ORIGINAL RESEARCH ARTICLE

Immediate postpartum versus 6-week postpartum intrauterine device insertion: a feasibility study of a randomized controlled trial

Amy G. Bryant[*1], *Gift Kamanga*[2], *Gretchen S. Stuart*[1], *Lisa B. Haddad*[3], *Tarek Meguid*[4], *Chisale Mhango*[5]

[1]Department of Obstetrics and Gynecology, Division of Women's Primary Healthcare, University of North Carolina; [2]UNC Project *Tidziwe Centre* Private Bag A-104. Lilongwe Malawi; [3]Department of Gynecology & Obstetrics, Division of Family Planning, Faculty Office Building, Atlanta, GA; [4]Department of Obstetrics and Gynecology, Kamuzu Central Hospital and Bwaila District Maternity Hospital, Malawi; [5]Reproductive Health Unit, Malawi Ministry of Health, Lilongwe, Malawi

***For correspondence:** *Email:* amy_bryant@med.unc.edu; Tel: (919) 843-9546

Abstract

This study aimed to evaluate the feasibility of conducting a randomized controlled trial of postpartum intrauterine device insertion and to demonstrate that the postpartum intrauterine device is acceptable to women. Women attending prenatal care at a maternity hospital in Lilongwe, Malawi were recruited into a trial comparing immediate (10 minutes to 48 hours) to 6 week postpartum insertion. Feasibility of recruiting and consenting 140 women and randomizing 70% of them was evaluated. Satisfaction with the intrauterine device was also assessed. One hundred fifteen women consented and 49 (61%) were randomized. Twenty-six women were assigned to immediate insertion, and 23 to insertion at 6 weeks postpartum. Thirty (24%) women received the device as part of the study protocol, and 28(93%) had the device in place at 12 weeks postpartum. The intrauterine device is acceptable to some postpartum women in Malawi, but conducting a randomized clinical trial may not be feasible. (ClinicalTrials.gov NCT01175161) (*Afr J Reprod Health 2013; 17[2]: 72-79).*

Résumé

Cette étude comme objectif d'évaluer la faisabilité d'un essai contrôlé randomisé de l'insertion d'un dispositif intra-utérin du postpartum et de démontrer que le dispositif intra-utérin du postpartum est acceptable pour les femmes. Les femmes qui reçoivent des soins prénatals dans un hôpital de maternité à Lilongwe, au Malawi ont été recrutées dans un essai comparant immédiat (10 minutes à 48 heures) à l'insertion des six semaines du post-partum. La faisabilité du recrutement et du consentement et de la randomisation de 140 femmes dont 70% ont été évaluées. La satisfaction à l'égard du dispositif intra-utérin a également été évaluée. Cent quinze femmes ont consenti et 49 (61%) ont été randomisées. Vingt-six femmes ont été affectées à l'insertion immédiate, et 23 à l'insertion à 6 semaines après l'accouchement. Trente (24%) des femmes ont reçu du dispositif dans le cadre du protocole de l'étude, et 28 (93%) avaient le dispositif en place à 12 semaines après l'accouchement. Le dispositif intra-utérin est acceptable aux certaines femmes en post-partum au Malawi, mais un essai clinique randomisé peut ne pas être possible d'effectuer. (*Afr J Reprod Health 2013; 17[2]: 72-79).*

Keywords: postpartum intrauterine device, IUD, Africa, randomized controlled trial, long-acting reversible contraception

Introduction

Studies examining non-traditional time frames for intrauterine device (IUD) insertion have shown promising results. Several postpartum times for insertion of the levonorgestrel-releasing intrauterine systems in the United States have been found to be feasible and acceptable[1-4]. Expanding the time frames available for IUD insertion has an added benefit in resource-limited countries where access to health care may be inconsistent and additional barriers may limit care[5-7].

Placing an IUD after a woman delivers but prior to leaving the hospital has the advantage of convenience. A person skilled in postpartum IUD insertion does not need to be present at the delivery, but can place the IUD at any point before the woman leaves the hospital. Immediate postpartum IUD insertion requires further study to understand definitively its efficacy and feasibility,

as it involves a different insertion technique from traditional IUD insertion, expulsion rates reported in the literature vary greatly, and factors related to successful insertion are not well-understood[7, 8]. Further investigation is necessary to determine expulsion rates and understand which women are the best candidates for immediate postpartum IUD insertion.

