

## ORIGINAL ARTICLE

# Immediate versus Delayed IUD Insertion after Uterine Aspiration

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## ABSTRACT

**BACKGROUND**

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Intrauterine devices (IUDs) provide highly effective, reversible, long-term contraception that is appropriate for many women after first-trimester uterine aspiration. However, the effects of immediate versus delayed IUD insertion after uterine aspiration on rates of complications and IUD use are uncertain.

**METHODS**

We performed a randomized noninferiority trial involving women undergoing uterine aspiration for induced or spontaneous abortion at 5 to 12 weeks of gestation who desired an IUD. Subjects were randomly assigned (in a 5:6 ratio) to IUD insertion immediately after the procedure or 2 to 6 weeks afterward (delayed insertion). The primary outcome was the rate of IUD expulsion 6 months after IUD insertion; an expulsion rate 8 percentage points higher in the immediate-insertion group was defined as inferior.

**RESULTS**

Among 575 women who underwent randomization, an IUD was inserted in 100% (258 of 258) of the women in the immediate-insertion group and in 71.3% (226 of 317) of those in the delayed-insertion group (difference, 28.7 percentage points; 95% confidence interval [CI], 23.7 to 33.7). The 6-month expulsion risk was 5.0% (13 of 258 women) after immediate insertion and 2.7% (6 of 226) after delayed insertion (difference, 2.3 percentage points; 95% CI, -1.0 to 5.8), which was consistent with the predefined criterion for noninferiority. Six-month rates of IUD use were higher in the immediate-insertion group (92.3%, vs. 76.6% after delayed insertion;  $P < 0.001$ ). Adverse events were rare and did not differ significantly between groups. No pregnancies occurred in the immediate-insertion group; five occurred in the delayed-insertion group ( $P = 0.07$ ), all in women who never received an IUD.

**CONCLUSIONS**

The 6-month rate of expulsion of an IUD after immediate insertion was higher than but not inferior to that after delayed insertion. Immediate insertion resulted in higher rates of IUD use at 6 months, without an increased risk of complications. (Funded by the Susan Thompson Buffett Foundation; ClinicalTrials.gov number, NCT00562276.)

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**M**ORE THAN HALF OF ALL UNINTENDED pregnancies in the United States occur as a result of inconsistent or discontinued use of contraceptives.<sup>1</sup> Intrauterine devices (IUDs) provide safe, highly effective, long-term contraception, but they are underused.<sup>2</sup> Because IUDs do not require active use, once they have been inserted, and have a very low failure rate, their increased use has the potential to substantially reduce unintended pregnancies.<sup>3</sup>

Immediate initiation of any contraceptive method after an abortion has been linked to a reduced risk of repeat abortion,<sup>4</sup> with immediate use of an IUD the most effective method for reducing this risk.<sup>4,5</sup> IUD placement immediately after uterine aspiration could eliminate the need for an additional visit and ensure effective contraception by the time ovulation resumes, as early as 2 to 3 weeks after the procedure.<sup>6</sup> Although many women would prefer immediate IUD insertion,<sup>7</sup> such insertions have been limited by concerns about increased rates of expulsion, uterine perforation, and infection and by concern about increased cost.

One randomized trial comparing immediate insertion with delayed insertion of the Copper 7 IUD and several observational studies have shown low rates of perforation and infection when IUDs are inserted immediately after first-trimester uterine aspiration.<sup>8-14</sup> This approach, however, has not been evaluated in a randomized fashion for modern T-shaped IUDs. Furthermore, it is unclear whether an increase in IUD use with immediate insertion outweighs any potential increase in the expulsion rate. We designed the present trial to compare the rates of IUD expulsion, use, removal, and complications with immediate versus delayed IUD insertion after first-trimester uterine aspiration.

## METHODS

### STUDY DESIGN

Women were enrolled from May 2007 through December 2008 at four U.S. academic medical centers: Oregon Health and Science University (OHSU), University of Pittsburgh, Emory University, and the University of New Mexico. Enrollment sites included Planned Parenthood affiliates (in Portland, OR; Pittsburgh; and Albuquerque, NM), the Feminist Women's Health Center (at Emory University), a hospital-based abortion clinic (at Emo-

ry University), and academic faculty and resident offices (at OHSU and the University of Pittsburgh). The study was approved by the institutional review board at each institution. All subjects provided written informed consent before enrollment. The study was conducted in accordance with the protocol, which is available with the full text of this article at [NEJM.org](http://NEJM.org).

