Real-world satisfaction and menstrual bleeding pattern with available LNG-IUD among Spanish young women

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ABSTRACT

Objective: The aim of this study was to evaluate the satisfaction and menstrual bleeding pattern with levonorgestrel-releasing intrauterine systems (LNG-IUD) in young women.

Methods: A prospective, multicentre, non-interventional study with 1-year follow-up was conducted in Spain. Participants were women between 18 and 30 years old who freely choose any available LNG-IUD for contraception. Satisfaction with LNG-IUD was measured with a 5-point Likert scale. Type of LNG-IUD, menstrual bleeding pattern and satisfaction with it, easiness of insertion and pain during procedure were collected.

Results: A total of 555 women (37.3% parous, 62.7% nulliparous) (mean age 25.8 ± 3.5) completed the study. After 12 months, 92.4% of women were satisfied or very satisfied with the LNG-IUD, with no differences by parity status, type of IUD or baseline menstrual bleeding pattern. Satisfaction with the LNG-IUD correlated with satisfaction with menstrual bleeding pattern at 12 months. Up to 88.7% of women were satisfied or very satisfied with their menstrual bleeding pattern at 12 months in comparison to 41.5% at baseline (p < 0.001). Adverse events (AE)-related discontinuation rate was low (2.2%).

Conclusions: Satisfaction with LNG-IUD is very high among young Spanish women, regardless of parity and menstrual bleeding pattern at baseline.

Introduction

Between 2015 and 2019, there were 121 million unintended pregnancies worldwide, which may involve serious health, economic and social consequences. Even so, global unintended pregnancies have declined over the last 30 years, probably due to improved access to a choice of contraception [1]. Long-Acting Reversible Contraceptives (LARCs) –mainly intrauterine devices [IUD] and subdermal implants– are highly effective and safe contraceptive methods. In addition, LARCs show a high rate of adherence due to user-independent compliance [2-4]. Although National and International contraceptive guidelines recommend offering LARCs as first-line option to women of all ages [3-8], these are still underutilised.

The levonorgestrel-releasing IUD (LNG-IUD) is one of the most effective LARCs and has very low failure rates (0.1–0.2% during the first year) [9]. In Spain, there are four LNG-IUD available (two containing 52 mg, one containing 19.5 mg and one containing 13.5 mg of levonorgestrel) approved for contraceptive use for periods of 3–6 years. LNG-IUD users have reported high rates of satisfaction with the device for both contraception and non-contraception prescriptions worldwide [10–13], especially with the 52 mg LNG-IUD, which is also indicated for heavy menstrual bleeding (HMB) [14]. According to the ‘2020 Survey on Contraception in Spain’, the self-perceived main advantages of LNG-IUD include convenience, efficacy and safety [15]. Nevertheless, the prevalence of LNG-IUD use in women of reproductive age (15–49 years old) in Spain is poor (4%); and only 1.2% of survey respondents between 25–29 years old and none of the respondents between 15 and 24 years old reported using LNG-IUD [15]. Reasons for low use of LNG-IUD include the need of medical intervention; lack of professional guidance; misconceptions for IUD use in nulliparous, adolescents and other special populations; and potential adverse events (AEs), such as spontaneous expulsion or uterine perforation, although these occur at very low rates [2,16–18]. In addition, the potential bleeding pattern changes associated with LNG-IUD use, such as more frequent and/or prolonged bleeding for the first 3 months of use [19] are a common cause of dissatisfaction and discontinuation of LARCs [20–23]. In this way, concerns about these bleeding changes can prevent some women from considering using LARCs [12,24].

