GYNECOLOGY

One-year pregnancy and continuation rates after placement of levonorgestrel or copper intrauterine devices for emergency contraception: a randomized controlled trial

Jennifer E. Kaiser, MD; David K. Turok, MD; Alexandra Gero, MPH; Lori M. Gawron, MD; Rebecca G. Simmons, PhD; Jessica N. Sanders, PhD

BACKGROUND: Recent evidence demonstrates the effectiveness of the levonorgestrel 52-mg intrauterine device for emergency contraception vs the copper T380A intrauterine device. Of note, 1-year pregnancy and continuation rates after intrauterine device placement for emergency contraception remain understudied.

OBJECTIVE: This study compared 1-year pregnancy and intrauterine device continuation rates and reasons for discontinuation among emergency contraception users randomized to the levonorgestrel 52-mg intrauterine device or the copper intrauterine device.

STUDY DESIGN: This participant-masked, randomized noninferiority trial recruited emergency contraception individuals desiring an intrauterine device from 6 Utah family planning clinics between August 2016 and December 2019. Participants were randomized 1:1 to the levonorgestrel 52-mg intrauterine device group or the copper T380A intrauterine device group. Treatment allocation was revealed to participants at the 1-month follow-up. Trained personnel followed up the participants by phone, text, or e-mail at 5 time points in 1 year and reviewed electronic health records for pregnancy and intrauterine device continuation outcomes for both confirmation and nonresponders. We assessed the reasons for the discontinuation and used Cox proportional-hazard models, Kaplan-Meier estimates, and log-rank tests to assess differences in the continuation and pregnancy rates between the groups.

RESULTS: The levonorgestrel and copper intrauterine device groups included 327 and 328 participants, respectively, receiving the respective interventions. By intention-to-treat analysis at 1 year, the pregnancy rates were similar between intrauterine device types (2.8% [9/327] in levonorgestrel 52-mg intrauterine device vs 3.0% [10/328] in copper intrauterine device; risk ratio, 0.9; 95% confidence interval, 0.4−2.2; P=.82). Most pregnancies occurred in participants after intrauterine device removal, with only 1 device failure in each group. Of note, 1-year continuation rates did not differ between groups with 204 of 327 levonorgestrel 52-mg intrauterine device users (62.4%) and 183 of 328 copper T380A intrauterine device users (55.8%) continuing intrauterine device use at 1 year (risk ratio, 1.1; 95% confidence interval, 1.0−1.2; P=.09). There were differences concerning the reasons for discontinuation between intrauterine device types, with more bleeding and cramping cited among copper intrauterine device users.

CONCLUSION: The pregnancy rates were low and similar between intrauterine device types. Of note, 6 of 10 intrauterine device emergency contraception users continued use at 1 year. Moreover, 1-year continuation rates were similar between intrauterine device types.

Key words: emergency contraception, intrauterine device

Introduction

The use of the copper (Cu) intrauterine device (IUD) for emergency contraception (EC) revolutionized people's options for postcoital contraception, which is highly effective for EC and provides ongoing pregnancy prevention. However, many people selecting an IUD for reasons other than EC have a strong preference for the levonorgestrel (LNG) IUD vs the Cu IUD.[1] Our recent randomized controlled trial demonstrated noninferior 1-month EC pregnancy rates among users of the LNG 52-mg IUD (1 pregnancy in 317 users; pregnancy rate, 0.3%; 95% confidence interval [CI], 0.01−1.70) and the Cu T380A IUD (0 pregnancies in 321 users; pregnancy rate, 0%; 95% CI, 0.0−1.1).[2] Applying these data can expand patient autonomy and respond to patient preferences by offering both IUD options to those seeking EC.

The added benefit of IUD use for EC is the potential for a reduction in future unintended pregnancies through continued long-term use. Our previous study examined IUD continuation rates after placement for EC when study participants selected the LNG 52-mg IUD along with oral LNG for EC (before the LNG IUD alone demonstrated EC efficacy) or the Cu T380A IUD alone. Of note, 1-year continuation rates after participant-selected IUD type for EC (Cu IUD or LNG IUD plus oral LNG) were 60% for Cu IUD users and 70% for LNG IUD users.[3] People selecting an IUD in a non-EC context have higher 1-year continuation rates: 88% for LNG IUD users and 84% for Cu IUD users.[4] Outside of EC use, previous studies that randomized participants to IUD type did not provide long-term follow-up pregnancy or continuation rates.[5,6] However, 1 study that randomized participants to long-acting or short-acting methods reported that 78.4% of participants continued their self-selected IUD for 1 year and that 0.7% experienced an unintended pregnancy.[7]

Cite this article as: Kaiser JE, Turok DK, Gero A, et al. One-year pregnancy and continuation rates after placement of levonorgestrel or copper intrauterine devices for emergency contraception: a randomized controlled trial. Am J Obstet Gynecol 2023;228:438.e1-10.

0002-9378/$36.00

https://doi.org/10.1016/j.ajog.2022.11.1296

AJOG at a Glance

Why was this study conducted?

This study aimed to assess the difference in 1-year pregnancy and continuation rates among emergency contraception (EC) users randomly assigned to the levonorgestrel or copper intrauterine device (IUD).

