Title

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Journal

Contraception, 85(3)

ISSN

0010-7824

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Publication Date

2012-03-01

DOI

10.1016/j.contraception.2011.08.002

Peer reviewed

ELSEVIER

Contraception 85 (2012) 240 – 245

Contraception

Original research article

Immediate versus delayed insertion of the levonorgestrel-releasing intrauterine device following dilation and evacuation: a randomized controlled trial☆,☆☆

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Received 5 May 2011; revised 2 August 2011; accepted 4 August 2011

Abstract

Background: The study was conducted to compare 6-month usage of the levonorgestrel-releasing intrauterine device (LNG-IUD) when placed immediately or 3 to 6 weeks after dilation and evacuation (D&E) procedure.

Study Design: We enrolled women undergoing D&E at 15 to 23 weeks of gestation. After completion of the D&E, subjects without contraindications to immediate IUD insertion were randomized to immediate or delayed (3 to 6 weeks later) LNG-IUD insertion. Subjects in the immediate group had the LNG-IUD placed using ultrasound guidance. All subjects returned at 3 to 6 weeks and 8 to 10 weeks after D&E and were contacted by phone at 6 months.

Results: Of the 93 subjects enrolled, 88 were randomized. All 44 subjects (100%) randomized to immediate insertion had successful IUD placement, while only 20 (45.5%) of the 44 subjects randomized to delayed insertion returned for IUD placement, all of which were successful [difference 54.5%, 95% confidence interval (CI) 39.8%–69.3%]. Seventeen (38.6%) participants in each group were lost to follow-up. Of subjects contacted at the 6-month follow-up phone call, 23 of 27 women (85.2%) and 17 of 27 women (62.9%) were utilizing the LNG-IUD in the immediate and delayed groups, respectively (difference 22.2%, 95% CI −0.4% to 44.8%). Intrauterine device expulsion occurred in three subjects (6.8%) and one subject (5.0%) in whom the IUD was placed in the immediate and delayed groups, respectively (p=1.0). No significant adverse events occurred.

Conclusion: Significantly more participants had the LNG-IUD placed in the immediate insertion group compared with the delayed insertion group. Given the low risk of complications, immediate post-D&E insertion of the LNG-IUD should be offered, especially for populations that may have difficulty returning for follow-up.

Keywords: Levonorgestrel-releasing intrauterine device; Contraception; Induced abortion; Dilation and evacuation

1. Introduction

Postabortal insertion of intrauterine devices (IUDs) has been shown to be a safe and effective means of providing contraception [1–6]. However, this option may not be routinely offered to patients. Women presenting for dilation and evacuation (D&E) often have barriers that prevent easy access to reproductive health care. Eliminating barriers to highly effective contraception is an important step to increasing contraceptive use with the ultimate goal of decreasing unintended pregnancy.

☆ The findings and conclusions in this article are those of the authors and do not necessarily represent the views of Planned Parenthood Federation of America, Inc.

☆☆ Source of support: anonymous foundation.

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doi:10.1016/j.contraception.2011.08.002

Cremer et al. [7] examined the usage of the copper T380A IUD in a randomized trial of immediate or delayed (2 to 4 weeks) insertion after an abortion at greater than 12 weeks of gestational age in 159 women. Women who had insertion immediately after the abortion were more likely to be using the IUD at 6 months compared to subjects in the delayed group. In the delayed group, 57% failed to return for IUD insertion [7,8]. The investigators however failed to find a significantly decreased pregnancy risk between randomization groups [7].

The importance of increased access to IUDs is highlighted by the failure of another effective contraceptive, depot medroxyprogesterone acetate (DMPA), to prevent pregnancy when used immediately after abortion. In a trial of postabortal injection of DMPA, Goldberg et al. [9] found a discontinuation rate of 76%–81% at 12 months, despite monetary compensation. Twenty-two percent of women in the study were pregnant at the end of 12 months.

Although prior studies have demonstrated the safety and efficacy of placing LNG-IUDs immediately after either first- or second-trimester abortion [6,10,11], a randomized comparison of immediate versus delayed insertion of the LNG-IUD after D&E has not been reported. The purpose of this study was to assess the 6-month usage of the LNG-IUD when placed immediately after second-trimester D&E compared to 3 to 6 weeks later.