### SUBJECTS

Study participants were women 18 years of age or older who presented to participating sites requesting uterine aspiration for induced or spontaneous abortion between 5 and 12 weeks of gestation and who desired intrauterine contraception. Gestational age was determined by ultrasonography. Women were excluded if they had evidence of cervicitis or pelvic inflammatory disease, a uterine anomaly or fibroid distorting the cavity, known or suspected molar or ectopic pregnancy, or pelvic inflammatory disease or sexually transmitted infection within the previous 3 months. Neither osmotic dilators nor misoprostol was used for uterine aspiration or IUD insertion in this study.

### STUDY PROCEDURES

All subjects were screened for chlamydia immediately before uterine aspiration; subjects with positive results were treated with antibiotics according to Centers for Disease Control and Prevention guidelines. All subjects received perioperative prophylactic doxycycline at the time of uterine aspiration.

Participants selected either a levonorgestrel-releasing IUD (Mirena, Bayer HealthCare Pharmaceuticals) or a copper IUD (ParaGard T380A, Teva Pharmaceuticals [formerly Duramed Pharmaceuticals]) before undergoing uterine aspiration. (For more information regarding the IUD selection process, see the Supplementary Appendix, available at [NEJM.org](http://NEJM.org).) All aspiration procedures were performed by a study investigator or a resident physician directly supervised by a study investigator. Randomization to either immediate IUD insertion (within 15 minutes after completion of the procedure) or delayed IUD insertion (2 to 6 weeks later) was accomplished by permuted-block randomization with random block sizes of 5 and 6, stratified by study center. Within each stratum, we randomly assigned subjects to immediate or delayed insertion in an overall ratio of approxi-

mately 5:6 by using a ratio of 2:3 for a block size of 5 and a ratio of 3:3 for a block size of 6. Sequentially numbered, opaque envelopes containing cards with the computer-generated assignments were used.

The envelopes were opened only after the aspiration procedure had been completed and the investigator had determined that immediate IUD insertion was feasible (i.e., the IUD could be safely placed if the subject was randomly assigned to immediate insertion). Subjects were excluded from randomization in cases of failure to confirm completion of the aspiration, hemorrhage, perforation, or any other condition that, in the opinion of the surgeon, precluded safe IUD insertion.

All IUDs were placed by study investigators. This occurred after randomization in the case of subjects in the immediate-insertion group; those randomly assigned to delayed insertion were given appointments for follow-up visits. Subjects maintained daily diaries of bleeding, cramping or pain, and medication use from the day of the aspiration to 1 month after IUD insertion. Subjects were also asked to contact the study investigators regarding any unexpected symptoms or concerns related to the IUD.

Duramed Pharmaceuticals donated ParaGard for the study. Neither Teva Pharmaceuticals nor the Susan Thompson Buffett Foundation, which provided grant support for the study, had access to the data or involvement in the study design, data collection or analysis, the writing of the manuscript, or the decision to submit the manuscript for publication.

#### FOLLOW-UP

Subjects were followed for 6 months after IUD insertion, with evaluations at 1, 3, and 6 months. The follow-up 1 month after insertion was conducted as an office visit that included review of the diary, completion of a questionnaire, a physical examination, and ultrasonographic verification of the intra-uterine location of the IUD; clinicians assessing IUD location were aware of group assignments. Attempts were made to contact all subjects by telephone to complete a questionnaire 3 and 6 months after IUD insertion (or a scheduled appointment for subjects who did not return for IUD insertion). Subjects who had concerns about the IUD were seen at unscheduled visits by study investigators whenever possible. At all scheduled and unscheduled visits, subjects were evaluated for expulsion, continued use, or removal of the IUD, as well as

for infection, pain, bleeding, pregnancy, and other IUD-related or medical concerns.