Key findings

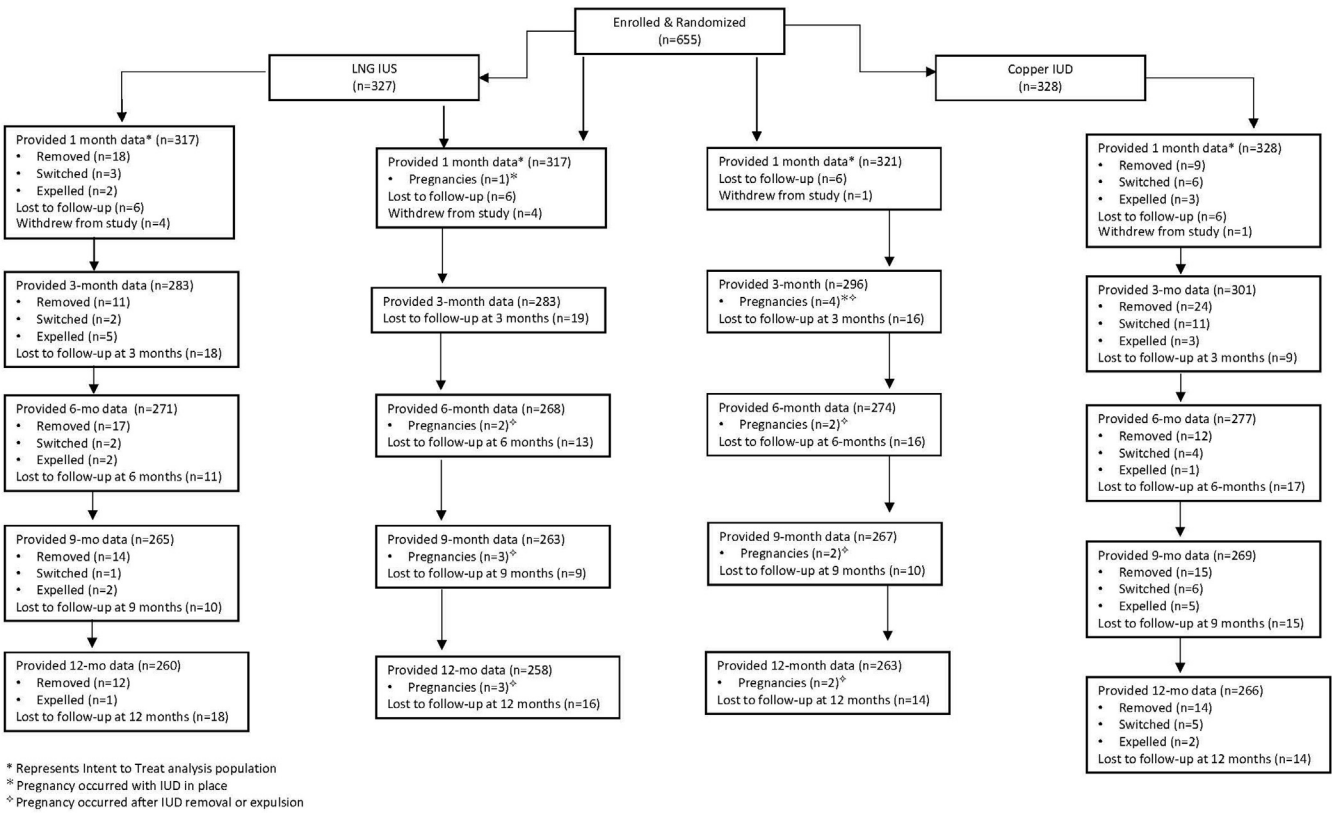
This study found no difference in pregnancy or continuation rates between the groups. Of note, most pregnancies occurred among those who had their IUDs removed with 1 pregnancy occurring in each group as a result of IUD failure.

What does this add to what is known?

Limited data addressed IUD continuation after random assignment, and the continuation rates were lower in this population of EC users than in conventional IUD users.

We aimed to address the above knowledge gap by comparing 1-year pregnancy and IUD continuation rates among EC users randomized to the Cu T380A IUD or LNG 52-mg IUD. We hypothesized that EC users randomized to the Cu IUD would have higher discontinuation rates than those randomized to the LNG IUD and would subsequently switch to less effective methods. Thus, we hypothesized that 1-year pregnancy rates would be lower for EC users randomized to the LNG IUD than for those randomized to the Cu IUD. We anticipated lower continuation rates in both groups compared to previous studies in both non-EC settings and in patient-preference settings because we randomized participants to IUD type and because EC IUD users in our study did not initially visit the clinic intending on getting an IUD placed. We expected higher continuation rates in LNG IUD users than in Cu IUD users because of demonstrated client preferences and higher continuation rates in previous studies.[7]

FIGURE 1
Flowchart of participants timing of removal, expulsion, and pregnancy



IUD, intrauterine device; *IUS*, intrauterine system; *LNG*, levonorgestrel.

Kaiser. One-year follow-up after intrauterine devices for emergency contraception. Am J Obstet Gynecol 2023.