2. Materials and methods

This multisite prospective trial was conducted between February 2007 and April 2009 at Magee-Womens Hospital and Planned Parenthood of Western Pennsylvania (PPWP), Pittsburgh, PA. The University of Pittsburgh Institutional Review Board and Planned Parenthood Federation of America research department both approved the study. We enrolled women age 18 years or greater, previously consented for and planning to undergo a D&E procedure between the gestational ages of 15 0/7 and 23 6/7 weeks confirmed with ultrasound, interested in using the LNG-IUD (Mirena®, Bayer HealthCare Pharmaceuticals, Wayne, NJ, USA) for contraception after the procedure and able to sign a consent in English. Potential subjects were identified during the preoperative evaluation, after contraception counseling was completed. If a woman expressed interest in using the LNG-IUD for contraception, she was referred to one of the study investigators to discuss the trial. All subjects recruited from PPWP were no more than 18 0/7 weeks' gestation and had their preoperative evaluation on the same day as their D&E. Subjects at Magee-Womens Hospital had the preoperative evaluation either on the same day or 1 day prior to D&E based on gestational age and office and operating room availability. All subjects had an ultrasound to estimate gestational age. Subject with a known last menstrual period (LMP) were assigned a gestational age by LMP if their gestational age was within 4 days as determined by a first-trimester ultrasound (crown rump length) or within 10 days of a second-trimester ultrasound (composite gestational age). Subjects without a known LMP or an LMP that differed from the ultrasound findings were assigned the gestational age as determined by ultrasound. Subjects who had D&Es for fetal demise were assigned a gestational age based on the ultrasound that diagnosed the demise. The D&E was not considered part of the research study; thus, providers used their clinical judgment in performing preoperative screening for sexually transmitted infections. Women at our institution undergoing induced abortion generally receive preoperative doxycycline 200 mg for infection prophylaxis without additional antibiotics afterwards. Women with fetal demise receive antibiotics as clinical indicated. Data on antibiotics were not directly collected as the D&E procedure was not considered part of the study. All subjects who were recruited from Magee-Womens Hospital had their D&E in the operating room with twilight sedation provided by an anesthesiologist . Subjects recruited at PPWP could choose to have local anesthesia, oral diazepam or intravenous conscious sedation with fentanyl and midazolam. The LNG-IUD was provided to subjects without charge through the study.

Subjects were excluded for allergy to either polyethylene or levonorgestrel, urgent need for termination of pregnancy (active bleeding or infection), exposure to or treatment for gonorrhea or chlamydia within the preceding 90 days, diagnosis of pelvic inflammatory disease within the past year, presence of one or more leiomyomata greater than 3 cm in diameter, uterine anomaly (other than a repaired septate uterus) or current participation in any other intervention trial.

After informed consent was obtained, data were collected, including demographics and medical, surgical, obstetric, gynecologic, contraceptive and sexually transmitted infection history. Subjects also completed a questionnaire and quality of life assessment. Further contraceptive counseling was provided to subjects in the event they withdrew from the study prior to the D&E procedure, were randomized to the delayed group or were excluded from the study at the time of D&E.

After completion of the D&E and the procedure was noted to be complete, subjects were excluded from randomization for uterine perforation, hemorrhage (defined by need for transfusion, estimated blood loss greater than 500 mL, intrauterine placement of a Foley catheter or the use of three or more doses of uterotonic medications) or evidence of infection at the time of the D&E, including fever (temperature $\geq$38°C) or mucopurulent discharge. Subjects ineligible for randomization were referred for an LNG-IUD insertion through their gynecologic provider in 3–6 weeks.

Eligible subjects were randomized by opening the next sequentially numbered sealed opaque envelope in the operating room. A statistician not affiliated with the conduct of the study prepared the envelopes. Subjects were stratified into two strata by parity (parous or nulliparous) with random block sizes of 2, 4 and 6 using a computer-generated sequence.