#### OUTCOMES AND ADVERSE EVENTS

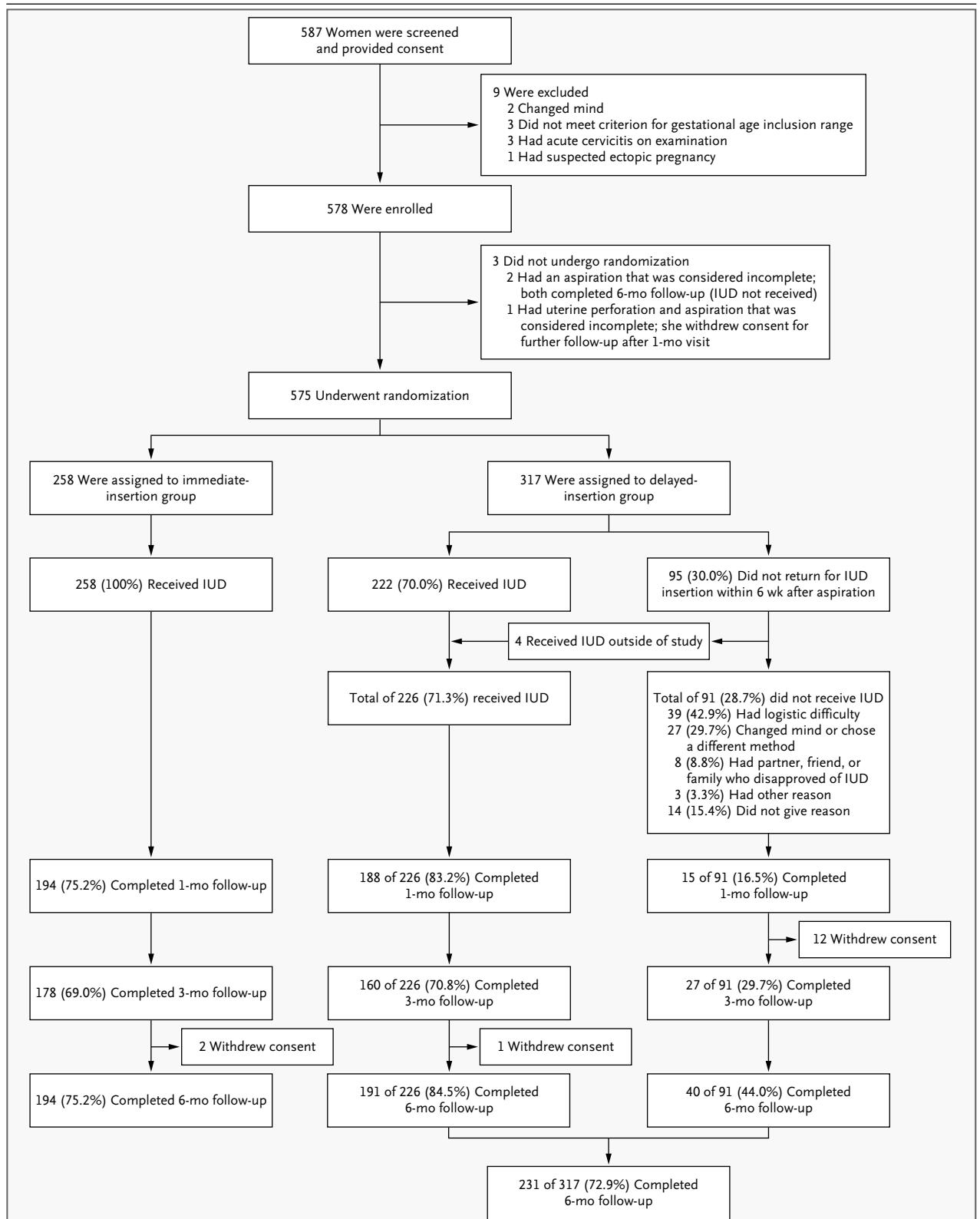
Partial expulsion was defined as the presence of the IUD within the cervical canal, and complete expulsion was defined as the passage of the IUD out of the cervix entirely. Pelvic infection was considered to be present in women with purulent discharge, cervical or uterine tenderness, or a tender adnexal mass, with or without fever or leukocytosis. To ensure that all IUD-related events during the study period were identified, we reviewed medical records for subjects who reported care at non-study sites.

#### STATISTICAL ANALYSIS

The primary outcome was the rate of IUD expulsion 6 months after IUD insertion in women randomly assigned to undergo immediate or delayed insertion. Secondary outcomes included continued use of the IUD, removal (and reason for removal), reinsertion after expulsion or removal, and adverse events, including perforation, pelvic infection, and subsequent unintended pregnancy.

All analyses were performed in the intention-to-treat population. Additional analyses were restricted to women with complete follow-up data at 6 months. The time from insertion to expulsion was evaluated with the use of the Kaplan–Meier method. Logistic regression was used in separate models to assess prespecified potential predictors of IUD expulsion, use, and removal, including gravidity, parity, age, race or ethnic group, gestational age at uterine aspiration, reason for aspiration, IUD type, and study site. Variables that were associated with these outcomes in univariate analyses, with a P value of less than 0.10, were retained in the multivariable model, along with study site and randomization group. For all analyses, two-tailed P values of less than 0.05 were considered to indicate statistical significance. All analyses were completed with the use of SAS software, version 9.2 (SAS Institute).

We based our sample-size calculation on a non-inferiority test of two independent proportions<sup>15,16</sup> and defined an expulsion rate in the immediate-insertion group that was increased by 8 percentage points or more as inferior (upper bound of the 95% confidence interval for noninferiority, 11 percentage points). Using estimated 6-month expulsion rates of 6% with immediate insertion and 3% with delayed insertion and assuming an alpha



**Figure 1. Randomization and Follow-up of Study Participants.**

Women who missed an evaluation could return for later follow-up visits.

level of 0.05 for a one-sided test, we calculated that a sample of 212 subjects in each group who underwent IUD insertion would result in 80% power. The sample size per group was increased to 266 to allow for a 20% rate of loss to follow-up over the 6-month period. In addition, the size of the delayed-insertion group was increased further to account for an estimated 15% nonreturn rate for delayed insertion, resulting in a sample of 266 subjects in the immediate-insertion group and 312 in the delayed-insertion group (5:6 ratio).