TABLE 1
Baseline demographic characteristics

Characteristic	Levonorgestrel IUD (n=327)	Copper IUD (n=328)	*P* value
Mean age (y)	24.00±0.27	23.90±0.25	.74
Body mass index category (kg/m^2)			.37
<25.0	168 (51.4)	155 (47.3)	
25.0–29.9	70 (21.4)	85 (25.9)	
≥30.0	89 (27.2)	88 (26.8)	
Education			.88
High school or less	169 (51.8)	168 (51.5)	
In college	123 (37.7)	120 (36.8)	
College degree or higher	34 (10.4)	38 (11.7)	
Annual income			.52
<$12,000	133 (40.8)	141 (43.3)	
$12,000–$35,999	151 (46.3)	152 (46.6)	
>$36,000	42 (12.9)	33 (10.1)	
Insurance coverage			.49
Private insurance	91 (28.1)	108 (33.1)	
Public insurance	27 (8.3)	28 (8.6)	
Uninsured	159 (49.1)	151 (46.3)	
Do not know	47 (14.5)	39 (12.0)	
Race and ethnicity			.85
White	179 (54.7)	190 (57.9)	
Hispanic or Latina	108 (33.0)	98 (29.9)	
Black or African American	12 (3.7)	12 (3.7)	
Other	28 (8.6)	28 (8.5)	
Relationship status			.87
Married	16 (4.9)	21 (6.4)	
Living together or in a committed relationship	112 (34.4)	107 (32.8)	
Single or actively dating	169 (51.8)	171 (52.5)	
Divorced or separated	17 (5.2)	18 (5.5)	
Other or did not answer	12 (3.7)	9 (2.8)	
Reason for seeking emergency contraception			.03
Did not use any method at last sex	132 (40.7)	165 (50.5)	
Incorrect use of rhythm or withdrawal method	61 (18.8)	68 (20.8)	
Condom broke	61 (18.8)	41 (12.5)	
Ran out of contraception or missed dose	15 (4.6)	8 (2.5)	
Did not plan or was forced to have sex	40 (12.4)	28 (8.6)	
Other	15 (4.6)	17 (5.2)	

Kaiser. One-year follow-up after intrauterine devices for emergency contraception. Am J Obstet Gynecol 2023.

(continued)

Materials and Methods

Trial design

This was a secondary analysis of the Randomized Controlled Trial Assessing Pregnancy for IUDs as Emergency Contraception (RAPID EC). RAPID EC randomized masked participants 1:1 to either an LNG 52-mg IUD or a Cu T380A IUD for EC. The trial design, enrollment, and follow-up procedures have been previously described.[2] Here, we provided a succinct summary. The study staff approached women seeking EC at 6 Utah family planning clinics from August 2016 to December 2019. All participants provided informed consent. The institutional review board of the University of Utah approved the RAPID EC protocol.

Participants

Eligible participants included those fluent in English or Spanish and aged 18 to 35 years requesting EC after unprotected intercourse within the previous 5 days (120 hours) with a desire to prevent pregnancy for at least 1 year and an interest in an IUD. Participants were counseled on potential side effects for both types of IUDs before randomization.

Trial procedures

We generated the randomization sequence with balanced blocks of 4 stratified by site and uploaded the blinded sequence to the Research Electronic Data Capture (REDCap),[8] a secure Web-based application system. After screening and participant consent, REDCap was used to randomly assign participants 1:1 to the placement of either the (1) LNG 52-mg IUD or the (2) Cu T380A IUD just before entering the procedure room. Participants were masked to the intervention, using a covered tray and drape, but IUD appearance and inserter differences prevented masking providers. All participants received a urine pregnancy test to complete 1 month after IUD insertion.

Of note, the 1-month follow-up included an optional clinic visit, a home or clinic urine pregnancy test, and completion of the online survey.

TABLE 1
Baseline demographic characteristics *(continued)*

Characteristic	Levonorgestrel IUD (n=327)	Copper IUD (n=328)	*P* value
Parity			.05
Nulliparous	242 (74.9)	221 (68.0)	
Parous	81 (25.1)	104 (32.0)	

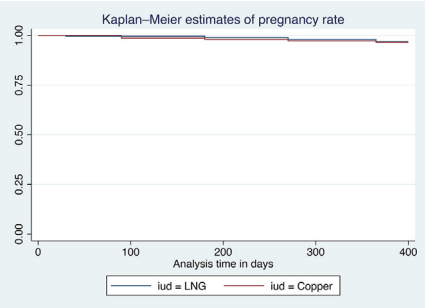
IUD, intrauterine device.

Kaiser. One-year follow-up after intrauterine devices for emergency contraception. Am J Obstet Gynecol 2023.

Furthermore, participants were informed of their assigned IUD type, were able to ask questions, and were able to discontinue or switch to the other IUD at no cost if desired. All participating study health centers were Title X clinical sites. If participants desired an alternative contraceptive method at any point during the study, they received contraceptive counseling from available clinicians and staff who provided this per their usual practice. For participants switching to a contraceptive method other than an IUD, all were provided their method through health insurance coverage or on a sliding payment scale that slid to zero, excluding the contraceptive implant.

All remaining follow-ups at 3, 6, 9, and 12 months after enrollment occurred through REDCap with invitations via text, e-mail, or phone, per participant-stated preference at enrollment. Research staff administered the survey over the phone for participants preferring this option. If follow-up surveys were not completed on initial contact, then the study staff attempted 3 contacts each in the next week by text message, e-mail message, and phone. If needed, the study staff attempted to reach alternative contacts provided at enrollment. If all efforts to complete follow-up surveys yielded no survey completion, we reviewed the clinic electronic health record notes from the Planned Parenthood Association of Utah and the 2 largest hospital systems in Utah to assess documentation of IUD use and pregnancy status. Participant reimbursement included $10 for each completed follow-up survey at 1, 3, 6, 9, and 12 months. Moreover, individuals received an extra $30 for presenting in person for a clinic visit at 1 and 12 months.