We conducted a pilot study of a randomized controlled trial comparing immediate postpartum insertion of the CuT380A-IUD to insertion at the traditional postpartum visit. Limits were set for recruitment to determine the feasibility of this study design. The primary objective was to determine IUD use at 12 weeks postpartum. The secondary objective was to assess the acceptability of the IUD.

Materials and Methods

We conducted this study at the Bwaila Maternity Hospital in Lilongwe, Malawi. The study was approved by the Institutional Review Board at the University of North Carolina and the Malawi National Health Sciences Research Committee. Prior to beginning the trial, a total of 58 health care providers at the clinical sites attended trainings for IUD placement in the interval and immediate postpartum timeframes.

During study recruitment, nurses involved in recruitment for this study augmented the routine morning educational activities for all patients with information regarding interval and postpartum IUD insertion. Women were invited to participate in the study if they expressed a desire to use the IUD after delivery, were 18-45 years old, and greater than 34 weeks pregnant. Informed consent and other study assessments were conducted by the study nurses verbally in the local language, Chichewa. After informed consent, women were screened for eligibility. Exclusion criteria included: prior cesarean delivery, treatment for pelvic inflammatory disease within 3 months prior to pregnancy, known uterine anomalies, pelvic tuberculosis, or genital tract cancer, and clinical evidence of anemia. Women with HIV were included if they were clinically well on antiretroviral therapy or WHO Clinical Stage 1 or 2. The screening included a pelvic exam to assess for cervical abnormalities or infection, and women were excluded and referred if these abnormalities were present.

After delivery, additional eligibility criteria included vaginal delivery within the last 48 hours, no postpartum hemorrhage, not having ruptured membranes for greater than 24 hours prior to delivery, no infection, and no fever of greater than 38° during labor or delivery. If post-delivery eligibility criteria were not met, the woman was not randomized and was referred to standard family planning services at her 6 week postpartum visit and exited from the study.

If all post-delivery eligibility criteria were met, and the woman agreed to have an IUD placed in the postpartum period, the randomization allocation envelope was opened and the participant was notified of her study assignment by the study nurse. Randomization was computer-generated with varying blocks of four and six by a person not involved in the collection or analysis of study data. Allocation was concealed within opaque, sequentially numbered sealed envelopes until interventions were assigned. Neither participants nor study personnel were blinded due to the nature of the intervention.

Women assigned to immediate postpartum insertion had the IUD placed by a trained health care provider. Immediate postpartum IUDs were placed using two ring forceps in the technique described by O'Hanley: one ring forceps was used to grasp the anterior lip of the cervix, while the second ring forceps was used to place the IUD at the uterine fundus[9]. Women randomized to receive the IUD at 6 weeks postpartum were given a date for the postpartum visit at which time the IUD was placed in the standard fashion by a trained health care provider.

Follow-up visits were scheduled at four, eight, and twelve weeks after IUD insertion. Data collected at each visit included method satisfaction and fertility intentions. A pelvic exam was performed to assess presence or absence of the IUD in the uterus. If the IUD strings were not visible and the woman did not recall that the IUD had been expelled, an ultrasound was performed to check for intrauterine placement. If the IUD was expelled, women were offered another IUD or were referred to the family planning clinic to

receive routine family planning clinical services. Participants received reimbursement for travel costs for each study visit.

The sample size selected was based on convenience. We planned to stop recruitment at 140 women or after 4 months of recruitment, whichever came first. We estimated we would randomize 70% of the women who met all eligibility criteria. We did not attempt to calculate a sample size based on specific events such as expulsion rates.

The primary outcome was use of the IUD at 12 weeks postpartum. Secondary outcomes included follow-up visits attended, satisfaction with the IUD as a method of birth control, and IUD expulsion. Satisfaction was assessed using questionnaires during insertion and at each follow-up visit.

The CONSORT guidelines were used to report on the conduct and analysis of the randomized controlled trial, and to report on the secondary outcome of patient satisfaction with the IUD[10]. We doubly entered data into Access and imported it into Stata 11.0 for analysis. The data were initially examined for distributional assumptions and the possibility of erroneous outliers. Neither participants nor investigators were blinded as to treatment assigned. Analysis of the randomized controlled trial was performed and reported according to intention-to-treat principles. Baseline characteristics were compared using the chi-square or Mann-U Whitney test.