Post-D&E LNG-IUD insertion was performed under transabdominal ultrasound guidance using the prepackaged LNG-IUD inserter. The IUD strings were trimmed flush to the external cervical os. Subjects were informed of whether or not an immediate insertion occurred only after completing questionnaires about their experience of pain with their D&E. Pain was assessed by visual analog scale (VAS) [12,13]. On a 100-mm line, with 0 being equal to *no pain* and 100 being equal to *severe pain*, subjects were asked to mark the amount of pain experienced with their D&E. If they were randomized to immediate insertion, they then completed a questionnaire about their experience of pain with the IUD insertion. Similarly, pain with IUD insertion was assessed by VAS using the same technique described above. The subjects completed these questionnaires just prior to discharge, usually between 30 min and 2 h after their procedures. Subjects randomized to the delayed insertion group were given a prescription for their interim contraceptive of choice. If a subject chose DMPA, it was given in the recovery room. All subjects were given a follow-up appointment 3 to 6 weeks after their D&E and received a reminder phone call within a week prior to the scheduled visit.

At the 3- to 6-week follow-up, all subjects received a urine pregnancy test and pelvic exam as well as completed questionnaires about their bleeding, pain, sexual activity and quality of life. Subjects in the immediate insertion group had transvaginal ultrasonography to assess IUD location. Subjects in the delayed group who returned for the 3- to 6-week follow-up visit had LNG-IUD insertion if they still desired the IUD. The LNG-IUD insertion was performed in the standard fashion using the prepackaged IUD inserter. Ultrasound guidance could be used at the discretion of the investigator doing the insertion. The IUD strings were trimmed to approximately 3 cm from the external cervical os. All subjects who had delayed insertion were asked to complete the same questionnaire about their experience of pain with the IUD insertion as the subjects randomized to the immediate group. Subjects who did not return for delayed insertion by 6 weeks postprocedure were still followed through 6 months but did not receive an LNG-IUD through the study.

Subjects had another follow-up visit at 8 to 10 weeks after D & E and a phone follow-up at 6 months after D & E. Study staff for these evaluations were blinded to subjects' randomization assignments. At the 8- to 10-week follow-up, all subjects had a urine pregnancy test, pelvic examination and transvaginal ultrasonography to assess IUD location, and completed a questionnaire and quality of life survey. At the 6-month phone follow-up, subjects were asked questions about their pain, bleeding, current contraceptive method, intervening pregnancy history and quality of life. Subjects were considered lost to follow-up if they could not be contacted at 6 months after the D&E.

The primary outcome was 6-month utilization of the LNG-IUD post-D&E. Secondary outcomes included continuation of the LNG-IUD, expulsion, pregnancy, infection, uterine perforation, pain with insertion, quality of life and contraceptive usage. A complete expulsion was defined as no LNG-IUD identified within the uterine cavity with either a clinical history of expulsion or an abdominal radiograph demonstrating the absence of the IUD in the abdominal cavity. A partial expulsion was defined as either a speculum exam demonstrating the IUD protruding from the external cervical os or an endovaginal sonogram demonstrating the distal end of the LNG-IUD to be below the internal os of the cervix. Subjects who experienced IUD expulsion were eligible to have their IUD replaced as part of the study.

Sample size was estimated based on the assumption that successful LNG-IUD placement would occur in 100% and 70% of subjects in the immediate and delayed groups, respectively. We anticipated a 10% discontinuation rate at 6 months for immediate group subjects and a 5% rate for women in the delayed group. Thus, we estimate 6-month usage at 90% in the immediate group and 66.5% in the delayed group, a difference of 23.5%. To detect this difference in LNG-IUD usage at 6 months at a significance of .05 with 80% power, 44 subjects needed to be randomized in each group.

Data analysis was performed using Stata 10 (StataCorp LP, College Station, TX, USA). The primary outcome analyzed was the usage of the LNG-IUD at 6 months using an intention-to-treat analysis. Proportions were analyzed using either χ^2 or Fisher's Exact Test, as appropriate. Exact binomial 95% confidence intervals (CIs) were calculated for expulsions and LNG-IUD utilization at 6 months.

3. Results

A total of 93 subjects were enrolled and 88 women were randomized between February 2007 and December 2008 (Fig. 1). Demographic information was not significantly different between the two groups (Table 1).