FIGURE 2
Kaplan-Meier estimates of pregnancy rate among participants by IUD type



IUD, intrauterine device; *LNG*, levonorgestrel.

Kaiser. One-year follow-up after intrauterine devices for emergency contraception. Am J Obstet Gynecol 2023.

Outcomes and adverse events

We defined the co-primary outcomes as pregnancy and IUD continuation rates within 1 year of enrollment. The secondary outcomes included reasons for elective IUD discontinuation, expulsion rates, and predictors of discontinuation. We defined continuation as participants with the randomly assigned IUD in place at 12 months. Elective discontinuation encompasses those with removals for any reason other than switching IUD type, IUD expulsion, or device failure. Those who switched from the randomized IUD to the other IUD, expulsions, and those lost to follow-up were not considered part of the discontinuation category. For participants reporting pregnancy, we assessed the timing of pregnancy concerning IUD discontinuation or expulsion and whether the desire for pregnancy was the reason for discontinuation. Of note, in this article, we chose to address all pregnancies instead of just those that were unintended to obtain a greater appreciation for the range of pregnancy intention; therefore, we included all pregnancies in the analysis and acknowledged those that achieved pregnancy after IUD removal for conception purposes. To contextualize pregnancy rates, we also surveyed participants at 3, 6, 9, and 12 months on the frequency of intercourse in the past 3 months and all methods of contraception or sexually transmitted infection protection used in the past 4 weeks. This included methods in addition to the IUD for those still using it and methods other than an IUD for those not using an IUD.

All surveys included an open-ended query of receipt of any medical care related to the IUD in any setting to assess adverse events. A data safety monitoring committee limited their evaluation to pregnancies resulting from EC failure in the LNG 52-mg IUD group. Here, we limited the reporting of adverse outcomes to concerns specifically related to IUD use.

Statistical analysis

Sample size

The RAPIC EC primary outcome of the first-month pregnancy rate determined the sample size with a recruitment goal of 706 participants. This provided sufficient power to detect an expected 12% difference between the 2 groups in 1-year continuation rates. Based on previous clinical data from participating sites, we anticipated a 76% 1-year continuation rate in the LNG IUD group and a 64% 1-year continuation rate in the Cu IUD group.

Analysis

We performed an intention-to-treat analysis using Kaplan-Meier estimates and log-rank tests to assess differences in the discontinuation rates between IUD types. We conducted univariate Cox proportional-hazards analyses for all categorical predictors of discontinuation, including IUD type, age, insurance,

TABLE 2
Pregnancy, elective discontinuation, switching, and expulsion rates for IUD users at 1 year by assigned IUD type

Variable	Levonorgestrel IUD (n=327), n (%)	Copper IUD (n=328), n (%)	RR (95% CI)	*P* value
Pregnancies reported over 12 mo	9 (2.8)	10 (3.0)	0.9 (0.4–2.2)	.82
Lost to follow-up for 12 mo: pregnancy outcome	67 (20.5)	63 (19.2)	1.1 (0.8–1.5)	.68
Total removals over 12 mo	72 (22.0)	74 (22.3)	1.0 (0.7–1.3)	.87
Total switches over 12 mo	8 (2.4)	32 (9.8)	0.3 (0.1–0.5)	<.01
Lost to follow-up for 12 mo: removal outcome	67 (20.5)	62 (18.9)	1.1 (0.8–1.5)	.61
Expulsions	12 (3.7)	14 (4.3)	0.9 (0.4–1.8)	.69
Reasons cited for discontinuation[a]				
Excessive bleeding	29	62	0.6 (0.4–0.9)	<.01
Excessive cramping	41	75	0.7 (0.6–0.9)	<.01
Infection	13	8	2.0 (0.9–4.9)	.06
Pelvic pain	32	56	0.7 (0.5–1.0)	.08
Breast symptoms	11	12	1.2 (0.6–2.6)	.62
Weight gain	22	20	1.4 (0.9–2.5)	.16
Moodiness	33	36	1.2 (0.8–1.8)	.31
Headaches	24	28	1.1 (0.7–1.8)	.59
Bloating	28	35	1.0 (0.7–1.6)	.78
Wanted to get pregnant	5	6	1.0 (0.3–3.5)	.87
Pregnancy because of IUD failure	1	1	0.9 (0.1–14.4)	.94

Lost to follow-up rates for each primary outcome (pregnancy and continuation) are also represented.

CI, confidence interval; *IUD*, intrauterine device; *RR*, risk ratio.

[a] Participants could select multiple reasons for choosing to discontinue.

Kaiser. One-year follow-up after intrauterine devices for emergency contraception. Am J Obstet Gynecol 2023.

reasons for needing EC, body mass index, race and ethnicity, relationship status, income, and parity. We considered variables with log-rank test *P* values of <.25 for inclusion.[9] Despite not meeting our statistical inclusion threshold, reason for needing EC, age, and parity were included as covariates in the multivariate model based on previous literature and relevant studies.