## RESULTS

## STUDY PARTICIPANTS

A total of 578 subjects were enrolled, but 3 did not undergo randomization because excessive bleeding after the uterine aspiration raised concern about incomplete aspiration. (These women were offered delayed IUD insertion.) Of the remaining 575 women, 317 were randomly assigned to delayed IUD insertion and 258 to immediate insertion (Fig. 1).

**Table 1. Baseline Characteristics of the Study Participants.\***

Characteristic	Immediate IUD Insertion (N = 258)	Delayed IUD Insertion (N = 317)	P Value†
Age — yr	27.5±6.4	26.9±6.3	0.31
Race or ethnic group — no. (%)‡			0.06
White	163 (63.2)	180 (56.8)	
Black	57 (22.1)	77 (24.3)	
Hispanic	29 (11.2)	33 (10.4)	
Other	9 (3.5)	27 (8.5)	
Marital status — no. (%)			0.81
Single	197 (76.4)	235 (74.1)	
Married	34 (13.2)	47 (14.8)	
Divorced, separated, or widowed	27 (10.5)	35 (11.0)	
Living with current partner — no. (%)	126 (48.8)	162 (51.1)	0.59
Educational level — no. (%)			0.19
High-school graduate or less	92 (35.7)	117 (36.9)	
Some college	105 (40.7)	144 (45.4)	
College graduate or postgraduate	61 (23.6)	56 (17.7)	
Annual household income, in U.S. \$ — no. (%)			0.73
Less than 10,000	44 (17.1)	60 (18.9)	
10,000 to 29,999	105 (40.7)	115 (36.3)	
30,000 to 49,999	34 (13.2)	47 (14.8)	
50,000 or more	75 (29.1)	95 (30.0)	
Body-mass index§	26.9±6.3	27.1±6.6	0.81
Gravidity — no. (%)			0.92
1	53 (20.5)	66 (20.8)	
2	53 (20.5)	64 (20.2)	
3	55 (21.3)	61 (19.2)	
4 or more	97 (37.6)	126 (39.7)	
Parity — no. (%)			0.95
0	91 (35.3)	110 (34.7)	
1	75 (29.1)	90 (28.4)	
2 or more	92 (35.7)	117 (36.9)	
Previous abortions — no. (%)¶			0.27
0	134 (52.1)	178 (56.2)	
1	85 (33.1)	85 (26.8)	
2 or more	39 (15.2)	54 (17.0)	

Table 1. (Continued.)			
Characteristic	Immediate IUD Insertion (N = 258)	Delayed IUD Insertion (N = 317)	P Value†
Reason for aspiration — no. (%)			0.07
Induced abortion	253 (98.1)	302 (95.3)	
Spontaneous abortion	5 (1.9)	15 (4.7)	
Chlamydia screen positive‖	9 (3.5)	10 (3.2)	0.82
Gestational age — no. (%)			0.48
36–49 days	73 (28.3)	105 (33.1)	
50–63 days	111 (43.0)	128 (40.4)	
64–84 days	73 (28.3)	84 (26.5)	
IUD type chosen — no. (%)			0.81
LNG-IUS	199 (77.1)	249 (78.5)	
Copper IUD	59 (22.9)	68 (21.5)	
History of any sexually transmitted infection — no. (%)	79 (30.6)	90 (28.4)	0.56
History of chlamydia — no. (%)	39 (15.1)	49 (15.5)	0.89
History of pelvic inflammatory disease — no. (%)	7 (2.7)	7 (2.2)	0.70

\* Plus–minus values are means  $\pm$ SD. IUD denotes intrauterine device, and LNG-IUS levonorgestrel intrauterine system.

† All P values were calculated with the use of the chi-square test or Student's t-test, as appropriate.

‡ Race or ethnic group was self-reported.

§ Body-mass index is the weight in kilograms divided by the square of the height in meters.

¶ Data point for one woman in the immediate-insertion group was missing.

‖ Chlamydia nucleic acid amplification screening was performed immediately before the uterine aspiration procedure in 245 subjects in the immediate-insertion group and 304 subjects in the delayed-insertion group; 26 subjects (4.5%) were not screened for chlamydia before the aspiration procedure.

