

1 Effect of Baseline Menstrual Bleeding Pattern on
2 Copper Intrauterine Device Continuation

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1 CONDENSATION

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3 Participants who reported moderately heavy or heavy baseline menstrual bleeding prior to
4 initiation of copper intrauterine device were not at increased risk for method discontinuation.

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8 Short title: Menstrual bleeding and copper IUD discontinuation

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1 ABSTRACT

2 **Background:** Heavy menstrual bleeding is a leading cause of copper intrauterine device (IUD)
3 discontinuation. Thus, women with heavy baseline menstrual bleeding may be at increased risk
4 for early copper IUD discontinuation. Our objective was to assess if there was an association
5 between baseline menstrual bleeding pattern prior to IUD insertion and discontinuation rate at 12
6 months among study participants who chose copper IUD at baseline.

7 **Study Design:** We performed a secondary analysis of the Contraceptive CHOICE Project, a
8 prospective observational cohort study of 9,256 women offered no cost contraception for 2-3
9 years. Included in our study were participants who chose copper IUD for contraception and for
10 whom method continuation data at 12 months were available. Prior to contraception initiation,
11 participants were asked to qualify their menstrual bleeding over the past year as: light, moderate,
12 moderately heavy or heavy. Light bleeding corresponded to using 10 or fewer pads/tampons per
13 period. Moderate, moderately heavy and heavy bleeding corresponded to 11-20 pads/tampons,
14 21-30 pads/tampons, and more than 30 pads/tampons per period, respectively. Subjects were
15 then categorized into either a “heavy” baseline group (those reporting moderately heavy or heavy
16 bleeding at baseline), or a “not heavy” group (those reporting light or moderate bleeding). The
17 12-month continuation rate for each group was then calculated using Kaplan-Meier survival
18 function, and hazard ratio for risk of discontinuation was evaluated using a Cox proportional
19 hazard model to determine if moderately heavy or heavy bleeding at baseline was associated
20 with early discontinuation.

21 **Results:** Of the 918 women meeting the inclusion criteria for this analysis, 165 were in the
22 heavy baseline bleeding group, while 753 were in the not heavy bleeding group. The 12-month
23 continuation rates for groups were similar: 80.2% (heavy) and 85.0% (not heavy; P=0.24).

1 Patients reporting either moderately heavy or heavy baseline bleeding were not at increased risk
2 for early discontinuation of copper IUD (hazard ratio 1.21, 95% CI 0.88, 1.66). Our sample size
3 provided greater than 90% power to detect a clinically important difference of 15% (assuming
4 20% discontinuation rate in not heavy bleeding group and a 35% discontinuation rate in the
5 heavy bleeding group).

6 **Conclusions:** We did not find that women who reported baseline moderately heavy or heavy
7 menstrual bleeding were at increased risk for early discontinuation. Thus, we do not believe that
8 women with heavy menstrual bleeding should be discouraged from using this safe and highly-
9 effective form of contraception.

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11 Key words: Heavy menstrual bleeding, copper intrauterine device, discontinuation

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1 INTRODUCTION

2 Recent reports have documented significant declines in teen pregnancy and abortions in
3 the US.^{1,2} One proposed explanation for this decrease is the increased use of the most effective
4 methods of contraception: long-acting reversible contraception or LARC.³ Intrauterine devices
5 (IUDs) constitute the predominant form of LARC, with an estimated 4.4 million users (10.4% of
6 total contraceptive use) in the US.⁴ These devices demonstrate low failure rates in tandem with
7 high continuation rates. The copper IUD, for example, has a first-year unintended pregnancy rate
8 of 0.8% with 12-month and 24-month continuation rates of 85% and 77%, respectively.^{5,6} IUDs
9 are cost-effective as well. One analysis found that, over a 5-year period, the cost-effectiveness of
10 IUDs and vasectomy were similar when taking into account both method cost and the cost of
11 unintended pregnancy.⁵

12 The copper IUD was originally introduced in the 1970s. This device has a long history of
13 being both safe and effective.⁷ In addition to its low failure rate, the copper IUD offers a
14 hormone-free, reversible contraceptive option, and is currently approved for up to 10 years of use
15 in the US. However, heavy menstrual bleeding is one of the most common side effects of the
16 copper IUD resulting in device removal.⁸ The objective of this study was to evaluate if there was
17 an association between baseline heavy menstrual bleeding and early copper IUD removal. Our
18 hypothesis was that women with a pattern of heavy menses prior to insertion were more likely to
19 discontinue a copper IUD within 12 months.

