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Acceptability of randomization to levonorgestrel versus copper intrauterine device among women requesting IUD insertion for contraception[☆]

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Abstract

Objective: Assess feasibility of randomizing women to intrauterine device (IUD) type.

Study Design: Women enrolling in a 2-month study who desired an IUD for contraception were randomized 1:1 to receive a levonorgestrel-releasing 52-mg IUD (LNG-IUD) or copper T380A IUD (Cu-IUD), understanding they could switch IUD type at the end of the study.

Results: Randomization to IUD type was acceptable to 54/55 (98%) women who screened. All 32 enrolled participants completed follow-up. Two women exchanged their IUD (Cu-IUD to LNG-IUD), and two requested removal (one LNG-IUD, one Cu-IUD). Overall, 88% continued their assigned IUD.

Conclusions: Randomization to IUD type is feasible, and few women change their IUD.

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Keywords: Contraception; Randomization; Intrauterine device; IUD randomization

1. Introduction

Intrauterine devices (IUDs) are highly effective contraceptives and are the most commonly used form of long-acting reversible contraception worldwide [1]. Hormonal and copper

IUDs (Cu-IUDs) are available in the US and are used by 10.3% of contracepting US women [2]. Both IUD types can induce changes in menstrual characteristics; however, the anticipated changes are markedly different [3,4].

Randomized studies comparing hormonal and nonhormonal IUD use offer a scientifically sound means of comparison and minimize bias. Clinical researchers may be reluctant to perform trials that randomize women to disparate IUD types due to concerns for participant acceptability and satisfaction impacting ease of study recruitment and contraceptive continuation. Accordingly, the experience with randomization to hormonal versus nonhormonal IUDs and assessment of participant satisfaction is limited. One published study randomized 23 adolescents to a levonorgestrel-releasing (LNG-IUD) or Cu-IUD and found that continuation and satisfaction were higher among those randomized to the LNG-IUD (75% and 90%, respectively) than the Cu-IUD (45% and 67%, respectively) [5]. Other published IUD randomization studies report data only on discontinuation rates and not participant satisfaction. In

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addition, the option to switch IUD type at study end has not been previously offered, and we hypothesize that most women will be willing to accept randomization with this option available.

We conducted and published the primary results of a clinical trial designed to quantify immune cells in the genital tract in which participants were randomized to the LNG-IUD or Cu-IUD [6]. This report is a planned secondary analysis of IUD continuation and participant satisfaction with their assigned IUD.

2. Materials and methods

We enrolled healthy women aged 18–40 years seeking an IUD for contraception in a randomized clinical trial that included lower and upper genital tract sampling at enrollment and at 2-month follow-up/study exit; full study methodology, participant demographics and primary results have been previously published [6]. The University of Pittsburgh Institutional Review Board approved this study.

After signing informed consent, participants were assigned randomly 1:1 to receive a 52-mg LNG-IUD (Mirena®, Bayer Healthcare, Whippany, NJ, USA) or Cu-IUD (ParaGard®, Teva Pharmaceuticals, North Wales, PA, USA) as previously described [6]. The IUD was inserted per standard clinical practice at the enrollment visit. Neither clinical study staff nor participants were blinded to IUD type. At no cost at the final visit, women could choose to keep the randomized IUD, remove the IUD or exchange for the other IUD type.

At both enrollment and follow-up, we collected data on menstrual characteristics (flow on the heaviest day and severity of typical cramps on the day with most severe cramps) using visual analog scales (VASs). The 100-mm VAS lines for flow were anchored with “light” and “heavy,” and the lines for cramping were anchored with “none” and “severe.” At follow-up, we asked participants if they were satisfied with the randomly assigned IUD and if they would like to keep, remove or replace the IUD.

Data analyses were conducted using the Student’s *t* test, Mann–Whitney *U* test and Fisher’s Exact Test as appropriate.

3. Results

Randomization to IUD type was acceptable to 54/55 (98%) women presenting for screening. We enrolled 34 women seeking an IUD for contraception between December 2010 and July 2011, randomized equally to LNG-IUD and Cu-IUD. All 34 received their randomized IUDs. One participant in the LNG-IUD arm was withdrawn due to postenrollment ineligibility, and one participant in the Cu-IUD arm withdrew consent for personal reasons leaving 16 participants in each IUD group for evaluation of whom none were lost to follow-up.