There were no significant differences in demographic or baseline clinical characteristics between the randomized groups (Table 1). IUDs were inserted in all 258 women in the immediate-insertion group (100%) and in all 226 women in the delayed-insertion group who returned for their insertion visit (71.3%) (difference, 28.7 percentage points; 95% confidence interval [CI], 23.7 to 33.7;  $P < 0.001$ ). At least one follow-up visit was completed by 235 subjects (91.1%) in the immediate-insertion group and 258 (81.4%) in the delayed-insertion group, and complete 6-month data were available for 194 subjects (75.2%) and 231 subjects (72.9%), respectively. In both groups of women who received an IUD, those who were younger, had a lower income, or were Hispanic were less likely to complete the 6-month follow-up. (Baseline characteristics of women who completed follow-up and those who did not among subjects who underwent immediate or delayed IUD insertion, as well as among those in the delayed-insertion group who did not undergo insertion, are summarized in the Supplementary Appendix.)

#### OUTCOMES

Expulsions occurred in 13 women (5.0%; 95% CI, 2.7 to 8.5) in the immediate-insertion group and 6 (2.7%; 95% CI, 1.0 to 5.7) in the delayed-insertion group (absolute difference, 2.3 percentage points; 95% CI,  $-1.0$  to 5.8) (Table 2). Of these expulsions, 13 were partial expulsions that were diagnosed by ultrasonography. All but 1 of these women noted symptoms (e.g., increased cramping, lengthening strings, or the IUD itself at the cervix) for which they were evaluated at extra (unscheduled) visits. There were 6 complete expulsions, all of which were recognized and reported by the subjects. Fifteen expulsions (78.9%) occurred within 2 months of insertion (Fig. 2). In multivariate analyses, the only factor significantly associated with expulsion was the body-mass index; a higher body-mass index was associated with higher odds of expulsion in both groups.

Of the 13 subjects in the immediate-insertion group who had an expulsion, 7 requested and received a second IUD. Of these subjects, 5 (71%) had a second expulsion, 1 requested removal of the IUD, and 1 still had the IUD in place at the last

**Table 2. Outcomes of Immediate versus Delayed IUD Insertion after Uterine Aspiration.\***

Outcome	Immediate Insertion	Delayed Insertion	P Value†	Difference in Percentage Points (95% CI)	Risk Ratio (95% CI)
	<i>no./total no. (%)</i>				
Insertion‡	258/258 (100)	226/317 (71.3)	<0.001	28.7 (23.7 to 33.7)	1.40 (1.31 to 1.50)
LNG-IUS	199/258 (77.1)	178/226 (78.8)			
Copper IUD	59/258 (22.9)	48/226 (21.2)			
Expulsion§	13/258 (5.0)	6/226 (2.7)	0.19	2.3 (–1.0 to 5.8)	1.90 (0.73 to 4.91)
Partial	8/258 (3.1)	5/226 (2.2)			
Complete	5/258 (1.9)	1/226 (0.4)			
By type of IUD¶					
LNG-IUS	11/199 (5.5)	6/178 (3.4)			
Copper IUD	2/59 (3.4)	0/48			
Removal§	16/258 (6.2)	11/226 (4.9)	0.60	1.3 (–2.7 to 5.4)	1.27 (0.60 to 2.69)
LNG-IUS	10/199 (5.0)	8/178 (4.5)			
Copper IUD	6/59 (10.2)	3/48 (6.2)			
Reinsertion			NA		
After expulsion	7/13 (53.8)	0/6			
After removal	2/16 (12.5)	0/11			
Use at 6 months	179/194 (92.3)	177/231 (76.6)	<0.001	15.7 (8.7 to 21.9)	1.20 (1.11 to 1.31)
LNG-IUS	143/152 (94.1)	139/148 (93.9)			
Copper IUD	36/42 (85.7)	38/41 (92.7)			

\* IUD denotes intrauterine device, LNG-IUS levonorgestrel intrauterine system, and NA not applicable.

† All P values were calculated with the use of the chi-square test.

‡ Insertion rates are based on all subjects who underwent randomization.

§ Expulsion and removal rates at 6 months are based on all subjects who had an IUD inserted at any time after randomization. The type of IUD did not differ significantly within the immediate-insertion group or within the delayed-insertion group.

¶ Numbers are totals for partial and complete expulsions.

|| Rates of use at 6 months are based on subjects for whom 6-month follow-up data were available. IUD-specific use at 6 months is based on subjects who had an IUD insertion and had 6-month follow-up data.

contact. None of the 6 subjects in the delayed-insertion group who had an expulsion requested a second IUD.

At 6 months, the IUD utilization rate was significantly higher in the immediate-insertion group than in the delayed-insertion group (92.3% vs. 76.6%,  $P<0.001$ ). The frequency of requests for IUD removal due to cramping or pain was similar in the two groups (Table 2). Of the 27 subjects who requested removal after initial insertion, only 2 (both in the immediate-insertion group) requested reinsertion; both still had the IUD in place at 6 months. Among subjects in the delayed-insertion group who never received an IUD, the most common alternative choices for contraception were condoms (in 31.9%) and no method (in 25.2%).