In addition, we employed Cox regression models in an exploratory fashion to compare patient characteristics and time to discontinuation between the Cu T380A IUD group and the LNG 52-mg IUD group. In the co-primary analysis, we censored those lost to follow-up per the standard non-informative assumption at the time of last contact. This method assumes that participants who dropped out of the study did so for reasons unrelated to the study and that censored patients are considered to have survival prospects similar to participants who continued to be observed.[10] Furthermore, we explored the interactions among potentially significant variables and used Cox-Snell residuals to confirm that the final model fit the data. We performed all analyses using Stata statistical software (version 17.0; StataCorp, College Station, TX).

Results

Of 655 participants enrolled, 327 were randomized to the LNG IUD group, and 328 were randomized to the Cu IUD group. Figure 1 depicts pregnancies, IUD switches, expulsions, removals, and loss to follow-up at 1, 3, 6, 9, and 12 months by randomized group. Complete details of enrollment and participation can be found in the parent publication.[2] Baseline characteristics were similar between groups except in reasons for seeking EC and parity (Table 1). The primary outcome of pregnancy rates at 1 year did not differ between IUD types (9 for LNG IUD [2.8%] vs 10 for Cu IUD [3.0%]; risk ratio [RR], 0.9; 95% CI, 0.4–2.2) (Figure 2, Table 2). Of note, 5 participants in the LNG IUD group and 6 participants in the Cu IUD group removed the device because of desiring pregnancy. Of those participants, 2 LNG IUD and 3 Cu IUD users reported achieving pregnancy. Outcomes were known for 4 of these pregnancies: 2 of the previous LNG IUD users and 1 of the previous Cu IUD users intended to parent, and one of the previous Cu IUD users planned an abortion. At 1 year, all other participants who discontinued the IUD were considered at risk of pregnancy, with all LNG and Cu IUD

TABLE 3
Sexual activity and contraception usage among elective discontinuers by randomized IUD type

Variable	Levonorgestrel IUD (n=72)	Copper IUD (n=74)	*P* value
Sex since entering the study, as reported at the time of discontinuation			.81
Yes	44 (77.2)	49 (79.0)	
No	13 (22.8)	13 (21.0)	
Frequency of intercourse			.67
Daily	5 (11.4)	6 (12.2)	
≥3 times per week	16 (36.4)	21 (42.9)	
Once per week	13 (29.6)	8 (16.3)	
Less than once per week	4 (9.1)	6 (12.2)	
Once a month	6 (13.6)	8 (16.3)	
Condom use during intercourse			.85
Always	3 (7.0)	2 (4.2)	
Most of the time	2 (4.7)	4 (8.3)	
Some of the time	8 (18.6)	9 (18.8)	
Never	30 (69.8)	33 (68.8)	
Any contraception use in the last 4 wk			.73
No	35 (63.6)	40 (66.7)	
Yes	20 (36.4)	20 (33.3)	
Subsequent contraceptive method reported among discontinuers			
Pill	5 (6.9)	4 (5.4)	.41
Implant	0 (0)	2 (2.7)	
Ring	1 (1.4)	2 (2.7)	
Depo	4 (5.6)	1 (1.4)	
Condoms	7 (9.7)	11 (14.9)	
Oral emergency contraception	1 (1.4)	0 (0)	
None reported	54 (75.0)	54 (73.0)	

IUD, intrauterine device.
Kaiser. One-year follow-up after intrauterine devices for emergency contraception. Am J Obstet Gynecol 2023.

discontinuers reporting intercourse once per month or more frequently in the past 3 months (Table 3). However, 63.6% of LNG IUD discontinuers and 66.7% of Cu IUD discontinuers reported not using a method of contraception in the 4 weeks after discontinuation (Table 3). Of those using an alternate method after discontinuation, the method mix is reported in Table 3. Table 4 presents the timing and setting of each pregnancy and demonstrates that most pregnancies occurred in participants after IUD removal, with only 1 device failure in each group.

The co-primary outcome of the assigned IUD continuation rate at 1 year demonstrated a 1-year continuation rate of 62.4% for LNG IUD users and 55.8% for Cu IUD users (RR, 1.1; 95% CI, 1.0−1.3; *P*=.09), with a marginally higher continuation rate among those initially randomized to the LNG IUD group. Elective discontinuation rates, excluding switching, expulsions, or removal for device failure, are represented in Figure 3. We found similarities between groups in the presentation for the total number of IUD removals and expulsions; however, more Cu IUD users cited excessive bleeding (RR, 0.6; 95% CI, 0.4−0.8) or excessive cramping (RR, 0.7; 95% CI, 0.6−0.9) as the reason for discontinuation than LNG IUD users (Table 2). Other reasons for discontinuation included pelvic pain, breast symptoms, weight gain, moodiness, infection, and headaches, which did not differ by group assignment (Table 2).

Unadjusted analyses of predictors of risk of elective discontinuation or switching showed that those assigned to the LNG IUD group, those with an annual income of $12,000 to $35,999, and those identifying as Hispanic or Latin were less likely to switch (Table 5). In adjusted analyses, only those assigned to the LNG IUD group and those with an annual income of $12,000 to $35,999 were less likely to switch (Table 6). There was no significant predictor of removal (Tables 5 and 6).

