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# Association of Baseline Bleeding Pattern on Amenorrhea with Levonorgestrel Intrauterine System Use

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## Abstract

**OBJECTIVE—**To evaluate the effect of baseline bleeding patterns on rates of amenorrhea reported at 12 months in LNG (levonorgestrel) 52 mg IUS (intrauterine system) users. We also assessed the effect of baseline bleeding patterns at three and six months post-insertion.

**STUDY DESIGN—**In this secondary analysis of the Contraceptive CHOICE Project, we included participants who had a LNG-IUS inserted within one month of enrollment and continued use for 12 months. Using 12-month telephone survey data, we defined amenorrhea at 12 months of use as no bleeding or spotting during the previous six months. We used chi-square and multivariable logistic regression to assess the association of baseline bleeding pattern with amenorrhea while controlling for confounding variables.

**RESULTS—**Of 1802 continuous 12-month IUS users, amenorrhea was reported by 4.9%, 14.8% and 15.4% of participants at three, six, and 12 months, receptively. Participants with light baseline bleeding or short duration of flow reported higher rates of amenorrhea at three and six months post-insertion ($p<0.03$), while LNG-IUS users with heavy or prolonged flow were less likely to report amenorrhea at 3 and 6 months ($p<0.03$). In a multivariable analysis, participants with self-reported heavy bleeding at baseline were less likely to report amenorrhea at 12 months than those who reported moderate bleeding ($OR_{adj}$, 0.36; 95% CI, 0.16–0.69).

**CONCLUSION—**Women with heavier menstrual bleeding are less likely than women with moderate flow to report amenorrhea following 12 months of LNG-IUS use.

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**Keywords**

Intrauterine device; IUD; IUS; intrauterine system; amenorrhea; LARC

## INTRODUCTION

The levonorgestrel-releasing intrauterine system (LNG-IUS) is one of the most effective long-acting reversible contraceptive (LARC) methods, and its effectiveness is not user-dependent [1,2]. The LNG-IUS causes changes in menstrual bleeding patterns by altering endometrial histology; characteristic changes include endometrial thinning and stromal and glandular atrophy [3]. As such, one documented non-contraceptive benefit is potential amenorrhea. Reportedly, nearly 20% of women will become amenorrheic within one year of insertion with increasing rates of over time [4–6]. Changes in bleeding patterns may have varying levels of desirability, affecting the choice to continue or discontinue method use [7]. However, most women see amenorrhea as a beneficial side effect [8].

Previous studies have suggested possible predictors of amenorrhea after LNG-IUS use, such as small uterine cavity measurements and the absence of heavy bleeding prior to insertion [9–10]. Body mass index (BMI) has also been investigated with mixed results [11]. However, there is still a relative lack of data regarding women's baseline bleeding patterns as a predictor of amenorrhea.

The purpose of this study is to examine the association of baseline bleeding patterns on amenorrhea at 12 months in levonorgestrel 52 mg intrauterine system (LNG-IUS) users. We hypothesized that women with self-reported light (10 or fewer pads or tampons per menstrual cycle) and short (less than four days per month) baseline bleeding patterns would be more likely to experience amenorrhea at 12 months following LNG-IUS insertion than those with moderate amount (11–20 pads or tampons) and duration (four to six days per month) of flow.

## METHODS

The Contraceptive CHOICE Project (CHOICE) is a prospective cohort study of 9256 women from the St. Louis region who were provided with reversible contraception at no cost for two to three years. The methods have been previously published [12]. This study represents a secondary analysis of participants who chose and received a LNG-IUS at baseline enrollment.

Briefly, we recruited CHOICE participants from specific clinic locations in the St. Louis region between 2007–2011 and deemed eligible to participate if they were 14–45 years of age, sexually active or anticipated sexual activity with a male partner in the next six months, and did not desire pregnancy in the year following enrollment. Prior to enrollment, we obtained written informed consent from every participant.