During the 6 months of follow-up, there were

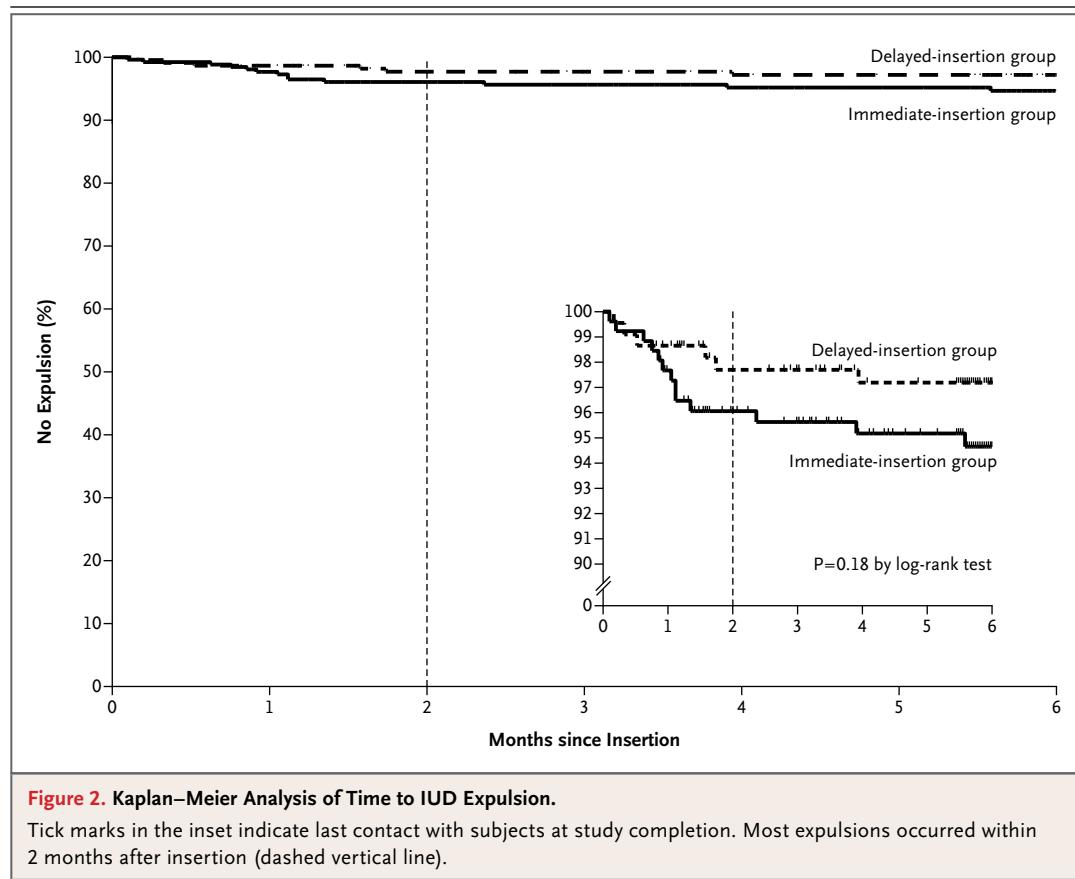
no pregnancies in the immediate-insertion group, as compared with five in the delayed-insertion group ( $P=0.07$ ), all among women who never received an IUD.

Two of the three subjects who did not undergo randomization completed the 6-month follow-up; neither received an IUD, and one became pregnant.

#### ADVERSE EVENTS

There were no significant differences between groups in rates of any adverse events, including pelvic infection (Table 3). No IUD perforations were noted.

Two women (0.8%) in the immediate-insertion group and three (0.9%) in the delayed-insertion group had an incomplete abortion and required



a repeat uterine aspiration ( $P=1.00$ ). Both women in the immediate-insertion group had their IUDs removed before reaspiration; neither required hospitalization or elected IUD reinsertion. All three women in the delayed-insertion group underwent reaspiration before the scheduled visit for IUD insertion. One woman (0.4%) in the immediate-insertion group had a failed abortion, with an ongoing pregnancy that was diagnosed at 21 weeks. She chose to continue the pregnancy and had an uncomplicated repeat cesarean section at 36 weeks, after the onset of spontaneous labor. The IUD was removed at that time, and she chose to undergo tubal ligation.