As previously reported, in the first month of use, 15 LNG users (4.6%) and 11 Cu IUD users (3.4%) sought care for an IUD-related concern (bleeding, cramping, pain, or other IUD-related concerns, such as positioning or strings).[2] Thereafter, 43 LNG IUD users (13.1%) and 82 Cu IUD users (25%) reported seeking care in months 3 to 12 for IUD-related complications or concerns.

Comment

Principal findings

Pregnancy rates 1 year after randomization to the LNG 52-mg IUD group or Cu T380A IUD group for EC showed pregnancies in 3 per 100 participants in both groups. Moreover, we found no statistically significant difference in IUD continuation rates between the groups. The discontinuation and expulsion rates were similar between the groups, but more Cu IUD users discontinued for excessive bleeding or cramping.

TABLE 4
Pregnancies reported by IUD type and circumstance

	Levonorgestrel IUD			Copper IUD		
Variable	Frequency	Removal reported	Pregnancy reported	Frequency	Removal reported	Pregnancy reported
IUD failures	1	—	1 mo	1	—	3 mo
Pregnancy after IUD removal	5	1 mo	9 mo	8	1 mo	3 mo
		6 mo	12 mo		3 mo[a]	3 mo
		6 mo[a]	12 mo		3 mo	3 mo
		9 mo	9 mo		3 mo[a]	6 mo
		12 mo[a]	12 mo		6 mo[a]	9 mo
					6 mo	12 mo
					9 mo	9 mo
					9 mo	12 mo
Pregnancy after IUD expulsion	3	1 mo	9 mo	1	3 mo	9 mo
		3 mo	6 mo			
		6 mo	6 mo			

IUD, intrauterine device.

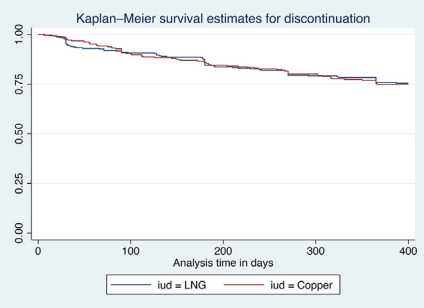
[a] Indicates that the participant cited desire for pregnancy as reason for IUD removal.

Kaiser. One-year follow-up after intrauterine devices for emergency contraception. Am J Obstet Gynecol 2023.

Results in the context of what is known

Of note, 1-year pregnancy rates of 3% after presentation for EC were lower than the 5% to 12% previously reported for those followed up for 1 year after oral EC use.[11–14] Our 1-year continuation rates were similar to a previous nonrandomized study in which participants selected the LNG 52-mg IUD along with oral LNG for EC or the Cu T380A IUD, which demonstrated a 70% and 60% continuation rate, respectively.[3] Our findings showed similar 1-year continuation rates with randomization to IUD type with the ability to switch type without cost. Another randomized study of LNG and Cu IUDs with a smaller sample size only followed up participants for 2 months and supported higher continuation rates in the LNG IUD group (94% in the LNG IUD group vs 81% in the Cu IUD group). This previous study only allowed switching at study end with 2 of 32 participants switching from Cu IUD to LNG IUD.[5] In participant-selected IUD type for non-EC, 1-year continuation rates were higher than in our EC study: 88% for LNG IUD users and 84% for Cu IUD users, possibly because of the indication for choosing an IUD (EC vs contraception).[4] Finally, although we do not have a comparator to assess 12-month pregnancy rates after randomizing participants to LNG IUD vs Cu IUD for EC, 12-month IUD continuation and pregnancy rates among those selecting the Cu IUD for EC were 64% and 6.5%, respectively.[15] Although the continuation rate was similar to Cu IUD users in this study, the previously reported pregnancy rate was higher (6.5% vs 3.0%). This higher proportion of pregnancies in the Cu IUD group in the smaller study may have been due to the lack of precision with a smaller sample size.

FIGURE 3
Kaplan-Meier estimate of discontinuation



The estimate excludes those that switched IUD type and those lost to follow-up.

IUD, intrauterine device; *LNG*, levonorgestrel.

Kaiser. One-year follow-up after intrauterine devices for emergency contraception. Am J Obstet Gynecol 2023.

Clinical implications

The 1-year data we reported demonstrated that 59% of IUD EC users continued IUD use for 1 year and that this population, including those who discontinued the IUD, had low 1-year pregnancy rates. This further supported the LNG 52-mg IUD as an important option for EC and showed favorable IUD continuation and pregnancy rates for 1 year for users of both IUD types after EC placement.

Research implications (unanswered questions and proposals for future research)

In addition, the results reported here, further information that focuses on

TABLE 5
Unadjusted HRs predicting risk of IUD elective discontinuation or switching from the randomly assigned IUD type to the other IUD type

