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Emergency contraception with a Copper IUD or oral levonorgestrel: an observational study of 1-year pregnancy rates

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Abstract

Objective—We investigated the one-year pregnancy rates for emergency contraception (EC) users who selected the copper T380 IUD or oral levonorgestrel (LNG) for EC.

Study Design—This prospective study followed women for 1 year after choosing either the copper T380 IUD or oral LNG for EC. The study was powered to detect a 6% difference in pregnancy rates within the year after presenting for EC.

Results—Of the 542 women who presented for EC, agreed to participate in the trial, and meet inclusion criteria, 215 (40%) chose the copper IUD and 327 (60%) chose oral LNG. In the IUD group, 127 (59%) were nulligravid. IUD insertion failed in 42 women (19%). The 1-year follow-up rate was 443/542 (82%); 64% of IUD users contacted at 1 year still had their IUDs in place. The 1-year cumulative pregnancy rate in women choosing the IUD was 6.5% vs. 12.2% in those

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choosing oral LNG (HR= 0.53, 95% CI: 0.29–0.97, p=0.041). By type of EC method actually received, corresponding values were 5.2% for copper IUD users vs. 12.3% for oral LNG users, HR 0.42 (95% CI: 0.20–0.85, p= 0.017). A multivariable logistic regression model controlling for demographic variables demonstrates that women who chose the IUD for EC had fewer pregnancies in the following year than those who chose oral LNG (HR 0.50, 95% CI: 0.26–0.96, p=0.037).

Conclusion—One year after presenting for EC women choosing the copper IUD for EC were half as likely to have a pregnancy compared to those choosing oral LNG.

Keywords

emergency contraception; IUD; oral levonrgestrel; pregnancy

INTRODUCTION

Methods of emergency contraception (EC) represent the only options to reduce the risk of unintended pregnancy following unprotected intercourse. However, EC pills do not provide ongoing contraception for a group of women who remain at high risk of unplanned pregnancy, and this may partially explain why their wide availability has not reduced population abortion rates (1, 2). The copper IUD is the most effective method of EC (pregnancy rates of ≤0.1%) (3–5) and offers continued highly effective contraception for over a decade. While its use for EC is supported by a Cochrane Review (6), ACOG (7), and many others (8–16), it is rarely used in this capacity. However, when surveyed, 13% of EC users express interest in having an IUD inserted at the time of the visit (17, 18).

EC users are an ideal target group to offer highly effective contraception as they are at high risk and acting to acutely reduce their risk of unintended pregnancy. The copper IUD presents an opportunity to essentially eliminate the short-term risk of unplanned pregnancy while simultaneously providing ongoing highly effective contraception. A pilot study at our site demonstrated that EC users were interested in the copper IUD for EC(19). This study was designed to compare the pregnancy rates for the year following presentation for EC in women who selected either oral LNG or the copper IUD for EC.

MATERIALS AND METHODS

Women presenting for EC at two family planning clinics in Salt Lake City, Utah were offered participation in this prospective observational study comparing oral LNG or the copper IUD for EC from November, 2009 to July, 2010. Study participants were age 18–30 years and had unprotected intercourse within 120 hours of presenting. Participants over 30 years of age were excluded to maximize participant fertility. Exclusion criteria were uterine infection within the past 3 months and gonorrhea or chlamydia infection in the last 60 days. The clinics were chosen for this study because they are high volume providers of EC administering > 10,000 doses of EC each year. Data are not available on the many women who wished to rapidly receive EC pills and were not interested in participating in research.

Potential participants received information on the study and if interested underwent the informed consent process. Following informed consent, participants were provided scripted counseling on both methods (see Appendix 1). Either method was provided to the patient without charge and compensation for completion of follow up questionnaires at 1, 6, and 12 months was $10, $20, and $20 respectively. The study was not advertised outside of the clinic in order to minimize the potential of women presenting for the study just for the purpose of obtaining a free IUD.

The primary outcome was the rate of unplanned pregnancy in the 12 months after presenting for EC. Secondary outcomes were use of an effective method of contraception with a typical use pregnancy rate of less than or equal to 9% per year (20), IUD expulsions and removals. EC failures were defined as pregnancies occurring during the first month after presentation for EC. Oral LNG was dispensed as per the clinic protocol for EC, which is in accordance with state laws and regulations. All follow-up was done by phone and pregnancies were confirmed by chart review at local clinics and hospitals.