A total of 10 pelvic infections were reported, 5 in each group (Table 3). Of 19 women whose screening tests for chlamydia were positive before uterine aspiration, 1 woman (in the immediate-insertion group) later received a diagnosis of pelvic infection. She was treated with antibiotics on an outpatient basis and did not have the IUD removed. Three subjects who tested negative for chlamydia before the procedure (2 in the immediate-insertion group and 1 in the delayed-insertion group) later

received a diagnosis of pelvic infection and required intravenous antibiotics. The IUDs were removed from the 2 subjects in the immediate-insertion group; the subject in the delayed-insertion group had not yet received an IUD. Six additional women who tested negative for chlamydia before the procedure (2 in the immediate-insertion group and 4 in the delayed-insertion group) later received a diagnosis of pelvic infection and were treated with antibiotics on an outpatient basis; 5 did not have the IUD removed, and 1 had not yet received an IUD.

## DISCUSSION

This trial showed that when IUD insertion is performed immediately after first-trimester uterine aspiration, the rate of IUD expulsion, although higher than that with delayed insertion, is low and statistically noninferior to the rate with delayed insertion. Our results are compatible with an expulsion rate for immediate insertion that is 1.0 percentage point lower to 5.8 percentage points higher than that for delayed insertion. In addi-

**Table 3. Adverse Events in the Immediate-Insertion and Delayed-Insertion Groups.**

Adverse Event	Immediate Insertion (N=258)	Delayed Insertion (N=317)	P Value*
	number (percent)		
IUD uterine perforation	0	0	1.0
Diagnosis of pelvic infection after aspiration†	5 (1.9)	5 (1.6)	0.76
Incomplete abortion	2 (0.8)	3 (0.9)	1.0
Failed abortion, ongoing pregnancy	1 (0.4)	0	0.45

\* All P values were calculated with the use of Fisher's exact test.

† One woman in the immediate-insertion group and none in the delayed-insertion group were positive for chlamydia at the time of aspiration.

tion, immediate insertion was associated with significantly higher rates of IUD use at 6 months, with no increase in the risk of adverse events, including uterine perforation and pelvic infection.

Pelvic infection was uncommon after IUD insertion, even in women with a history of pelvic inflammatory disease or positive screening results for chlamydia at the time of aspiration. These findings support the expansion of access to IUDs after first-trimester uterine aspiration, including elimination of an additional visit to test for sexually transmitted infection when no infection is clinically evident. In addition, these data add to the growing body of evidence supporting the safety and effectiveness of IUD use among a wider range of women who previously may not have been considered good candidates for an IUD.

The IUD is among the most effective reversible contraceptive methods; the failure rate with typical use is 0.1 to 0.8% in the first year, which is similar to the failure rate with female sterilization.<sup>1</sup> In contrast, 9% of first-time users of combined oral contraceptives become pregnant in the first year.<sup>1</sup> The majority of subjects in the delayed-insertion group who did not return for an IUD chose a substantially less effective contraceptive method than an IUD, or they used no contraception. Our results confirm previously published data showing that 25 to 68% of women who make an appointment for IUD placement after an abortion do not return.<sup>7,9,11,17</sup>

In the present trial, five pregnancies occurred in the delayed-insertion group, as compared with none in the immediate-insertion group, and all pregnancies occurred in women not using IUDs. Although this difference was not statistically sig-

nificant, our study was not powered for this outcome and involved only 6 months of follow-up. A greater cumulative effect would be expected over a longer period.

A limitation of the study is the substantial loss to follow-up, with 6-month follow-up rates of 73% in the immediate-insertion group and 75% in the delayed-insertion group. However, ongoing contact with women who have undergone an abortion is difficult. Many women travel far for abortion care.<sup>18</sup> They also wish to maintain their privacy, and many decline follow-up.<sup>8,19</sup> The high rates of loss to follow-up may have resulted in underestimation of rates of expulsion, unintended pregnancy, and infection. Also, women who did not return for follow-up had characteristics (e.g., younger age and lower income) that are associated with an increased risk of unintended pregnancy. Given the similar overall rates of loss to follow-up, we would expect rates of underreporting to be similar in the two groups for all outcomes except unintended pregnancy, which may have been more frequent in the delayed-insertion group (because women who did not return for IUD insertion may have been at higher risk for unintended pregnancy).

The majority of the expulsions were identified during the first 2 months, and the time to expulsion was similar in the two groups (Fig. 2), findings that are consistent with previous data showing that most expulsions occur during this time frame.<sup>20</sup> Because later study contacts involved self-reporting of IUD expulsion or removal, it is possible that IUD expulsion was underreported. However, unrecognized expulsion is rare (estimated to account for <1% of expulsions),<sup>21</sup> and the accuracy

of self-reports would not be expected to differ between groups.