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1 MATERIALS & METHODS

2 We performed a secondary analysis of the Contraceptive CHOICE Project to evaluate the
3 effect of baseline menstrual bleeding on copper IUD continuation. CHOICE was a prospective
4 observational cohort study conducted between 2007 and 2013. The Project offered 2-3 years of
5 contraception at no cost to participants in an attempt to promote use of the most effective
6 methods of contraception to reduce unintended pregnancies in the St. Louis region. All FDA-
7 approved methods of reversible contraception were offered to study participants. Methods were
8 introduced in order of effectiveness; LARC methods (implant, IUD) were introduced first.

9 Eligible females were between the ages of 14-45, sexually active with a male partner (or
10 soon to be), and currently either not using any form of contraception or willing to initiate a new
11 form of reversible contraception. Participants were recruited from a variety of settings (e.g.
12 abortion clinics, university-based research clinics, ambulatory clinics, etc.) and included
13 students, women of all income and socioeconomic strata, post-abortion and postpartum patients,
14 and friends and acquaintances of participants.

15 Study participants underwent an initial in-person interview to collect baseline
16 demographic, reproductive, and medical data. Participants were asked questions pertaining to
17 menstrual history as part of the baseline survey. Subjects were asked to categorize their baseline
18 menstrual bleeding as light (using 10 or fewer pads/tampons per period), moderate (11-20
19 pads/tampons), moderately heavy (21-30 pads/tampons), heavy (more than 30 pads/tampons), or
20 too variable or irregular to say. These responses provided the foundation for our analysis. Of
21 note, only two women (0.2% of participants choosing copper IUD) reported bleeding as too
22 variable or too irregular to describe. These participants were therefore excluded from our
23 analysis.

1 Our analysis focused on the association of baseline bleeding pattern on copper IUD
2 discontinuation. Method continuation was monitored by periodic telephone surveys at 3 and 6
3 months following method initiation, and then for every 6 months of participation in the project.
4 The primary outcome of our study was discontinuation at 12 months from the time of initiation.
5 Women who chose copper IUD at enrollment and had method use data to determine continuation
6 status by 12 months survey were included in this analysis.

7 Prior to statistical analysis, we evaluated the distribution of baseline bleeding patterns.
8 Due to the small number of participants citing heavy baseline bleeding, we combined the
9 moderately heavy and heavy bleeding groups into our “heavy” baseline bleeding group, and
10 included the light and moderate bleeding groups into the “not heavy group.” Means and standard
11 deviations, or frequencies and percentages were used to describe demographic characteristics of
12 participants based on the data type, and chi-square test or t-test were used to compare the
13 participants characteristics between group 1 and group 2 participants. A survival analysis
14 approach was applied where the outcome event was defined as copper IUD discontinuation, and
15 time to event was defined as the time period from method initiation to the time point when the
16 participant discontinued copper IUD.

17 If the participant was lost to follow-up, she was censored at her last time of contact.
18 Participants were censored if the contraceptive method was discontinued to attempt pregnancy.
19 The Kaplan-Meier survival curve was calculated and was used to estimate the 12-month
20 continuation/discontinuation rates. A Cox proportional hazard model was used to estimate the
21 association between baseline bleeding and pattern 12-month discontinuation. We considered a
22 covariate a confounder if it changed the effect estimate by 10% or more when the covariate was
23 added to the model. Effect modification was assessed by evaluating the significance of the

1 interaction term between the covariate and bleeding pattern in the model. A P-value of less than
2 0.05 was considered statistically significant. Stata software (version 11, StataCorp, College
3 station, Texas) was used for all analyses.

4 Since this was a secondary analysis of an existing dataset, we did not do an *a priori*
5 power/sample size analysis. However, our *post hoc* power analysis revealed a greater than 90%
6 power to detect a clinically important difference of 15% (assuming 20% discontinuation rate in
7 not heavy bleeding group and a 35% discontinuation rate in the heavy bleeding group) based on
8 our sample size.

9 10 **RESULTS**

11 A total of 1102 study participants initially chose a copper IUD for contraception, 918
12 (83.3%) of which initiated copper IUD by 3 months survey and had continuation data available
13 at 12 months. Of these 918 subjects, 165 reported either moderately heavy (n=141) or heavy
14 (n=24) bleeding prior to IUD insertion, and thus constituted the heavy baseline bleeding group.
15 The remaining 753 copper IUD users reported either light (n=192) or moderate (n=561) baseline
16 bleeding and therefore were placed in the not heavy group (see Figure 1, Flow Diagram).