All subjects randomized to the immediate insertion group (n=44) had successful IUD placements (100%, 95% CI 93.4%–100%). Of subjects randomized to the delayed group (n=44), 20 (45.5%, 95% CI 30.4%–61.6%) returned for their IUD insertion at 3 to 6 weeks after D&E, and all had successful IUD placement. Thus, 54.5% more women received LNG-IUDs in the immediate group than in the delayed group (95% CI 39.8%–69.3%, p<.0001), with a risk ratio for insertion of 2.2 (95% CI 1.59–3.04). Subjects randomized to immediate insertion reported significantly less pain with IUD insertion compared to subjects who had their IUD placed 3 to 6 weeks after D&E (Table 2), with mean VAS scores of 4.3±15.7 in the immediate insertion group and 23.7±22.1 in the delayed insertion group (p<.01). This result reflects the fact that over 86% of subjects had their D&E performed in the operating room with twilight sedation or greater. Pain reported with D&E was not

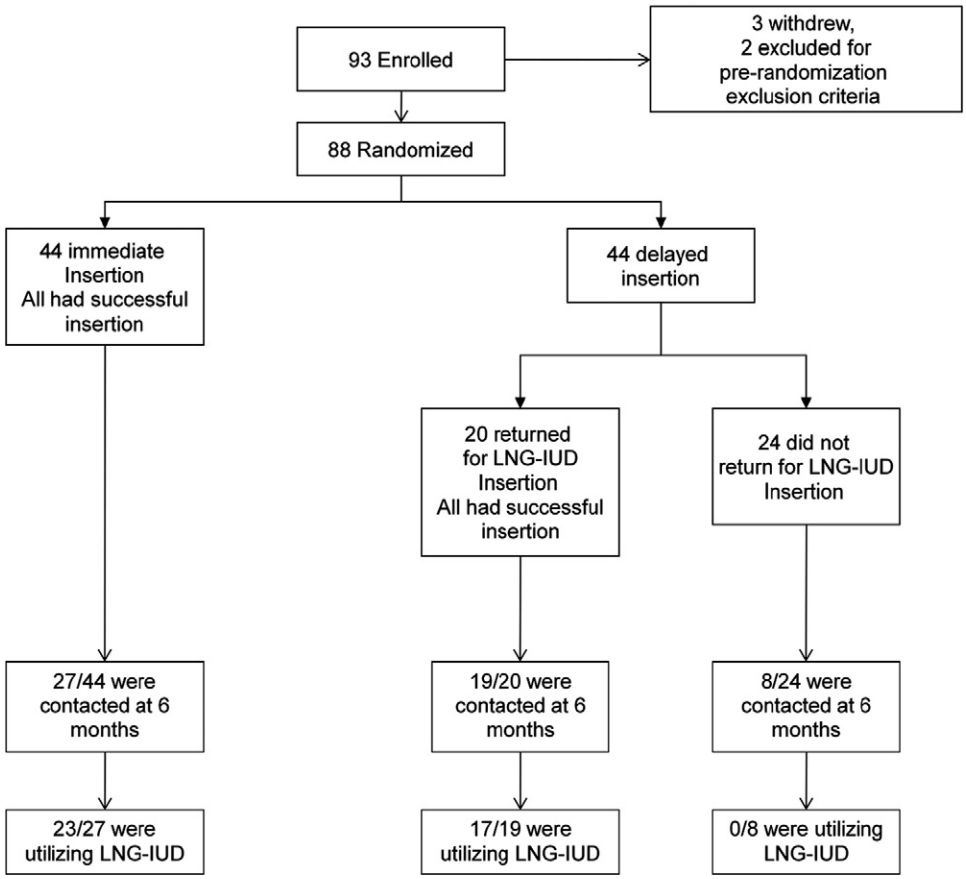

Fig. 1. Patient flow diagram.

significantly different between the two groups (Table 2). The mean days from D&E until reported return to sexual activity did not differ between the groups (20.2±2.1 and 26.1±2.7, respectively, p=.08).