Results

Between October 10, 2010 and February 28, 2011, a total of 123 women were consented and screened and 115 met all primary eligibility criteria. (Figure 1). Of the women enrolled, 30 delivered at home or another facility and 5 withdrew at their husband's request prior to delivery. Eighty women delivered at Bwaila and 49 (61%) were randomized. Thirty-one women were not randomized after delivery; 13 (42%) did not meet secondary eligibility criteria, 9 (29%) declined to participate due to their husbands' request, 6 (19%) declined to participate for unstated reasons prior to randomization, and 3 (10%) women who delivered at Bwaila were not contacted by study staff and were therefore unable to be randomized.

Of the 26 randomized to immediate insertion, 12 received it, four declined further participation, 2 withdrew due to their husband's request, and 8 opted for 6 week insertion. Of the 8 women who declined the immediate placement and opted for 6 week insertion, 3 returned at six weeks for insertion. Two of the three women received the IUD at 6 weeks and are included in the immediate group for intention-to-treat analyses. The third woman did not receive the IUD because the provider had difficulty with insertion, and she was exited from the study at that time. The remaining five women who declined immediate insertion and opted for 6 week insertion did not return for the 6-week appointment.

Of the 23 women who were randomized to 6-week insertion, 16 received it. Four women never returned for their follow-up, and 3 women withdrew just after randomization due to changing their minds about participation. In summary, of the 115 women who were screened from the prenatal clinic, 49 (43%) were randomized, and 30 (26%) received the IUD.

Baseline demographics and clinical characteristics were similar between the randomized groups (Table 1). At 12 weeks, 28/30 (93%) of the women who had the IUD placed as part of the study still had the IUD in place, and there was no difference between the two groups. One woman who received the IUD immediately postpartum expelled it one week after insertion. Another woman returned two weeks after immediate placement to have the IUD removed at her husband's request. Of the women randomized to receive the IUD immediately postpartum, 46% had the IUD in place at 12 weeks. Of those randomized to have the IUD at 6 weeks postpartum, 61% had it in place at 12 weeks. This difference was not statistically significant.

Women in the study reported favorable assessments of the timing and method of IUD insertion (Table 2). At the time of insertion, most (n=28, 93%) reported they would have the IUD placed at the same time frame again, and all women said that they would recommend the IUD to a friend. Women also reported high satisfaction

with the IUD at all three follow-up visits, and attendance at the follow up visits was high, with 93% (28 of 30 women) attending all three follow-up visits. At the 4 week follow-up, 100% of