17 The baseline demographic and reproductive characteristics of our sample of copper IUD
18 users stratified by baseline bleeding pattern are provided in the Table. Subjects in the heavy
19 bleeding group were more likely to be obese and to have a history of a sexually transmitted
20 infection (STI) than participants in the not heavy group. There were no significant differences in
21 age, race, education, marital status, socioeconomic status, insurance, or other baseline
22 characteristics when we compared the two groups.

1 At 12 months from the time of copper IUD initiation, participants in the heavy and the
2 not heavy baseline bleeding groups had similar continuation rates: 80.2% and 85.0%,
3 respectively (P=0.24; Figure 2). Patients in the heavy bleeding group were not at increased risk
4 for early discontinuation (hazard ratio 1.21, 95% CI 0.88, 1.66). None of the participant variables
5 listed in the Table were determined to be confounders or effect modifiers; therefore, a
6 multivariable analysis was not performed.

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8 **COMMENT**

9 The goal of our study was to assess if women with baseline heavy menstrual bleeding
10 were more likely to discontinue copper IUD at one year as compared to women without heavy
11 bleeding. Our analysis, however, did not show a significant relationship between baseline heavy
12 menstrual bleeding and discontinuation of copper IUD at one year. This was somewhat
13 surprising because, as previously mentioned, heavy bleeding is one of the most common side
14 effects cited for early copper IUD discontinuation.^{8,9}

15 Of note, our hypothesis was that women with heavy baseline bleeding would be at
16 increased risk of copper IUD discontinuation. This was based on the premise that any further
17 bleeding caused by the device would prompt its removal. It is possible, however, that individuals
18 with heavy baseline bleeding could be more tolerant of the bleeding associated with copper IUD,
19 and therefore less likely to discontinue use of this device.

20 We attempted to compare the results of our study with existing data pertaining to the
21 relationship between baseline menstrual bleeding and copper IUD discontinuation. We found
22 only one relevant study in our search of the existing literature. Zhang examined the effect of
23 various patient characteristics on copper IUD discontinuation, of which baseline bleeding was

1 included.¹⁰ Although not formally discussed in the report, menstrual flow prior to IUD insertion
2 (i.e. 'usual' versus 'more than usual') can be found in the table of patient characteristics. The
3 tabulated crude odds ratio (OR 1.1, 95% CI 0.5, 2.2) did not indicate a significant relationship
4 between bleeding and discontinuation¹⁰. However, the study was also likely under-powered to
5 evaluate this relationship given the low number of women reporting heavy baseline bleeding.

6 Additional studies were identified which examined patient characteristics and personal
7 reasons associated with copper IUD discontinuation, however baseline menstrual bleeding was
8 not among the factors evaluated.^{11,12} Stanback and Grimes did examine the effect of bleeding on
9 copper IUD discontinuation; however, in their study the assessment of bleeding occurred one
10 month after IUD insertion.¹³ Therefore, this study did not provide a direct comparison for our
11 analysis, which sought to investigate the relationship of bleeding prior to insertion.

12 One strength of our study is a reasonably large sample size of copper IUD users from a
13 prospective cohort study of a diverse sample of participants. Data were generated using a
14 standardized patient survey, and longitudinal follow-up included assessment of method
15 discontinuation supplemented with medical record review. Less than 20% of copper IUD users
16 were lost to follow up at 12 months.

17 Despite the overall large number of CHOICE subjects selecting copper IUD, the greatest
18 limitation of our analysis was the small number of participants reporting heavy baseline bleeding
19 (n=24). We did, however, have over 140 participants who stated their baseline bleeding pattern
20 was moderately heavy. It is possible the low number of participants in the heavy bleeding
21 category was the result of either patients or providers choosing not to use copper IUD in the
22 setting of reported heavy baseline bleeding, given the concern for increased bleeding and
23 subsequent early discontinuation. This low number of heavy bleeders limited our power to assess

1 copper IUD continuation rates based upon the original four categories of bleeding. Thus, the
2 power of our study to assess this group is limited, and there is a possibility of a type II error.

3 While our dataset was considered a strength of this study, the subjective nature of the
4 data itself (i.e. self-reported bleeding) could also be perceived as a limitation. Patient-reported
5 menstrual bleeding patterns have long been shown to correlate poorly with objective measures of
6 menorrhagia¹⁴. Reporting of pad or tampon usage (which defined each of the original subgroups)
7 is also likely prone to recall bias. Further, variability likely exists with regards to how often
8 pads/tampons are replaced, or to what degree products are soiled prior to changing. Despite these
9 limitations, we must keep in mind that it is the patient's perception of heavy bleeding that can
10 both influence contraceptive counseling and thus limit the use of the copper IUD.