Outcome of Randomized IUDs at 2 months

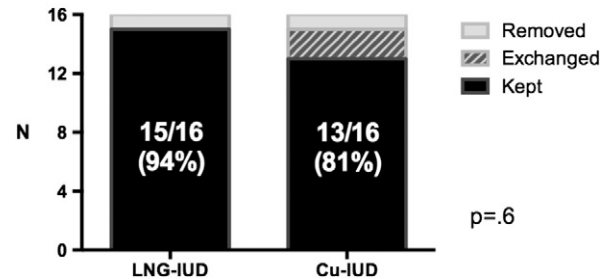


Fig. 1. IUD use status at 2 months in women randomized to a levonorgestrel or Cu-IUD.

Two women opted to exchange their IUD (Cu-IUD to LNG-IUD), and two opted for IUD removal (1 LNG-IUD, 1 Cu-IUD) (Fig. 1). The overall continuation rate at 2 months was 88% with the randomized IUD and 94% with any IUD.

Based on VAS results, LNG-IUD users reported significantly less bleeding and cramping (Table 1). Five (16%) participants were dissatisfied with their assigned IUD: 1/16 randomized to LNG-IUD and 4/16 randomized to Cu-IUD ($p = 0.33$). All dissatisfied participants cited menstrual changes as the reason for dissatisfaction. Of note, one of the dissatisfied participants (Cu-IUD) opted to keep her IUD.

4. Discussion

Randomization of women to disparate types of IUDs for contraceptive research is feasible and acceptable to women seeking an IUD for contraception. The Contraceptive CHOICE project cited bleeding or cramping as the most common reasons for IUD discontinuation [7]. We similarly found that dissatisfaction with IUD type was most often

Table 1

Menstrual characteristics assessed by visual analogue scale in women randomized to a levonorgestrel or copper IUD.

	LNG-IUD (n = 16)	Cu-IUD (n = 16)	p-value*
Menstrual flow			
Enrollment	6.4 ± 1.4	6.2 ± 2.3	0.79
Follow-up visit	3.6 ± 2.4	7.9 ± 1.7	<0.001
Individual change	-2.8 ± 3.0	1.7 ± 2.1	<0.001
Dysmenorrhea			
Enrollment	5.1 ± 3.1	5.6 ± 2.2	0.58
Follow-up visit	3.2 ± 3.0	6.9 ± 2.4	0.001
Individual change†	-2.1 ± 3.3	1.3 ± 2.5	0.004

Data presented as mean ± standard deviation.

LNG-IUD = levonorgestrel 52-mg IUD; Cu-IUD = Copper T380A IUD.

VAS for menstrual flow used a 100-mm line to assess bleeding on the heaviest day of menses with anchors of light at 0 mm and heavy at 100 mm. VAS for dysmenorrhea used a 100-mm line to assess intensity of typical cramps on the day of the most severe cramps with anchors of none at 0 mm and severe at 100 mm.

* p-value from Student’s *t* test.

† Individual change is the difference in VAS score from enrollment to follow-up.

related to menstrual changes after IUD initiation. Nevertheless, most participants (88%) chose to keep their assigned IUD after study completion even with the option to exchange at no cost. It is possible that participants opted not to exchange their assigned IUD due to reluctance to undergo IUD removal/reinsertion procedures related to concerns of discomfort and inconvenience.

A major study strength is that no enrolled participants were lost to follow-up. Study limitations include the small size, short interval follow-up and lack of information on participant preference for IUD type prior to randomization. Study participants may not represent the general population of women seeking IUDs for contraception because they were willing to be randomized. With a small study, it is difficult to assume that the results and satisfaction patterns would be maintained in a larger study; however, VAS differences by type of IUD in this study sample do follow well-established patterns. Although women were not asked in advance of randomization about their preference for IUD type, US studies allowing women to choose IUD type consistently find that approximately 80% chooses an LNG-IUD [7,8]. Future studies could assess long-term satisfaction in women randomized to IUD type. Furthermore, understanding the length of time that participants would be willing to continue IUDs or other contraceptive methods with which they have some dissatisfaction for the purpose of research participation would be beneficial.

Providing women with a no-cost option for switching contraception at study conclusion may increase feasibility in research trials that undertake randomization to IUD type.

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