All participants had a urine pregnancy test (Osom® card pregnancy test, Genzyme Diagnostics, hCG ≤ 20 IU/L) and a urine test for gonorrhea and chlamydia (Gen-Probe Aptima®). After completing the informed consent process and instructions, participants received their choice of oral LNG 1.5 mg as a single dose (Plan B one step, Duramed Pharmaceuticals, Inc.) or insertion of a copper T 380A IUD (Paragard, Duramed Pharmaceuticals, Inc.) by the clinician staffing the clinic that day. All IUDs were inserted by nurse practitioners with experience in IUD insertion.

Participants were instructed to check a home urine pregnancy test if they had not had their menses by the expected date. Oral LNG users were offered the clinic's standard contraceptive counseling which is written information about other contraceptive methods. Follow-up phone calls occurred at 1, 3, 6, 9, and 12 months. Satisfaction with the EC method received was assessed at the 1-month follow-up and satisfaction with current method of contraception was assessed at all other follow-ups using a 5-point Likert scale (very unsatisfied, unsatisfied, neutral, satisfied, very satisfied). When necessary, follow up was confirmed by review of clinic visit records or phone calls. The same methods were employed to contact all available participants. A power calculation was performed with a 2-side alpha value of 0.05 and power of 0.90. Based on a pilot study the ratio of oral LNG to copper IUD EC users was anticipated to be 2:1 (19). The primary outcome of unplanned pregnancy was anticipated to occur 7% of the time in oral LNG users and 1% of the time for copper IUD users, including approximately 25% of women who discontinued the IUD and selected a less effective method. This was based on pregnancy rates of 5–8% over 3–12 months in oral emergency contraception users (21–23).

The primary outcome of unplanned pregnancy was compared using life table analysis. Participants who reported pregnancy were excluded for appropriate periods as they were not at risk of pregnancy. Secondary outcomes reporting categorical variables were analyzed using a x^2 test and Fisher exact test where appropriate. Women who desired IUD insertion but did not receive it were given oral LNG for EC. Analysis was directed by the participant's selection of EC method so that women who had IUD insertion failures were

included in the IUD group for the primary analysis, which is labeled throughout the manuscript as “method of EC selected”. Had participants been randomized it would be appropriate to refer to this as an intention to treat analysis. A secondary analysis focused on the actual treatment received and this analysis is referred to as “method of EC received” throughout. A logistic regression model to determine the odds ratio for an unplanned pregnancy within one year was performed. The analysis was adjusted for age, insurance, race, income, parity and having ever heard of an IUD as contraception. Data analysis was performed utilizing *Stata 11 statistical software (*College Station, TX, StataCorp LP*)*. This study was approved by the Institutional Review Board of the University of Utah and the Planned Parenthood Federation of America Medical Affairs Department.

RESULTS

There were 548 women who presented to the 2 participating clinics requesting EC and were willing to participate in the study: 218 women who choose the IUD, and 330 selected oral LNG. After exclusion of 3 women in each group for protocol violations (all for age > 30 years old except for 1 woman in the oral LNG group who was not at risk of unintended pregnancy as she had a LNG IUD in place when she enrolled in the study and continued to use it), the analytic sample consisted of 215 women in the IUD group and 327 in the oral LNG group. Demographics are presented in Table 1. Women choosing the IUD were older, more likely to be uninsured, and were more likely to have heard of the IUD prior to their clinic visit than those choosing oral LNG. In both groups, more than 1/3 of women were not using any method of contraception when they presented for EC (35% in the IUD group and 42% in the oral LNG group) (see Table 2). Of the 215 who chose an IUD, 42 had IUD insertion failures and were not able to have the IUD placed. Thus, 173 participants actually received the IUD for EC. See Figure 1 for study flow. The details of the IUD insertion failures have been reported elsewhere (24).