Seventeen (38.6%) subjects were lost to follow-up at 6 months in each of the groups. Subjects who completed the study and those lost to follow-up did not differ significantly in terms of demographic variables, gestational age, prior

Table 1
Demographics of study population

Demographic characteristics	Immediate group	Delayed group	p
Age, years; mean (SD)	26.1 (5.9)	24.7 (4.7)	.20
Gestational age, weeks; *n* (%)			.24
15	13 (14.8)	14 (15.9)	
18	19 (21.6)	12 (13.6)	
21–23	12 (13.6)	18 (20.5)	
Parity, *n* (%)			.56
0	7 (15.9)	8 (18.1)	
1	16 (36.4)	10 (22.7)	
2	11 (25.0)	13 (29.6)	
3 or more	10 (22.7)	13 (29.6)	
Race, *n* (%)			.53
Caucasian	23 (52.2)	20 (45.4)	
African American	18 (40.9)	23 (52.3)	
Other	3 (6.9)	1 (2.3)	
Prior D&E, *n* (%)	8 (18.1)	5 (11.4)	.54
Enrollment and D&E same day, *n* (%)	6 (13.6)	5 (11.4)	.74

Table 2
IUD utilization and complications at 6 months

Outcome	Immediate insertion	Delayed insertion	p
LNG-IUD inserted, *n*/total (%)	44/44 (100)	20/44 (45.5)	<.001
Pain with D&E (VAS), mean (SD)	10.0 (20.5)	10.4 (24.4)	.9
Pain with IUD insertion (VAS), mean (SD)	4.3 (15.7)	23.7 (22.1)	<.001
IUD expulsion,[b] *n*/total (%)	3/44 (6.8)	1/20 (5.0)	1.0
Other discontinuations, *n*/total (%)	2/44 (4.5)	1/20 (5.0)	.9
Perforation,[b] *n*/total (%)	0/44 (0.0)	0/20 (0.0)	–
Pregnancy by 6 months, *n*/total (%)	0/27 (0.0)	1/27 (3.7)	.31
Infection, *n*/total (%)	0/27 (0.0)	1/20 (5.0)[a]	.43
LTFU, *n*/total (%)	17/44 (38.6)	17/44 (38.6)	1.0
LNG-IUD utilization at 6 months			
LTFU censored	23/27 (85.1)	17/27 (62.9)	.06
LTFU counted as failures	23/44 (52.3)	17/44 (38.6)	.19
LTFU counted as continued use	40/44 (90.9)	18/44 (40.9)	<.01

LTFU=lost to follow-up.
[a] Post-IUD insertion infection.
[b] Information only available for subjects who were not LTFU.

D&E, whether pregnancy was planned, parity or whether they lived with their partner.

In the women who could be contacted at 6 months (27 in each group, lost to follow-up censored), 23 (85.2%, 95% CI 66.3%–95.8%) in the immediate group and 17 (62.9%, 95% CI 42.4%–80.6%) in the delayed group were using LNG-IUDs. The difference in LNG-IUD usage at 6 months was 22.2% (95%CI −0.4% to 44.8%, p=.12). When subjects lost to follow-up were considered as not using the LNG-IUD as contraception at 6 months, usage at 6 months was 23/44 (52.3%, 95% CI 36.7%–67.5%) and 17/44 (38.6%, 95% CI 24.4%–54.5%) in the immediate and delayed groups, respectively (p=.19). If we assume that all subjects who were lost to follow-up were using the IUD at 6 months, then we would have utilization rates of 40/44 (91%, 95% CI 78.3%–97.5%) and 18/44 (40.9%, 95% CI 26.3%–55.4%) in the immediate and delayed groups, respectively (p<.01) (Table 2). All subjects in the delayed group utilizing the IUD at 6 months had the IUD placed through the study. Of the three subjects who had the IUD placed but were not utilizing this method of contraception at 6 months, one was lost to follow-up (thus, we could not confirm that she was utilizing the LNG-IUD), one subject experienced an expulsion, and one subject had requested the IUD to be removed and was not using contraception at the time of 6-month follow-up.

Expulsions occurred in 3 of 44 women (6.8%, 95% CI 1.4%–18.7%) in the immediate group and 1 of 20 women (5%, 95% CI 0.1%–24.9%) in the delayed group (p=0.6) during the 6 months of follow-up for a risk ratio for expulsion of 1.35 (95% CI 0.97–1.88). One expulsion in each group was a partial expulsion. One subject who experienced an expulsion in the immediate group opted for a replacement LNG-IUD. At the 6-month follow-up, one subject in the delayed group reported a pregnancy during her 6-month follow-up. This participant had an expulsion of her study IUD and had chosen not to replace the IUD and had started oral contraceptives. Her pregnancy occurred during the 6-month follow-up while she was using oral contraceptives. At the 8- to 10-week follow-up, 38 of 39 total subjects (97.4%) stated that they would recommend the LNG-IUD to a friend.

