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Comparison of an additional early visit to routine postpartum care on initiation of long-acting reversible contraception: A randomized trial☆,☆☆

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ABSTRACT

Objective: To investigate whether an early 3-week postpartum visit in addition to the standard 6-week visit increases long-acting reversible contraception (LARC) initiation by 8 weeks postpartum compared to the routine 6-week visit alone.

Study design: We enrolled pregnant and immediate postpartum women into a prospective randomized, non-blinded trial comparing a single 6-week postpartum visit (routine care) to two visits at 3 and 6 weeks postpartum (intervention), with initiation of contraception at the 3-week visit, if desired. All participants received structured contraceptive counseling. Participants completed surveys in-person at baseline and at the time of each postpartum visit. A sample size of 200 total participants was needed to detect a 2-fold difference in LARC initiation (20% vs. 40%).

Results: Between May 2016 and March 2017, 200 participants enrolled; outcome data are available for 188. The majority of LARC initiation occurred immediately postpartum (25% of the intervention arm and 27% of the routine care arm). By 8 weeks postpartum, 34% of participants in the intervention arm initiated LARC, compared to 41% in the routine care arm (p=.35). Overall contraceptive initiation by 8 weeks was 83% and 84% in the intervention and routine care arms, respectively (p=.79). There was no difference between the arms in the proportion of women who attended at least one postpartum visit (70% vs. 74%, p=.56).

Conclusion: The addition of a 3-week postpartum visit to routine care does not increase LARC initiation by 8 weeks postpartum. The majority of LARC users desired immediate rather than interval postpartum initiation.

Clinical trial registration: Clinicaltrials.gov NCT02769676

Implications: The addition of a 3-week postpartum visit to routine care does not increase LARC or overall contraceptive initiation by 8 weeks postpartum when the option of immediate postpartum placement is available. The majority of LARC users desired immediate rather than interval postpartum initiation.

1. Introduction

Most women return to sexual activity and ovulation before the 6-week postpartum visit [1]. Therefore, it is recommended that women not exclusively breastfeeding initiate contraception by 3 weeks postpartum [1]. However, only 20% of women use contraception in the month following delivery [2]. Immediate postpartum (IPP) initiation of long-acting reversible contraception (LARC) is a successful strategy [3, 4]. However, not all patients desire IPP initiation, there is a higher expulsion rate with IPP intrauterine device (IUD) placement [5], and access to IPP LARC is limited. Strategies for improving postpartum LARC access must address the multiple post-discharge barriers [6–11].

A common barrier to LARC initiation at a 6-week visit is difficulty excluding pregnancy [12], prompting a second visit, thus reducing the likelihood of initiating any method [13]. LARC initiation before

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4 weeks postpartum eliminates this concern, as pregnancy can always be ruled out [14]. Additionally, many women lose public health insurance 6–8 weeks postpartum [15], making LARC unaffordable. Changing the model of postpartum care to include a 3-week visit with LARC initiation, if desired, has the potential to reduce these barriers.

Studies show 2–3 week postpartum IUD insertion is feasible and acceptable with lower expulsion rates compared to reported rates after IPP insertion [16–18]. However, variable methodology and populations and lack of availability of IPP insertion leave unanswered questions. One option is to schedule one early visit, but this may miss an opportunity to address issues that arise later. Adding an early visit to routine care is one strategy that addresses barriers to LARC access and provides comprehensive care. We hypothesized that two planned visits, at 3 and 6 weeks postpartum, compared to one 6-week visit, would increase LARC initiation by 8 weeks postpartum.

2. Materials and methods

This study was conducted from May 2016 to March 2017 at a tertiary academic medical center in St. Louis, Missouri. We obtained Institutional Review Board approval and registered at ClinicalTrials.gov (NCT02769676) prior to recruitment. We followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting randomized trials.

We performed a parallel, randomized, non-blinded trial in which participants were randomized with 1:1 allocation to two arms: the routine care arm participants were scheduled for the routine 6-week postpartum visit, while the intervention arm participants were scheduled for visits at 3 and 6 weeks postpartum. We initially recruited from the inpatient postpartum service, but due to slow enrollment we additionally recruited antepartum women in the outpatient obstetrics clinic. Research assistants screened potential participants during postpartum hospitalization or at routine antepartum visits and willing participants underwent written informed consent. We included women aged 14–45, ≥36 weeks' gestation or postpartum, planning to deliver or delivered at our hospital, and planning to attend postpartum care at the outpatient clinic. We excluded women who were unable to be approached, incarcerated or non-English speaking. Participants recruited postpartum were excluded if they already received IPP LARC or sterilization or if they experienced abortion, stillbirth, or neonatal death in this pregnancy.