There were 4 pregnancies resulting from EC failures in the oral LNG group (1%) and none in the IUD group. The 12-month follow-up for all participants was 82% with a trend toward greater contact at 12 months for those selecting the IUD 180/215 (84%) than those who selected oral LNG 263/327 (80%, p=0.082). Among those who selected the IUD, high rates of pregnancy over 12 months were observed in those who were unable to have the IUD inserted and received oral LNG (5 pregnancies in 42 women, 12%) and those who had the IUD removed (7 pregnancies in 37 women, 19%). Only 1 pregnancy occurred in a participant who had the IUD in place. The first pregnancy in the IUD group occurred 1.5 months after presenting for EC and was in a patient who had her IUD removed in the first month. Women reporting a desire for a pregnancy at any follow up point were excluded from the primary outcome analysis of unplanned pregnancy after that point. This occurred twice. One participant who had the copper IUD placed for EC had it removed at 6 months and stated she was trying to have a pregnancy. She reported a positive pregnancy test at 12-month follow up. The other report of pregnancy desire occurred at 1-month follow up in a participant who initially selected oral LNG for EC and was pregnant at 3 months. Among women who had the IUD inserted and were able to be contacted, 64% were still using the IUD at 12 months. Please see Figure 2 for detailed information on IUD expulsions and removals.

The risk of pregnancy in the 12 months after presenting for EC *based on the method of EC selected*(participants who desired an IUD but were not able to have it inserted were analyzed in the IUD group) shows fewer pregnancies in the IUD group by Kaplan Meier curves (log rank X^2 =4.18, p=0.041), HR 0.53 (95% CI 0.29–0.97) (See Figure 3). In the secondary analysis based on actual *method of EC received*, the risk of pregnancy in the 12 months after presenting for EC shows a further reduction in the risk of pregnancy in the IUD group by Kaplan Meier curves (log rank X^2 = 5.73, p=0.017), HR 0.42 (95% CI 0.20–0.85) (See Figure 4).

The multivariable logistic regression analysis based on the method of EC selected showed a lower risk of pregnancy at one year for the IUD group with OR = 0.50 (95% CI: 0.26–0.96, p = 0.037). When this analysis was repeated based on the actual method of EC received the OR for pregnancy at one year was even lower for IUD EC users 0.38 (95% CI: 0.18–0.80, p = 0.011). If a RCT were to show similar effect sizes, the number needed to treat (NNT) with a copper IUD rather than oral LNG for EC to prevent an unplanned pregnancy in the following year is 18. This NNT decreases to 15 when determined by the method of EC received.

At 1 year, women choosing the IUD were more likely to be using an effective method of contraception (typical use failure rate ≤9%) than women choosing oral LNG: 125/183 (68%) vs. 106/257 (41%), (p<0.0001). (See Figure 5). However, among women who initially selected oral LNG for EC, 26/257 (10%) were using a highly effective reversible method by 12 months (IUDs or the contraceptive implant). This included 11 women who initially selected oral LNG for EC and reported having obtained a LNG IUD (n=9) or a copper IUD (n=2) when contacted at 1 month. Among study participants, there were 303 reports of repeat use of oral LNG for EC over the 12 months following the initial clinic visit with 85% occurring in women who initially received oral LNG for EC. This included 119 women reporting use of oral EC at only 1 follow-up time point and 74 at 2 or more time points. There were no cases of IUD perforation, infection, or pelvic inflammatory disease in the IUD group.

Three quarters of women in both groups reported being satisfied or highly satisfied with their method of EC at 1 month, 78% of those who selected the IUD and 77% of those who selected oral LNG (p=0.80). Even among women who desired the IUD but received oral LNG for EC because of IUD insertion failure, 74% were satisfied or highly satisfied with their EC method at 1 month. At 12 months 47% of women who choose oral LNG for EC reported being satisfied or highly satisfied with the method of contraception they were using at that time, compared to 52% of the women who received the IUD for EC (p=0.90). Overall, the greatest satisfaction with contraceptive method in use at 12 months was reported in women who desired the IUD for EC, had it placed and continued using it at 12 months; 88% of these women reported being satisfied or highly satisfied with their contraceptive method compared to 81% (p=0.45) among women who desired the IUD but were unable to have it inserted at enrollment.

DISCUSSION

Twelve months after presenting for EC women who initially selected the copper IUD for EC were more likely to be using highly effective contraception and less likely to report having had a pregnancy than those who selected oral LNG. Among those selecting the IUD, women who were unable to have it placed or had the IUD removed had rates of unplanned pregnancy similar to oral LNG users.

