Children Outpatient Clinic, and Sarah Prager MD, MPH from the University of Washington.

This study was supported by a grant from the National Institute on Minority Health and Health Disparities of the National Institutes of Health under award number U54MD008149.

This study was also supported by the University of Hawai'i Department of Obstetrics, Gynecology & Women's Health, Ryan LARC Program.

Drs. Kaneshiro, Salcedo, and Soon receive research funding unrelated to this project from Merck, Gynuity Health Products, Mithra Pharmaceuticals, and Contramed.

Authors' Affiliations:
- Department of Obstetrics, Gynecology & Women's Health, John A. Burns School of Medicine, University of Hawai'i, Honolulu, HI (RS, JS, BK)
- Swedish Medical Center, Seattle, WA (KM)

Correspondence to:
Reni Soon MD, MPH; Dept. OB/GYN, University of Hawai'i, 1319 Punahou St., Ste. 824, Honolulu, HI 96826; Email: rsoon@hawaii.edu

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