	Removals		Reinsertions	
Variable	Unadjusted HR	*P* value	Univariate HR	*P* value
Randomization arm				
Copper IUD	Ref			
Levonorgestrel IUD	1.0	.88	0.3	<.01
Age	1.0	.51	1.1	.12
Body mass index category (kg/m^2)				
<25.0	Ref			
25.0–29.9	1.4	.07	0.8	.52
≥30.0	1.4	.10	0.7	.40
Education				
High school or less	Ref			
In college	0.7	.07	1.3	.45
College degree or higher	0.9	.60	2.2	.08
Annual income				
<$12,000	Ref			
$12,000–$35,999	0.9	.36	0.5	.04
>$36,000	0.6	.09	0.7	.39
Insurance coverage				
Private insurance	Ref			
Public insurance	1.6	.14	0.4	.15
Uninsured	1.0	.81	0.6	.27
Race and ethnicity				
White	Ref			
Hispanic or Latina	0.9	.59	0.3	.01
Black or African American	1.61	.20	0.8	.72
Other	1.7	.04	0.5	.32
Relationship status				
Cohabitating	Ref			
Single	1.0	.17	0.9	.71
Reason for seeking emergency contraception				
No method used at last intercourse	Ref			
Incorrect method use	1.07	.73	0.8	.51
Did not plan or was forced to have sex	1.0	.93	0.5	.35
Parity				
Nulliparous	Ref			
Parous	1.2	.31	1.2	.62

Cohabitating indicates married, living together, or in committed relationship, and single indicates single, actively dating, divorced, or widowed.

HR, hazard ratio; *IUD*, intrauterine device; *Ref*, reference.

Kaiser. One-year follow-up after intrauterine devices for emergency contraception. Am J Obstet Gynecol 2023.

continuation beyond 1 year after IUD placement for EC, will be helpful. Moreover, a better understanding of the user experiences in accessing the IUD in the EC setting will be important in future research. Given the discrepancy of continuation rates between IUDs placed for EC and IUDs placed for contraception at 1 year, we may see a continued trend of greater attrition among EC users. This is not surprising as those receiving an IUD for EC may not have known this was an option before the clinic visit and had not planned to have an IUD placed, possibly making their decision less firm than someone who had to schedule an appointment to receive their IUD and likely had more time and information about IUD use before placement. This in no way diminishes the need to offer this highly effective method of EC to those who can benefit from its short- and long-term benefits and calls on providers to increase public awareness about this option.

Strengths and limitations

This study has several strengths, including randomized study design, large sample size, low loss to follow-up at 1 year (approximately 20% in each IUD group), confirmatory medical record review, and intention-to-treat analysis. These findings may not be generalizable to people seeking an IUD for contraceptive purposes outside of EC or to more diverse populations given the limited diversity within our sampling frame. The implications of the data presented here are limited by the fact that the treatment assignment in this study was randomized, and in real-world clinical care where people will select their desired treatment, we would anticipate a potentially higher continuation rate.

Conclusions

Intention-to-treat analysis showed that 6 of 10 users continued their randomly assigned IUD for EC at 1 year. Although we found no significant difference in continuation rates when comparing those assigned to the LNG IUD with those assigned to the Cu IUD, more participants switched from the Cu IUD

TABLE 6
Adjusted HRs predicting risk of IUD discontinuation and switching from randomly assigned type to the other IUD type

	Removals		Reinsertions	
Variable	Adjusted HR	*P* value	Adjusted HR	*P* value
Randomization arm				
Copper IUD	Ref			
Levonorgestrel IUD	1.3	.22	0.1	<.01
Age	1.0	.64	1.1	.13
Body mass index category (kg/m^2)				
<25.0	Ref			
25.0–29.9	1.5	.09	0.6	.20
≥30.0	1.5	.10	0.9	.80
Education				
High school or less	Ref			
In college	0.8	.34	0.8	.68
College degree or higher	1.1	.74	1.4	.53
Insurance coverage				
Private	Ref			
Public insurance	1.1	.88	0.3	.18
None	0.90	.63	0.6	.27
Annual income				
<$12,000	Ref			
$12,000– $35,999	1.0	.87	0.3	<.01
>$36,000	0.44	.02	0.6	.43
Race and ethnicity				
White	Ref			
Hispanic or Latina	0.6	.08	0.4	.07
Black or African American	1.1	.90	2.3	.30
Other	1.3	.43	0.5	.37
Relationship status				
Cohabitating	Ref			
Single	0.9	.66	0.9	.73
Reason for seeking emergency contraception				
No method used at last intercourse	Ref			
Incorrect method use	1.1	.80	0.9	.79
Did not plan or was forced to have sex	1.0	1.0	0.6	.46
Parity				
Nulliparous	Ref			
Parous	1.3	.37	1.2	.79

Cohabitating indicates married, living together, or in committed relationship, and single indicates single, actively dating, divorced, or widowed.

HR, hazard ratio; *IUD*, intrauterine device; *Ref*, reference.

Kaiser. One-year follow-up after intrauterine devices for emergency contraception. Am J Obstet Gynecol 2023.

to the LNG IUD. Of note, 1-year pregnancy rates were low among all IUD EC users and similar between LNG 52-mg IUD and Cu IUD users. These data supported offering and using the LNG 52-mg IUD as EC. ■

Acknowledgments

We thank Gregory Stoddard, University of Utah School of Medicine, for his guidance on statistical analysis, Corinne Sexsmith and Indigo Mason for their assistance with follow-up, Marie Gibson for managing the study regulation, the Planned Parenthood Association of Utah for exceptional patient care and recruitment, and the participants for their contribution to advancements in the field of family planning. Named individuals have consented to the acknowledgments.