For this analysis, only women who chose and received the LNG IUS within one month of enrollment and continued using the method for 12 months are included. We included

participants with complete data on baseline bleeding patterns at three, six and 12 months. In addition, we excluded women if data about their baseline contraceptive use was missing, as contraceptive method prior to LNG-IUS insertion can affect menstrual cycle characteristics.

Upon enrollment, we assessed baseline bleeding patterns with several questions. Specifically, participants were asked to describe the average heaviness of bleeding during their period and the average length of their period during the previous 12 months. Participant responses for heaviness of bleeding were categorized as light, moderate, moderately heavy, heavy, or too variable or irregular to say. To assist the participant in choosing the answer most representative of their menstrual flow, survey responses were clarified by estimating the number of pads or tampons used per cycle (10 or fewer, 11–20, 21–30, more than 30, respectively). Responses for length of period were one to three days, four to six days, seven to nine days, 10 days or longer, or too variable or irregular to say. We defined a normal baseline bleeding pattern as only moderate flow and four to six days of bleeding [13].

We performed follow-up telephone interviews at three and six months, and then every 6 months thereafter. Participants were asked if and how their bleeding patterns had changed, as well as if menstruation ceased during the time between surveys. We assessed bleeding at three, six, and 12-months. At three and six months, we asked participants if they had any bleeding or spotting since the baseline or three-month survey, respectively. At the 12-month survey, participants were asked if they had any bleeding or spotting since the six-month survey. Our primary outcome was self-reported amenorrhea at 12 months, defined as no bleeding or spotting since the six-month interview. Although there is not one uniform definition of amenorrhea, many experts suggest 90 days of no bleeding or three missed menstrual cycles. We chose six months of no bleeding as our definition to be more conservative and consistent with the language used in the CHOICE surveys.

Because selecting only women who continued their method and completed all surveys at three, six, and 12 months may create selection bias, we performed two analyses. First, we evaluated women who continued LNG-IUS use and answered all surveys for 12 months, and second, women who continued use and answered any, but not necessarily all, of the surveys up to 12 months. The results for both evaluations did not vary so we only present data from our primary analysis with complete survey data.

We evaluated the relationship between baseline bleeding and self-reported amenorrhea at 12 months with bivariate analysis using chi-square for all categorical variables. Factors with a p-value less than or equal to 0.1 were included in the multivariate model. We defined confounders as variables that changed the odds ratio by ≥10% when added to the logistic regression model [14]. We included all resulting confounding factors significantly associated with amenorrhea in the final multivariable model. SPSS, version 22 was used for all statistical analyses. The statistical significance level was set at 0.05.

## RESULTS

Of 9256 total CHOICE participants, 3317 chose and initiated LNG-IUS use within one month of enrollment. We excluded 223 women with missing baseline bleeding data, one

with missing baseline contraceptive data, and 292 for not continuing LNG-IUS use for 12 months. We excluded another 999 women enrolled prior to addition of the bleeding questions at three through 12 months. Of the remaining 2094 women, 1802 provided bleeding data and continued LNG-IUS use through 12 months, comprising our primary cohort. The sample size differed by 267 participants between participants who completed all follow-up surveys and those who completed some, but not all, as described in the methods section. Our final analytic sample consisted of 1802 participants who had complete information regarding baseline bleeding pattern and contraceptive use, as well as continued use of the LNG-IUS and 12-month survey data. At three months, 88 participants (4.9%) reported no bleeding or spotting in the prior three months. At six months, 266 (14.8%) users reported no bleeding or spotting in the prior three months, and at 12 months, 278 (15.4%) reported no bleeding or spotting in the past six months.