Mathematical modeling suggests that a switch from delayed IUD insertion to immediate insertion could prevent more than 70,000 unintended pregnancies annually in the United States.<sup>3</sup> However, the availability of immediate IUD insertion is restricted by federal funding for contraceptive use, such as Title X and state Medicaid waiver programs, because the provision of contraceptive services on the day of an abortion in the same facility is prohibited. Such policies that require health care providers to separate contraception provision from abortion provision reduce the likelihood that women will obtain the contraception needed to prevent unintended pregnancy.

In summary, IUD insertion immediately after first-trimester induced or spontaneous abortion was associated with a risk of expulsion that was slightly higher but statistically noninferior to that associated with delayed insertion, and with similarly low complication rates. In addition, women assigned to immediate insertion had higher insertion rates and higher rates of IUD use at 6 months, effects that are likely to result in reduced rates of unintended pregnancy.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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## REFERENCES

- Trussell J. Contraceptive failure in the United States. *Contraception* 2004;70:89-96.
- Hubacher D, Cheng D. Intrauterine devices and reproductive health: American women in feast and famine. *Contraception* 2004;69:437-46.
- Reeves MF, Smith KJ, Creinin MD. Contraceptive effectiveness of immediate compared with delayed insertion of intrauterine devices after abortion: a decision analysis. *Obstet Gynecol* 2007;109:1286-94. [Erratum, *Obstet Gynecol* 2007;110:936.]
- Heikinheimo O, Gissler M, Suhonen S. Age, parity, history of abortion and contraceptive choices affect the risk of repeat abortion. *Contraception* 2008;78:149-54.
- Goodman S, Hendlish SK, Reeves MF, Foster-Rosales A. Impact of immediate postabortal insertion of intrauterine contraception on repeat abortion. *Contraception* 2008;78:143-8.
- Marrs RP, Kletzky OA, Howard WF, Mishell DR Jr. Disappearance of human chorionic gonadotropin and resumption of ovulation following abortion. *Am J Obstet Gynecol* 1979;135:731-6.
- Stanek AM, Bednarek PH, Nichols MD, Jensen JT, Edelman AB. Barriers associated with the failure to return for intrauterine device insertion following first-trimester abortion. *Contraception* 2009;79:216-20.
- Drey EA, Reeves MF, Ogawa DD, Sokoloff A, Darney PD, Steinauer JE. Insertion of intrauterine contraceptives immediately following first- and second-trimester abortions. *Contraception* 2009;79:397-402.
- El-Tagy A, Sakr E, Sokal DC, Issa AH. Safety and acceptability of post-abortal IUD insertion and the importance of counseling. *Contraception* 2003;67:229-34.
- Grimes DA, Lopez LM, Schulz KF, Stanwood NL. Immediate postabortal insertion of intrauterine devices. *Cochrane Database Syst Rev* 2010;6:CD001777.
- Pakarinen P, Toivonen J, Luukkainen T. Randomized comparison of levonorgestrel- and copper-releasing intrauterine systems immediately after abortion, with 5 years follow-up. *Contraception* 2003;68:31-4.
- Gillett PG, Lee NH, Yuzpe AA, Cerskus I. A comparison of the efficacy and acceptability of the Copper-7 intrauterine device following immediate or delayed insertion after first-trimester therapeutic abortion. *Fertil Steril* 1980;34:121-4.
- World Health Organization, Task Force on Intrauterine Devices for Fertility Regulation, Special Programme of Research, Development and Research Training in Human Reproduction. IUD insertion following termination of pregnancy: a clinical trial of the TCu 220C, Lippes loop D, and copper 7. *Stud Fam Plann* 1983;14:99-108.
- Idem*. IUD insertion following spontaneous abortion: a clinical trial of the TCu 220C, Lippes loop D, and copper 7. *Stud Fam Plann* 1983;14:109-14.
- D'Agostino RB, Chase W, Belanger A. The appropriateness of some common procedures for testing the equality of two independent binomial proportions. *Am Stat* 1988;42:198-202.
- Upton GJG. A comparison of alternative tests for the 2 × 2 comparative trial. *J R Stat Soc [A]* 1982;145:86-105.
- Stanwood NL, Grimes DA, Schulz KF. Insertion of an intrauterine contraceptive device after induced or spontaneous abortion: a review of the evidence. *BJOG* 2001;108:1168-73.
- Jones RK, Zolna MRS, Henshaw SK, Finer LB. Abortion in the United States: incidence and access to services, 2005. *Perspect Sex Reprod Health* 2008;40:6-16.
- Rose SB, Lawton BA, Brown SA. Uptake and adherence to long-acting reversible contraception post-abortion. *Contraception* 2010;82:345-53.
- Andersson K, Odland V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: a randomized comparative trial. *Contraception* 1994;49:56-72.
- Backman T, Rauramo I, Huhtala S, Koskenvuo M. Pregnancy during the use of levonorgestrel intrauterine system. *Am J Obstet Gynecol* 2004;190:50-4.

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