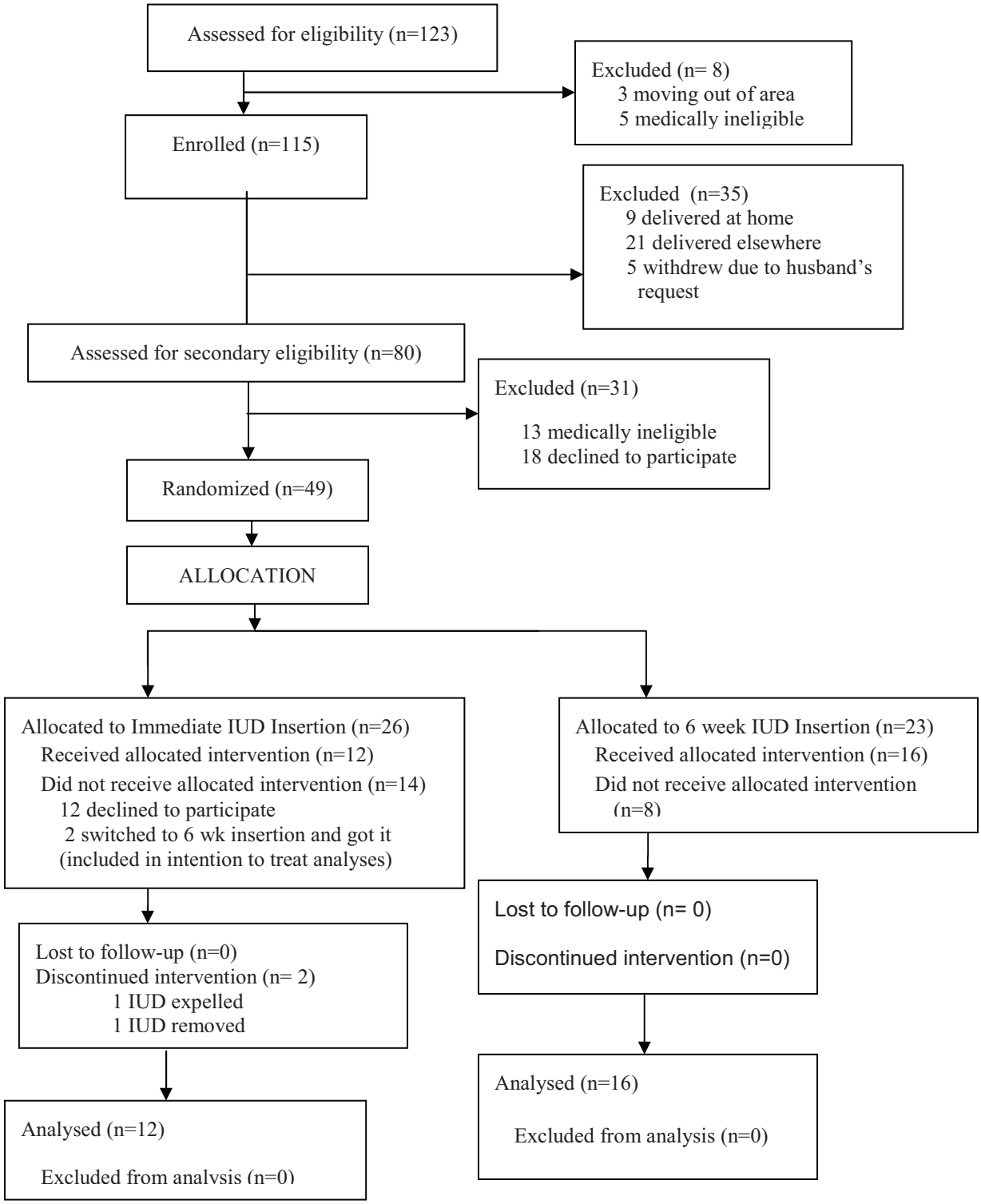

Figure 1: Postpartum IUD Study Flow Diagram

Table 1: Baseline Characteristics of the Study Participants.*

Characteristic	Immediate Insertion Group (n=26)	6 Week Insertion Group (n=23)
Age in years	26 [22,30]	25 [20, 25]
Gravidity	3 [2,5]	3 [2,5]
Parity	2 [1,4]	1 [1,3]
Number of living children	2 [1,4]	1 [1,3]
Gestational age in weeks at time of consent	34 [34, 36]	34 [34,34]
Level of education (primary or less)	13 (50)	13 (57)
Employed (Yes)	3 (12)	3 (13)
Number of people living in household (range)	4 (3,5)	4 (3,5)
HIV + (% Yes)	3 (12)	2 (9)
Relationship status (% not married)	0	2 (9)
How much of the time do you live with your partner		
All the time	22 (85)	15 (65)
Sometimes	4 (15)	6 (26)
Rarely	0	2 (9)
How would you feel if you became pregnant again in the next 12 months		
Happy	8 (32)	8 (35)
Upset	17 (68)	15 (65)
What is most important about using a BC		
Privacy	2 (8)	0
Effectiveness	13 (50)	13 (57)
Side effects	6 (23)	6 (26)
Ease of use	5 (19)	4 (17)

*Data are n (%), or median [interquartile range]

women in both groups reported that they liked using the IUD, were planning to keep the IUD for the next year, were not planning on switching methods, and would recommend the IUD to a friend. At the 12 week follow-up, all women reported that they liked using the IUD and would recommend it to a friend, but a small proportion of the women in each group reported they were thinking about switching methods (2 (8%) and 1 (4%) respectively), or did not want to continue using the IUD for the next year (1 (4%) and 0 respectively). These differences were not statistically significant.

Discussion

In this feasibility study, approximately one quarter of the women consented and screened during prenatal care actually received the treatment allocation. The large number of women required to be screened to achieve a sufficient treatment allocation makes a randomized controlled trial using this design not feasible. However, the IUD was acceptable to the women who received it, and following women in the study was feasible. Moreover, the findings of this study point to measures that could be taken to improve both uptake of the IUD and the conduct of a study of postpartum IUD insertion in Malawi.