Baseline demographic characteristics, stratified by amenorrhea status at 12 months, are shown in Table 1. Our sample was racially and ethically diverse; 45.1% were black and 4.3% were of Hispanic descent. Over half of our sample was under the age of 25. In our unadjusted analyses, age, race, gravidity, parity, contraceptive use at time of enrollment, BMI and history of sexually transmitted infection (STI) were found to be significantly associated with amenorrhea at 12 months. In our adjusted analyses, black women and women of other races, compared to white women, were less likely to be amenorrheic ($OR_{adj}$ 0.62; CI 0.45–0.86 and $OR_{adj}$ 0.55; CI 0.31–0.98, respectively), as were those with gravidity of three or greater ($OR_{adj}$ 0.65; CI 0.43–0.99).

One in five women (21.0%, n=74/353) with light bleeding at baseline reported amenorrhea at 12 months compared to 16.3% (n=166/1019) of those with moderate, 10.0% (n=29/292) of those with moderately heavy, and 5.2% (n=7/134) of those with heavy bleeding ($p<0.001$). A similar overall trend is apparent at 12 months when considering length of bleeding, although this latter association is not significant (p=0.10). Amenorrhea rates at three and six months also demonstrated an association with baseline bleeding patterns (Table 2). Participants with lighter bleeding and shorter duration of bleeding were more likely to report amenorrhea at three and six months following insertion.

Age, ethnicity, marital status, education level, contraceptive use at the time of enrollment, BMI and history of STI did not alter the association between baseline bleeding patterns and amenorrhea. However, race and gravidity remained significant confounders, and therefore are included in the multivariable analysis. In our final multivariable model (Table 3), participants with self-reported moderately heavy or heavy bleeding at baseline were less likely to experience amenorrhea at 12 months than the reference category of moderate bleeding ($OR_{adj}$, 0.60; CI, 0.39–0.93 and $OR_{adj}$, 0.36; CI, 0.16–0.69, respectively).

## DISCUSSION

We found that women with heavier menstrual flow at baseline were less likely to become amenorrheic at 12 months after LNG-IUS insertion. Overall rates of amenorrhea increased as time since insertion progressed from three to 12 months. We also found race and gravidity to have a small effect in the final model. One reason race may have been significantly

associated with heavier bleeding in our analysis may be related to a higher prevalence of uterine leiomyomata in black women, which can be associated with heavy menstrual flow [15]. We also noted that participants who report light flow and shorter durations of bleeding were more likely to report amenorrhea at three and six months post-insertion.

The LNG-IUS has characteristic and well-described hormonal effects on the endometrium, such as atrophy of endometrial glands and stromal decidualization [16]. These changes can become apparent as soon as one month after insertion and are maintained for as long as seven years, with a significant decrease in endometrial thickness by 10 weeks on pathologic examination [17]. As the effects of the LNG-IUS shift the endometrium from its normal cycling to a more inactive state, initial bleeding and spotting irregularities occur, followed by overall lighter bleeding [18].

We speculate that women with minimal baseline menstrual bleeding or shorter duration of flow may have a thinner endometrial lining than a woman with heavy, or even average, bleeding. These women may be more likely to experience amenorrhea with LNG-IUS use than women with normal or heavier flow. Jensen and colleagues [19] noted that LNG-IUS insertion in women with heavy menstrual bleeding resulted in lower than expected rates of amenorrhea at one year of use. Another report noted that post-abortion LNG-IUS insertion resulted in more favorable bleeding patterns compared to post-menstrual placement, perhaps due to most endometrial tissue being removed during the procedure [4].

An important strength of this study is the reproductive and demographic diversity of the participants. Additionally, our analysis had a large sample size of nearly 2000 women. These women chose their own contraceptive method and were not randomly assigned, which more realistically reflects the clinical setting. Notably, these women received their method specifically for contraception and not for management of menstrual bleeding. Finally, we had excellent follow-up rates (95% follow-up at 12 months and 87% at 24 months for CHOICE overall [20]), allowing us to maintain a large sample size by the 12-month follow-up survey.