EC failures for both groups were consistent with published data (25–28). The higher than expected pregnancy rate in the IUD group is largely driven by the fact that nearly half of the women who initially selected the IUD did not have one by the end of the study due to the cumulative effect of failed insertions, expulsions and removals. The rate of pregnancy in the oral LNG group was higher than anticipated (11% actual vs. 7% expected) though this is within the range of expected values for EC users followed after EC use (21–23). While only half of all women *desiring* the IUD were using it at the end of 1 year it is noteworthy that among all those *offered* the IUD for EC over one-fifth were using a highly effective long-term method of contraception 1 year later. This level of use in a high-risk population supports the policy of offering the IUD for EC.

Women in this predominantly nulliparous group did not present to the clinic expecting IUD insertion. This may have increased anxiety associated with insertion and the pain associated with insertion possibly causing providers to terminate their attempt at insertion. The majority of women choosing oral EC continued to use less effective methods of contraception, however, 10% of oral EC users eventually initiated use of an IUD or the contraceptive implant. It is possible that hearing of the IUD during the EC visit increased uptake of highly effective devices within the year.

Women were able to choose which method of EC they desired, and it is likely that those who selected the IUD were more likely to have greater motivation to prevent unintended pregnancy. This selection bias driven by greater motivation in those selecting the IUD for EC and the differential rate of loss to follow-up between the groups may have affected a difference in unplanned pregnancies between the groups. However, if all participants lost to follow-up were assumed to be pregnant then the pregnancy rates by method chosen would be 43/215 (20%) in the IUD group and 101/327 (31%) in the oral LNG group (Fisher's Exact Test, $p<0.0001$).

The substantial cost of the copper IUD is a significant barrier for many of the women in this study and elsewhere. A prior survey in this clinical setting showed that the majority of women who were interested in the IUD for EC were willing to pay $25 (17). In this study the device was offered free of charge and there was no charge for insertion. However in actual clinical practice in the U.S., the cost of copper IUD and insertion exceeds $500. The Affordable Care Act may have a strong positive result on increasing coverage for these expensive devices in the U.S. and may increase access to the copper IUD for EC.

Offering EC users the copper IUD, which nearly eliminates their short-term risk of unintended pregnancy and continues to provide highly effective contraception, is an

effective strategy to decrease unintended pregnancy rates. Broader use of the copper IUD for EC should be a component of community wide efforts to address this vexing problem.

Acknowledgments

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Implications

Compared to EC users who choose oral levonorgestrel, those who select the copper IUD have lower rates of pregnancy in the next year. Greater use of the copper IUD for EC may lower rates of unintended pregnancy in high-risk women.

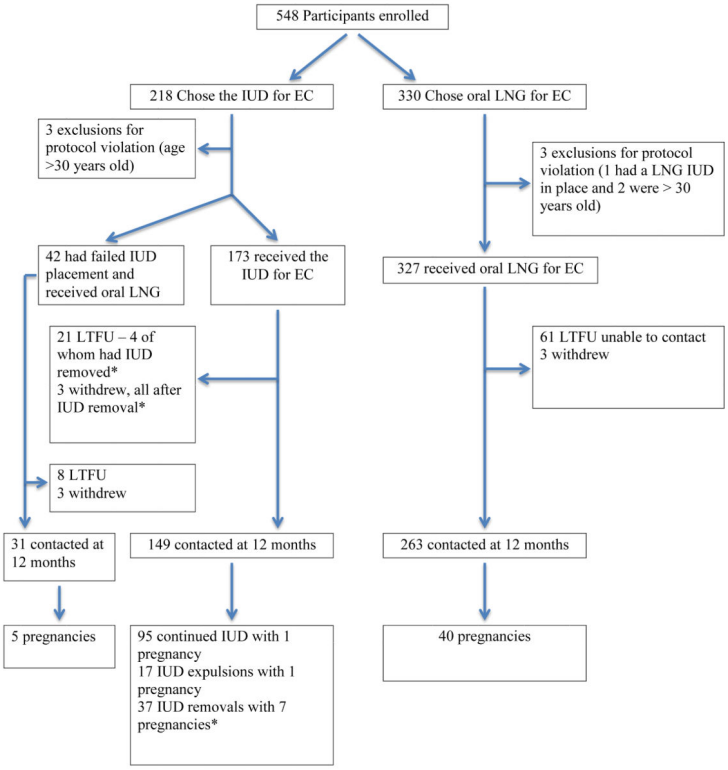

Fig. 1.

Study Flowchart

* There were 44 IUD removals in total including 4 from participants who were LTFU after removal, 3 who withdrew from the study after removal and 37 who were followed to 12 months.