References

1. Secura GM, Allsworth JE, Madden T, Mullersman JL, Peipert JF. The Contraceptive CHOICE Project: reducing barriers to long-acting reversible contraception. Am J Obstet Gynecol 2010;203:115.e1–7.
2. Turok DK, Gero A, Simmons RG, et al. Levonorgestrel vs. copper intrauterine devices for emergency contraception. N Engl J Med 2021;384:335–44.
3. Sanders JN, Turok DK, Royer PA, Thompson IS, Gawron LM, Storck KE. One-year continuation of copper or levonorgestrel intrauterine devices initiated at the time of emergency contraception. Contraception 2017;96:99–105.
4. Peipert JF, Zhao Q, Allsworth JE, et al. Continuation and satisfaction of reversible contraception. Obstet Gynecol 2011;117:1105–13.
5. Achilles SL, Chen BA, Lee JK, Gariepy AM, Creinin MD. Acceptability of randomization to levonorgestrel versus copper intrauterine device among women requesting IUD insertion for contraception. Contraception 2015;92:572–4.
6. Godfrey EM, Memmel LM, Neustadt A, et al. Intrauterine contraception for adolescents aged 14-18 years: a multicenter randomized pilot study of levonorgestrel-releasing intrauterine system compared to the Copper T 380A. Contraception 2010;81:123–7.
7. Hubacher D, Spector H, Monteith C, Chen PL, Hart C. Long-acting reversible contraceptive acceptability and unintended pregnancy among women presenting for short-acting methods: a randomized patient preference trial. Am J Obstet Gynecol 2017;216:101–9.
8. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research Electronic Data Capture (REDCap)–a metadata-driven methodology and workflow process for

providing translational research informatics support. J Biomed Inform 2009;42:377–81.
9. Bendel RB, Afifi AA. Comparison of stopping rules in forward "stepwise" regression. J Am Stat Assoc 1977;72:46–53.
10. Bland JM, Altman DG. Survival probabilities (the Kaplan-Meier method). BMJ 1998;317:1572.
11. Glasier A, Baird D. The effects of self-administering emergency contraception. N Engl J Med 1998;339:1–4.
12. Raine TR, Harper CC, Rocca CH, et al. Direct access to emergency contraception through pharmacies and effect on unintended pregnancy and STIs: a randomized controlled trial. JAMA 2005;293:54–62.
13. Walsh TL, Frezieres RG. Patterns of emergency contraception use by age and ethnicity from a randomized trial comparing advance provision and information only. Contraception 2006;74:110–7.
14. Sander PM, Raymond EG, Weaver MA. Emergency contraceptive use as a marker of future risky sex, pregnancy, and sexually transmitted infection. Am J Obstet Gynecol 2009;201:146.e1–6.
15. Turok DK, Jacobson JC, Dermish AI, et al. Emergency contraception with a copper IUD or oral levonorgestrel: an observational study of 1-year pregnancy rates. Contraception 2014;89:222–8.

Author and article information

From the Division of Family Planning, Department of Obstetrics and Gynecology, University of Utah, Salt Lake City, UT.

Received July 22, 2022; revised Nov. 8, 2022; accepted Nov. 17, 2022.

The Division of Family Planning in the University of Utah's Department of Obstetrics and Gynecology receives research funding from Bayer Women's Health Care, Organon & Co Inc, CooperSurgical, Sebela Pharmaceuticals, Femasys, and Medicines3360. D.K.T. serves as a consultant for Sebela Pharmaceuticals and the national principal investigator for Food and Drug Administration trials of 2 intrauterine devices. The other authors report no conflict of interest. D.K.T. receives support from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the Office of Research on Women's Health of the National Institute of Health (grant number K24HD087436). J.N.S. receives funding from the Agency for Healthcare Research and Quality (grant number K01HS02722). This publication was made possible through support from the Utah ASCENT Center for Sexual and Reproductive Health, Policy, and Research. The content is solely the responsibility of the authors and does not necessarily represent the official view of any of the funding agencies or participating institutions, including the National Institutes of Health (NIH), the University of Utah, or the Planned Parenthood Federation of America, Inc.

This project is funded by the NICHD (grant number 1R01HD083340). Additional support came from the University of Utah Population Health Research Foundation, with funding, in part, from the National Center for Research Resources and the National Center for Advancing Translational Sciences (NCATS), NIH, through grant number UL1TR002538 (formerly grant numbers 5UL1TR001067-05, 8UL1TR000105, and UL1RR025764). The use of Research Electronic Data Capture was provided by grant number 8UL1TR000105 (formerly grant number UL1RR025764) from the NCATS/NIH.

This study was registered on ClinicalTrials.gov (identification number: NCT02175030) on June 26, 2014. The date of initial participant enrollment was on August 2016.

Individual participant data will be available (including data dictionaries). Complete deidentified patient dataset will be shared. The study protocol is available online associated with the publication of the study's primary outcome at: https://www.nejm.org/doi/suppl/10.1056/NEJMoa2022141/suppl_file/nejmoa2022141_protocol.pdf. The data will be available from date of publication to 2 years after publication. Data will be made available for researchers with a query that can be addressed with the dataset. The research team will review data requests and provide the data for any valid research project or verification of results by any interested party with a legitimate interest. Data can only be transferred after obtaining a data transfer agreement between the University of Utah and the requesting institution's investigator.

Corresponding author: Jennifer E. Kaiser, MD. Jennifer.Kaiser@hsc.utah.edu