After enrollment, all participants received contraceptive counseling based on the Contraceptive CHOICE Project model [19], including information about all methods in order of effectiveness. Participants were block randomized in blocks of six, and allocation was revealed using sequentially numbered sealed opaque envelopes. Participants in the routine care arm were scheduled for a 6-week postpartum visit, and a post-operative visit at 2–3 weeks for those who underwent cesarean delivery, per our institution's practice. The post-operative visit did not routinely include contraceptive initiation, but may at the discretion of the provider. Participants in the intervention arm were scheduled for visits at 3 and 6 weeks postpartum. For those who underwent cesarean delivery, the post-operative and 3-week visits were combined. The 3-week visit in the intervention arm included initiation of contraception, including LARC, if desired, along with standard postpartum care. Early visits were scheduled with residents, who inserted LARC under the supervision of generalists or family planning providers. Ultrasound-guidance was available, but never used. The 6-week visits were scheduled with nurse practitioners or residents. Participants received appointment reminders via phone, text, or email, depending on preference.

Our primary outcome was LARC initiation by 8 weeks postpartum. Secondary outcomes were overall contraceptive initiation by 8 weeks postpartum and postpartum visit attendance. Baseline and outcome data were determined through electronic medical record (EMR) review and participant report, which was obtained via in-person questionnaire at each visit or by telephone within 1 month of an unattended visit. No discrepancies were noted between EMR and participant report. Data collected included contraceptive use, initiation timing, and visit attendance. Participants who discontinued or switched methods were classified based on final method by 8 weeks. For participants who did not attend the 6-week visit and were unreachable, we assumed their method was the most recently used method and included them in primary analysis based on allocated group. Participants who attended visits at the wrong time were analyzed based on their allocated group. Participants for whom we had no contact after enrollment were excluded from the analysis. Participants received gift cards as follows: $20 at enrollment, $20 for attending the additional visit, and $10 for each survey.

Data collection/management was performed using REDCap electronic data tools. Analyses were performed using SAS (Version 9.4, SAS Institute Inc., Cary, NC). All tests were two-sided with p-value<0.05 deemed statistically significant. Baseline characteristics were compared between the two arms using Student's *t* test, chi-square or Fisher's exact test, as appropriate. Primary and secondary outcomes were compared between the two arms using chi-square test.

Using billing data, we estimated an outpatient postpartum LARC initiation rate of 20%. We proposed that a 2-fold increase to 40% would be clinically significant. Using 80% power to detect this difference, given an alpha (type 1) error of 0.05, and accounting for 20% loss to follow-up, we estimated a sample size of 100 per arm.

Prior to study initiation, there was no insurance coverage for IPP LARC and it was rarely provided. After study initiation, Missouri State Medicaid authorized reimbursement for IPP LARC, and this practice was rapidly implemented. In order to evaluate the isolated effect of the post-discharge intervention, we performed post hoc analyses excluding participants who received IPP LARC or sterilization. Relative risks and 95% confidence intervals were generated to estimate the effects of assigned arm and attendance to an early postpartum visit, on LARC and overall contraceptive initiation.

3. Results

A total of 200 patients were enrolled and randomized, 99 in the intervention arm and 101 in the routine care arm (Fig. 1). Three were excluded post-randomization due to ineligibility: two enrolled postpartum in error (one already received an IPP IUD and one did not plan to attend our clinic) and one enrolled antepartum but underwent hysterectomy. Four participants in the intervention arm and five in the routine care arm were lost to follow-up, leaving 188 for analysis (93 in the intervention arm, 95 in the routine care arm). The two arms were similar (Table 1), including predominantly young, single, multiparous, black, low-income women, using Medicaid insurance, with a high rate of unintended pregnancy, consistent with our urban hospital-based clinic population. In each arm, approximately 1/3 of participants enrolled antepartum and 2/3 enrolled postpartum. At enrollment, 94% desired postpartum contraception; 77% preferred initiation as soon as possible, while 15% preferred initiation at the 6-week visit. After contraceptive counseling, approximately 40% in each arm planned to initiate LARC (see Table 1 for method breakdown). On enrollment, when queried about preference for postpartum visit timing, 62% preferred within 4 weeks, 28% preferred in 6 weeks, and only 2% preferred multiple visits. Preference for a visit within 4 weeks did not differ based on parity (multiparous 58% vs. nulliparous 73%, p=.086), but differed slightly based on enrollment timing (antepartum 52% vs. postpartum 67%, p=.047).

The rate of LARC initiation by 8 weeks postpartum was similar between the two arms (34% [32/93] in the intervention vs. 41% [39/95] in the routine care arm; p=.35) (Table 2). Most LARC users chose IPP initiation (25% [23/93] of the intervention arm [8 IUDs and 15 implants] and 27% [26/95] of the routine care arm [7 IUDs and 19 implants]).

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