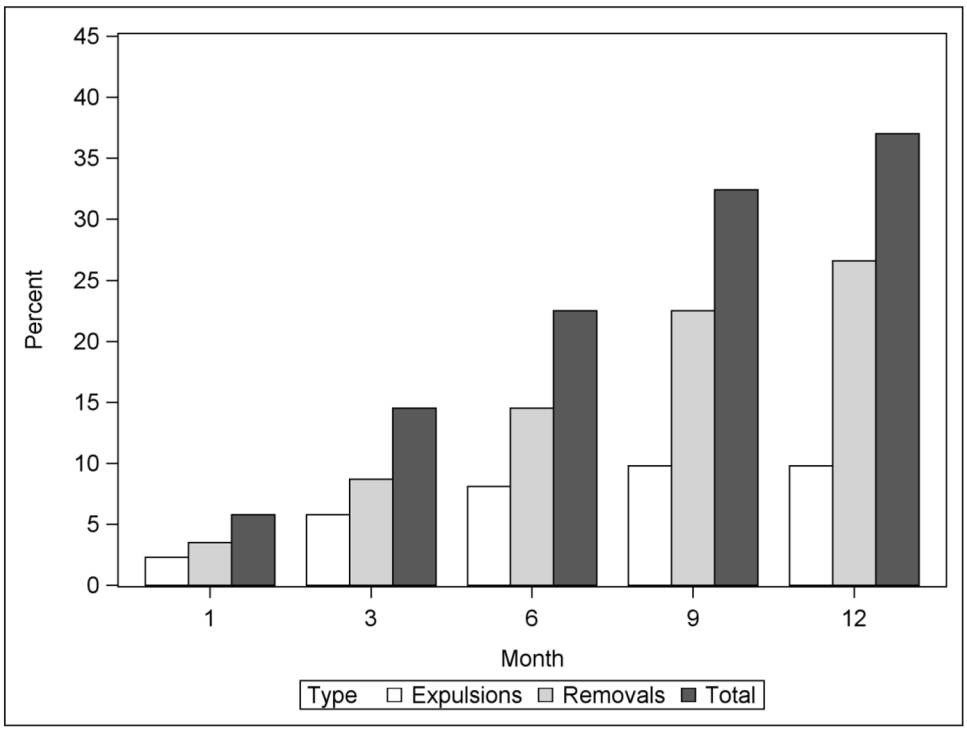

Figure 2.
Cumulative IUD discontinuations over 1 year

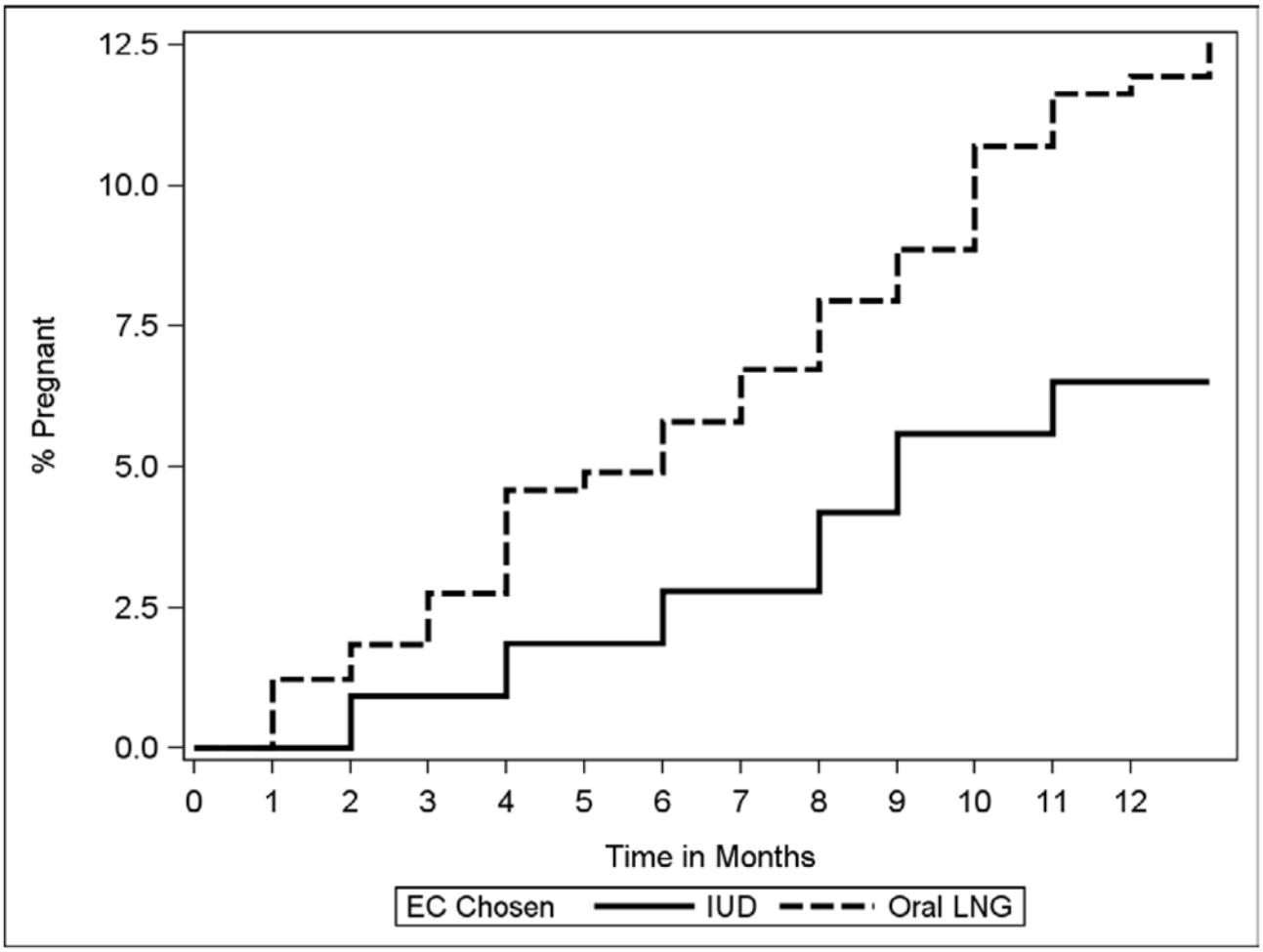

Figure 3.

The risk of pregnancy in the 12 months after presenting for EC ***based on the method of EC selected*** (participants who desired an IUD but were not able to have it inserted were analyzed in the IUD group) shows fewer pregnancies in the IUD group by Kaplan Meier curves (log rank X^2 =4.18) hazard ratio 0.53 (95% CI: 0.29–0.97, p= 0.041).