The low uptake of the IUD in this study may have been affected by the general lack of use of the IUD in the community[11, 12]. Many women were unfamiliar with the IUD or held misconceptions about it, therefore introducing this method as part of a study was challenging. The high proportion of women who withdrew at their husbands' request also suggests that their partners, who may play a critical role in contraceptive utilization, also lack knowledge or hold misconceptions about the IUD[13, 14]. Women may have enrolled in the study due to high enthusiasm from nurses, but then found they were not supported by their husbands

Table 2: Study participants' characteristics and satisfaction with the IUD at 12 week follow-up.[†]*

	By Intention-to-treat			By Intervention Received		
Characteristics	**Immediate Postpartum Insertion (n=26)**	**6 Week Postpartum Insertion (n=23)**	**P**	**Immediate Postpartum Insertion (n=12)**	**6 Week Postpartum Insertion (n=16)**	**P**
IUD in place	12(46)	14(61)	0.39	10(83)	16(100)	0.80
Planning on having more children in the future	8(31)	11(48)	0.25	8(67)	11(69)	0.90
Would feel upset she became pregnant again in the next 6 months	12(46)	15(65)	0.25	12(100)	15(94)	0.38
Would feel upset if she never became pregnant again	6(23)	7(30)	0.74	6(50)	7(44)	0.74
Planning to keep using the IUD for the next year	11(42)	16(70)	0.08	11(92)	15(94)	0.24
Would recommend the IUD to a friend	12(46)	16(70)	0.15	12(100)	16(100)	-
Would like to switch contraceptive methods	2 (8)	1 (4)	1.0	2 (17)	1 (6)	0.38

[†]All P values were calculated using the chi square test.
*Data are n (%).

or community to use the IUD. Postpartum nurses were educated regarding immediate postpartum IUD use, however it is possible that nurses influenced whether participants chose to receive the IUD or not. Providing more extensive information to nursing staff in general, and to women and their partners during prenatal care could emphasize the safety of the IUD[15].

To our knowledge, this study represents the first attempt to conduct a randomized controlled trial of IUD insertion after vaginal delivery in time frame from 10 minutes to 48 hours postpartum in Africa[6,16]. Although essentially a negative study, presenting these results adds to the growing body of literature on postpartum IUD insertion[1-4] and avoids publication bias[17,18]. A pilot study was necessary to test the ability to conduct a large, costly randomized controlled trial to investigate expulsion rates and acceptability of this time frame for IUD insertion. A number of activities could be changed or improved for a future study, including enhanced community education and outreach, enrolling women earlier in pregnancy to allow for more contact with study nurses, involving women's partners in decision-making, and improving strategies to retain women after randomization. Additionally, it would be important to ensure that the follow-up time was equal between the two groups. In this study, all women were followed for 12 weeks. Those that were followed after immediate insertion had more time with the IUD in place, which may have contributed to intervention bias. Randomized controlled trials are the gold standard for evidence-based care, and can be useful to assess various important clinical outcomes related to postpartum IUD use[1]. Alternatively, while a large-scale study of immediate postpartum IUD use is needed, other study designs may be warranted. In a recent report on a non-randomized, prospective cohort of 591 women receiving the IUD in the postpartum time frame in Zambia, a low proportion of expulsions

and high satisfaction with the IUD were found, though almost half of the women were lost to follow-up[19].

Evaluating convenient time frames for IUD insertion is a key strategy for increasing IUD use, and increased IUD use can lead to fewer unintended pregnancies, less maternal morbidity and lower maternal mortality[5,6]. The results of this study provide necessary insight that can be used to inform the design of future studies aimed at understanding the efficacy and acceptability of postpartum IUD insertion.

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Disclosure of interests

None of the authors have conflicts of interest to declare.

Details of ethics approval

Ethics approval was obtained from the National Health Services Research Committee in Malawi on June 14, 2010 and renewed on October 18, 2011 (Protocol #715). Approval from the University of North Carolina Institutional Review Board was received on August 16, 2010 and renewed on June 27, 2011. Written informed consent was obtained from all participants in the study.

Contribution of Authors

Amy Bryant and Gretchen Stuart contributed the development of concept and design, conduct of the study, interpretation of data and writing manuscript. Gift Kamanga and Tarek Meguid were involved in concept and design, conduct of the study, interpretation of data, and revisions of manuscript. Lisa Haddad contributed to interpretation of data, conduct of the study, and revisions of manuscript. Chisela Mhango contributed to the concept and design of the study. All of the authors have given approval for this manuscript.

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