Our analysis is not without limitation. One weakness of our analysis is our definition of amenorrhea. Elsewhere in the literature, amenorrhea is defined as no bleeding or spotting for three months [4,5]; our 12-month survey asked about bleeding over the previous six-month period instead. Our six-month definition was more stringent than the usual cut-off due to the language of the CHOICE surveys, potentially explaining why our rate of amenorrhea was lower than previous reported literature (14.5% vs. 20%) [4]. Notably, our definition of amenorrhea at three and six-month time points was still consistent with the traditional definition. Other weaknesses of this analysis include lack of information regarding uterine fibroids and subjective recall of bleeding patterns using telephone surveys as opposed to prospective collection with bleeding diaries. However, we feel that collection of diaries with such a large sample size would have been challenging and impractical. We believe the survey questions sufficiently assessed bleeding patterns and reflect participants' general bleeding trends. In addition, our approach of assessing bleeding patterns through participant recall is consistent with clinical scenarios.

Our results show that baseline bleeding pattern has a significant association with the likelihood of amenorrhea at 12 months. This knowledge may influence patients' contraceptive choice and practitioners' counseling. Anticipatory counseling, in the context of bleeding patterns and other predictors, may improve user satisfaction and continuation of the LNG-IUS. Efforts to improve continuation and satisfaction are an important strategy to continue to reduce unintended pregnancy and abortion rates.

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## IMPLICATIONS

Baseline heavy menstrual flow reduces the likelihood of amenorrhea with LNG-IUS use, information which could impact contraceptive counseling; anticipatory counseling can improve method satisfaction and continuation, an important strategy to continue to reduce unintended pregnancy and abortion rates.

## Table 1

Baseline characteristics of participants receiving LNG-IUS stratified by amenorrheic status at 12 months (n=1802)

| Characteristic | Total (n=1802) | Amenorrheic at 12 months (n=278) | Non-amenorrheic at 12 months (n=1524) | p-value |
|---|---|---|---|---|
| **Age** | | | | <0.01 |
| **<18** | 42 (2.3) | 10 (3.6) | 32 (2.1) | |
| **18–20** | 209 (11.6) | 31 (11.2) | 178 (11.7) | |
| **21–25** | 720 (40.0) | 126 (45.3) | 594 (39.0) | |
| **26–30** | 465 (25.8) | 75 (27.0) | 390 (25.6) | |
| **>30** | 366 (20.3) | 36 (12.9) | 330 (21.7) | |
| **Race** | | | | <0.01 |
| **Black** | 814 (45.1) | 88 (31.7) | 726 (47.6) | |
| **White** | 855 (47.4) | 174 (62.6) | 681 (44.7) | |
| **Other** | 133 (7.4) | 16 (5.8) | 117 (7.7) | |
| **Hispanic ethnicity** | 78 (4.3) | 11 (4.0) | 67 (4.4) | 0.74 |
| **Marital status** | | | | 0.43 |
| **Single/never married** | 1041 (57.8) | 169 (60.8) | 872 (57.3) | |
| **Married/living with partner** | 638 (35.4) | 94 (33.8) | 544 (35.7) | |
| **Separated/divorced/widowed** | 122 (6.8) | 15 (5.4) | 107 (7.0) | |
| **Education level** | | | | 0.18 |
| **< High school** | 462 (25.6) | 61 (21.9) | 401 (26.3) | |
| **Some college** | 801 (44.5) | 123 (44.2) | 678 (44.5) | |
| **College/grad** | 538 (29.9) | 94 (33.8) | 444 (29.2) | |
| **Gravidity** | | | | <0.01 |
| **0** | 515 (28.6) | 120 (43.2) | 395 (25.9) | |
| **1** | 370 (20.5) | 53 (19.1) | 317 (20.8) | |
| **2** | 341 (18.9) | 46 (16.5) | 295 (19.4) | |
| **≥3** | 576 (31.9) | 59 (21.2) | 517 (33.9) | |
| **Prior contraceptive use at time of enrollment** | | | | <0.01 |
| **PPR** | 522 (29.0) | 111 (39.9) | 411 (27.0) | |
| **LARC (IUD or implant)** | 23 (1.3) | 1 (0.4) | 22 (1.4) | |
| **DMPA** | 31 (1.7) | 4 (1.4) | 27 (1.8) | |
| **Other** | 708 (39.3) | 99 (35.6) | 609 (40.0) | |
| **None** | 518 (28.7) | 63 (22.7) | 455 (29.9) | |
| **BMI (kg/m$^2$)** | | | | 0.02 |
| **<18.5** | 41 (2.3) | 4 (1.5) | 37 (2.5) | |
| **18.5–24.9** | 666 (37.0) | 120 (43.8) | 546 (36.2) | |
| **25–29.9** | 481 (26.7) | 78 (28.5) | 403 (26.7) | |
| **≥30** | 593 (32.9) | 72 (26.3) | 521 (34.6) | |
| **Any history of STI (excluding BV & PID)** | 705 (39.1) | 87 (31.3) | 618 (40.6) | <0.01 |