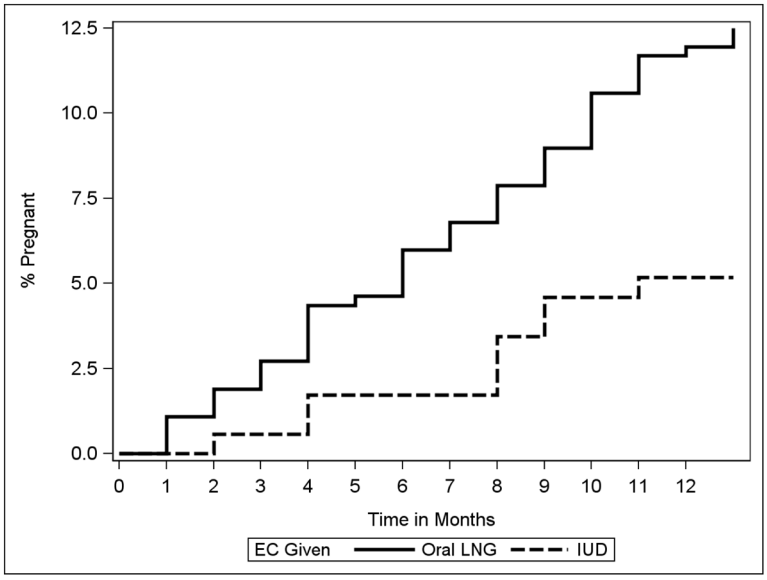

Figure 4.

The risk of pregnancy in the 12 months after presenting for EC ***based on the method of EC received*** (women who desired an IUD and were unable to have it inserted received oral LNG for EC and were analyzed in the oral LNG group) shows fewer pregnancies in the IUD group by Kaplan Meier curves HR 0.42 (95% CI: 0.20–0.85, X2 =5.73, p= 0.017).