11 Copper IUDs are safe, highly effective, and have a long and successful track record⁷. In
12 addition to providing a non-hormonal option for contraception, the copper IUD also has the
13 longest duration of use of all forms of reversible contraception. Further, some women hold a
14 desire to maintain monthly menses. Morrison et al. reported that the majority of women (83%) in
15 their survey viewed menstruation as natural, while only 32% viewed it as a "curse".¹⁵

16 Unfortunately, IUD use in general is significantly lower in the US when compared to
17 many other countries. IUDs – mostly copper – comprise an estimated 22.8% of contraceptive
18 methods used worldwide, and yet only 6.1% in the US¹⁶. Much of this discord likely stems from
19 counseling provided by medical providers. For example, Dehlendorf et al. found that, during
20 contraception counseling visits, providers were least likely to recommend the copper IUD¹⁷.
21 Another study concluded that providers do not routinely prepare patients interested in copper
22 IUD for the possibility of increased menstrual bleeding, thereby setting the stage for
23 dissatisfaction with the device¹⁸. There also seems a paucity of guidance in managing increased

1 bleeding associated with the initiation of a copper IUD, which has been shown to both diminish
2 with time and be responsive to medical therapy¹⁹.

3 In summary, the copper IUDs is a safe and highly-effective method of contraception.
4 Many clinicians may have a bias against copper IUD use due to concerns for increased bleeding,
5 especially in women with pre-existing heavy menses. Our analysis, however, did not
6 demonstrate a correlation between early copper IUD discontinuation and heavy baseline
7 menstrual bleeding. Incorporating this information, along with the other proven benefits of
8 LARC, into contraceptive counseling may improve utilization rates of the copper IUD.

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1 Table: Baseline Characteristics of Copper IUD Users by Baseline Bleeding Pattern

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	<i>Heavy Baseline Bleeding Group (n=165)</i>	<i>Not Heavy Baseline Bleeding Group (n=753)</i>	<i>P-value</i>
Age	28.5 ± 6.1	27.6 ± 6.3	0.13
Race			0.79
African American	58 (35.2)	272 (36.1)	
White	94 (57.0)	411 (54.6)	
Others	13 (7.9)	70 (9.3)	
Education			0.83
High school diploma or less	45 (27.3)	188 (25.0)	
Some college	68 (41.2)	320 (42.5)	
College degree or graduate school	52 (31.5)	245 (32.5)	
Income			0.84
None	26 (15.9)	135 (18.2)	
\$1-800	47 (28.7)	207 (27.9)	
\$801-1,600	45 (27.4)	210 (28.3)	
\$1,601 or more	46 (28.0)	189 (25.5)	
Body mass index			0.01
Underweight	2 (1.2)	19 (2.6)	
Normal	67 (40.9)	324 (43.5)	
Overweight	29 (17.7)	192 (25.8)	
Obese	66 (40.2)	210 (28.2)	
Low socioeconomic status			0.14
No	63 (38.2)	335 (44.5)	
Yes	102 (61.8)	417 (55.5)	
Insurance			0.81
None	67 (41.1)	301 (40.1)	
Private	80 (49.1)	363 (48.3)	
Public	16 (9.8)	87 (11.6)	
Gravidity			0.22
0	40 (24.2)	221 (29.3)	
1	32 (19.4)	108 (14.3)	
2	25 (15.2)	135 (17.9)	
3 or higher	68 (41.2)	289 (38.4)	
Parity			0.16
0	65 (39.4)	334 (44.4)	
1	30 (18.2)	162 (21.5)	
2	36 (21.8)	149 (19.8)	
3 or higher	34 (20.6)	108 (14.3)	
Unintended pregnancies			0.41
0	50 (30.3)	261 (34.7)	
1	43 (26.1)	154 (20.5)	
2	29 (17.6)	142 (18.9)	
3 or higher	43 (26.1)	195 (25.9)	
History of abortion			0.80
No	98 (59.4)	439 (58.3)	
Yes	67 (40.6)	314 (41.7)	
History of STI			0.04
No	87 (52.7)	463 (61.6)	

Yes	78 (47.3)	289 (38.4)	
Any current STI			0.81
No	157 (95.2)	715 (95.6)	
Yes	8 (4.8)	33 (4.4)	

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STI, sexually transmitted infection.

Data are mean \pm standard deviation or n (%) unless otherwise specified.

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1 **Figure 1:** Flow diagram and distribution of baseline bleeding patterns of CHOICE participants
2 using the copper IUD

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4 **Figure 2:** Kaplan-Meier survival curves comparing copper IUD continuation stratified by
5 baseline bleeding status (not heavy = light or moderate bleeding; heavy = moderately heavy or
6 heavy bleeding).

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