Data are presented as n (%).

PPR = pill, patch or ring; LARC = long-acting reversible contraception; IUD = intrauterine device; DMPA = depot medroxyprogesterone acetate injection

## Table 2

Amenorrhea rates at 3 and 6 months of LNG IUS use stratified by baseline menstrual characteristics (n=1802)

| | Number at 3 months | Amenorrheic at 3 months (n=88) | Number at 6 months | Amenorrheic at 6 months (n=266) |
|---|---|---|---|---|
| **Amount of bleeding** | | | | |
| Light | 353 | 27 (7.7) | 353 | 71 (20.1) |
| Moderate | 1019 | 50 (4.9) | 1019 | 146 (14.3) |
| Moderately Heavy | 292 | 8 (2.7) | 292 | 36 (12.3) |
| Heavy | 134 | 3 (2.2) | 134 | 10 (7.5) |
| | | *p=0.027* | | *p<0.001* |
| **Duration of Flow** | | | | |
| 1–3 days | 255 | 23 (9.0) | 255 | 47 (18.4) |
| 4–6 days | 1322 | 58 (4.4) | 1322 | 195 (14.8) |
| ≥7 days | 221 | 7 (3.5) | 221 | 22 (10.0) |
| | | *p=0.016* | | *p=0.025* |

Note: p-values in Table 2 represent the association of each baseline bleeding characteristic with amenorrhea at both 3 and 6 months.

Data are presented as n (%).

LNG-IUS = levonorgestrel intrauterine system

## Table 3

Multivariable model of the association between baseline menstrual characteristics and amenorrhea at 12 months in LNG 52 mg IUS users

| | Number at 12 months | Amenorrheic at 12 months (n=278) | OR (95% CI) Crude | OR (95% CI) Adjusted* |
|---|---|---|---|---|
| **Amount of bleeding** | | | | |
| Light | 353 | 74 (21.0) | 1.36 (1.00–1.85) | 1.26 (0.92–1.74) |
| Moderate | 1019 | 166 (16.3) | Reference | |
| Moderately Heavy | 292 | 29 (10.0) | 0.57 (0.37–0.86) | 0.60 (0.39–0.93) |
| Heavy | 134 | 7 (5.2) | 0.28 (0.13–0.62) | 0.36 (0.16–0.69) |
| **Duration of flow** | | | | |
| 1–3 days | 255 | 48 (18.8) | 1.26 (0.89–1.79) | 1.43 (0.99–2.07) |
| 4–6 days | 1322 | 205 (15.5) | Reference | |
| ≥7 days | 221 | 24 (10.9) | 0.66 (0.42–1.04) | 0.72 (0.45–1.15) |

Adjusted for race and gravidity.

Data are presented as n (%).

LNG-IUS = levonorgestrel intrauterine system