Complications were rare in both groups. Other than the expulsions reported above, one subject in the delayed group was diagnosed with post-IUD insertion infection (Table 2). In the immediate insertion group, there were no known pregnancies or postabortal infections. No IUD uterine perforations or other serious complications occurred in either group.

4. Discussion

Our study found that utilization of the LNG-IUD at 6 months was not statistically different between women who received the LNG-IUD immediately after D&E and those who received it a follow-up visit 3 to 6 weeks postprocedure. However, women who had D&Es exhibited poor follow-up, which is one of the more important findings from this trial. Although more participants had the LNG-IUD placed in the immediate insertion group, the high loss to follow-up rate limited our ability to detect a difference in LNG-IUD usage at 6 months. Given that the average subject in our study reported return to sexual activity between postoperative weeks 3 and 4, it appears crucial to provide women with effective contraception at the time of D&E.

Our study adds to prior research that demonstrates that immediate post-D&E insertion of the LNG-IUD is safe [5–7]. Our expulsion risk of 6.8% (95% CI 1.4%–18.7%) for the immediate group was similar to that of the delayed group. Although our expulsion risk with immediate insertion appears higher than the 2.2% to 3% range reported in the recent literature [5–7], the 95% CI from our sample is wide due to small sample size.

Although satisfaction with LNG-IUD was not directly asked, most (85.1%) of those who received the IUD and were contacted at 6 months were continuing to use this method of contraception. Additionally, of those subjects who followed up in person between 8 and 10 weeks, over 95% reported that they would recommend this method of contraception to a friend. Our data support that the LNG-IUD is highly acceptable when started after D&E.

The major limitation of this study was the high loss to follow-up. Jacot et al. [10] demonstrated in a chart review of all patients who underwent second trimester abortion at one institution a 14% in-person follow-up rate with 49% of patients lost to follow-up. In our study, despite at least three attempts to contact subjects by phone followed by a certified letter and monetary compensation for time and effort for follow-up, we were unable to contact approximately 39% of our subjects. This high lost to follow-up rate may have also impacted our ability to detect complications related to IUD insertion including expulsion and perforation.

This poor follow-up rate is similar to what has been demonstrated in prior similar studies with second-trimester abortion. Drey et al. [6] described a large cohort of subjects who received immediate IUD insertion after second-trimester abortion and reported a 51% follow-up rate at postoperative week 6. Cremer at al. [7] reported a 26% lost to follow-up rate in a study examining immediate versus delayed insertion of the copper T 380A after abortions at greater than 12 weeks of gestational age. Although our study population was not limited to women undergoing elective abortion, a large proportion of our study population was composed of such patients. Additionally, over 10% of our subjects reported having a prior D&E (Table 1), demonstrating that our subjects may have had social risk factors for poor follow-up. Prior studies have demonstrated that women who present for abortion in the second trimester have social risk factors that put them at risk for repeat unintended pregnancy and poor follow-up [7,14,15], further demonstrating the need to provide highly effective contraception immediately to such patients.

An additional limitation to our data is that 6-month utilization of the IUD was collected by telephone and not by physical exam. Although physical confirmation of the IUD was performed at the 3- to 6-week and the 8- to 10-week follow-up visits, not all subjects followed up for all visits, and there is the possibility that subjects may have had an unrecognized expulsion of the LNG-IUD that our study is unable to account for.

In summary, we found that immediate placement of the LNG-IUD after D&E is feasible and safe and, in the worst case, results in a similar utilization rate of the LNG-IUD use in both groups at 6 months postprocedure. Given the low risk of complications, immediate post-D&E insertion of the LNG-IUD should be offered, especially since this population is unlikely to follow up for delayed insertion. This will ensure that women will have a highly effective method of contraception available to them prior to resuming sexual activity.

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