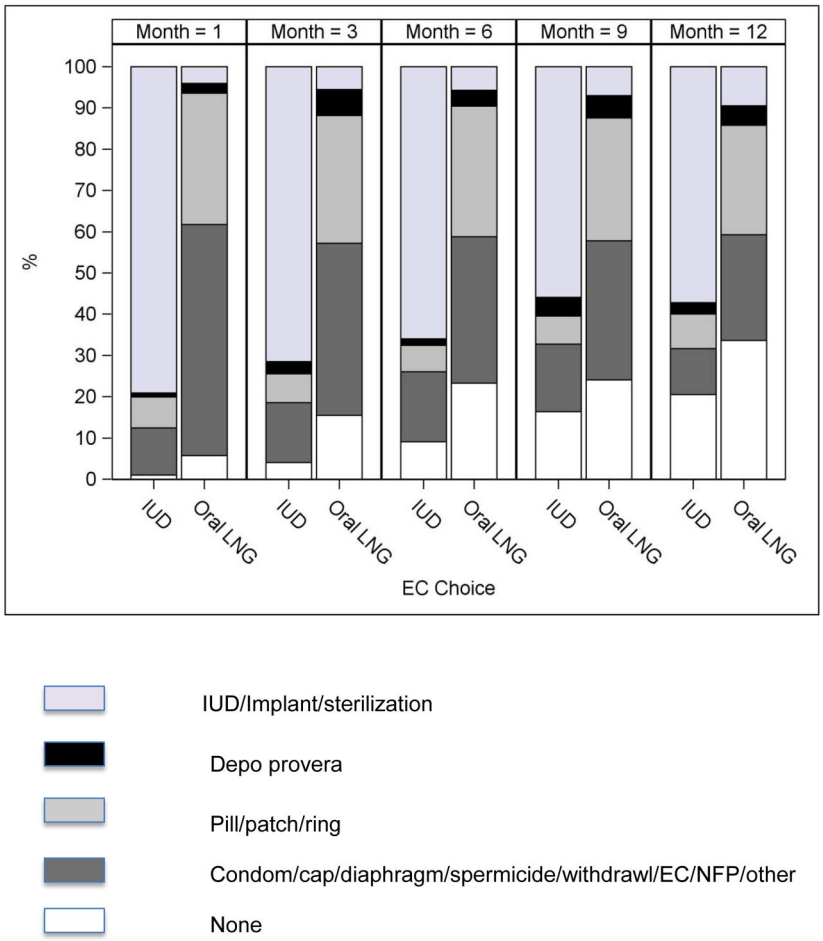

Figure 5.
Method of contraception at each follow up by initial EC choice

Table 1

Demographic characteristics

	IUD n=215	Oral LNG n=327	p-value
Age (mean, SD)	23.1 (3.5)	22.0 (3.3)	<0.001
Race (n, %)			
White	144 (67)	212 (65)	0.47
Hispanic/Latino	36 (17)	68 (21)	
Income			
<$20,000	136 (63)	205 (63)	0.85
$20,001–$40,000	59 (27)	84 (26)	
>$40,000	16 (7)	30 (9)	
Insurance			
Private insurance	80 (37)	122 (37)	0.014
Medicaid	11 (5)	43 (13)	
Uninsured	117 (54)	156 (48)	
Nulligravid	127 (59)	172 (53)	0.079
Prior abortion	34 (16)	48 (15)	0.72
Heard of IUD for birth control			
Yes	203 (94)	240 (73)	<0.001

Totals may not add to 100% due to rounding and missing data.

Table 2

Contraceptive method at baseline

	IUD n=215	Oral LNG n=327	p-value
Method of BC using when presenting for EC*			
None	76 (35)	137 (42)	0.16
Pill/Patch/Ring	30 (14)	39 (12)	
Depo	2 (1)	3 (1)	
Condom	63 (29)	96 (29)	
Natural Family Planning	2 (1)	0 (0.0)	
Withdrawal	5 (2)	8 (2)	
Hormonal Method+	13 (6)	28 (9)	
Condoms+	23 (11)	16 (5)	
MISSING	1	0	

* Condoms+ includes condoms plus one or more additional non-hormonal method (rhythm, withdrawal); Hormonal Method+ includes Pill/Patch/Ring/Depo plus one or more additional method (second hormonal method, condoms, rhythm, withdrawal)