Studies comparing satisfaction between LARCs and Short-Acting Reversible Contraceptives (SARC) (oral contraceptive pills, progestin-only pills, injectables, vaginal rings, and patches) are still scarce but show that women who use LARCs report higher satisfaction rates at 12 months [11,25,26]. Understanding the factors that affect women satisfaction with LNG-IUD could help health care practitioners to better contraceptive counselling. However, real-world data evaluating satisfaction with LNG-IUD among young Spanish women and comparing satisfaction between the different LNG-IUD available are scarce. Thus, the purpose of this study (BERTA study) was to assess, under real-life conditions, satisfaction with LNG-IUD in 18–30 years-old...
Spanish women after 12 months from device insertion, and to evaluate the potential influence of several factors such as parity status, menstrual bleeding pattern and satisfaction with it, type of LNG-IUD, reasons to choose a LNG-IUD, easiness of device insertion and pain at insertion.

Material and methods

Study design and participants

The BERTA study was a longitudinal, prospective, multi-centre, non-interventional study carried out in Spain. Women from 41 public or private gynaecology clinics across the country were consecutively recruited between April 2018 and November 2019. Inclusion criteria were: women between 18 and 30 years old, naive IUD users, who had chosen a LNG-IUD as contraceptive method; with no desire to conceive for at least 12 months; and with the ability to read and write. Women could have used any other contraceptive methods prior to inclusion (as well as no contraception). Exclusion criteria for the study, according to local market authorisation, included contraindications for LNG-IUD, mental incapacity to consent, and participation in other clinical trials with interventions conducted outside routine clinical practice.

The decision to use any of the available LNG-IUD was made independently by the women after a discussion with their health care provider at participating study centres. This discussion was conducted during a routine visit and followed standard clinical practice; therefore, the study did not interfere with women’s or physicians’ decisions on the most appropriate contraceptive. Women were subsequently informed about the study and invited to participate. Written informed consent was obtained from all participants. Women did not receive any compensation for participating in the study.

The study was approved by the ethics committee of the Hospital de la Santa Creu i Sant Pau of Barcelona, authorised by the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) and it was registered in ClinicalTrials.gov (identifier: NCT03493295) in April 2018.

Primary and secondary outcomes

The primary endpoint for this study was the overall satisfaction with LNG-IUD in young women after 12 months of use measured by a 5-point Likert scale that included the following categories: ‘very satisfied’, ‘satisfied’, ‘neither satisfied nor dissatisfied’, ‘dissatisfied’, and ‘very dissatisfied’. When indicated, ‘very satisfied’ and ‘satisfied’ results were pooled into ‘High satisfaction’ category; ‘dissatisfied’ and ‘very dissatisfied’ results into ‘Low satisfaction’ category and ‘neither satisfied nor dissatisfied’ results were considered as ‘Neutral satisfaction’ category.

The secondary outcomes of this study were to evaluate pain and easiness of device insertion, to analyse discontinuation rates and reasons for discontinuation, and to assess satisfaction with LNG-IUD at baseline, at 4–12 weeks and at 12 months after insertion according to different factors, including: parity status; reasons to change contraceptive method; type of LNG-IUD devices; menstrual bleeding pattern (frequency, regularity, quantity, duration of menstrual bleeding, pain, intermenstrual bleeding and interference with daily activities); and satisfaction with menstrual bleeding (5-point Likert scale). Recommendation of LNG-IUD to peers was evaluated at final visit. Lastly, AEs occurring during the study were also recorded and evaluated.

Data collection and analysis

Investigators collected demographic and clinical data from medical records and personal interviews, and satisfaction data from a user questionnaire. The investigators documented all the study-relevant data for each woman in an electronic case report form (eCRF). All raw data is stored and available upon request.

Data collection was performed in two or three visits, according to clinical practice of each centre: the IUD insertion visit (baseline visit), an optional follow-up visit at 4–12 weeks after insertion (only in those centres where this visit was common clinical practice) and at the 12 months visit (final visit).

Sample size calculation was based on the assumption of an 80% of women with satisfaction rating of 4 (satisfied) or 5 (very satisfied), according to previous studies [25], and a potential drop-out of 20%. Under these assumptions, a sample of 660 subjects was needed to estimate the 95% CI of the percentage with a precision of ± 5% (as per Clopper-Pearson estimation).

Statistical methods

A descriptive analysis was performed for all the variables recorded for the study population. For continuous variables, mean and standard deviation (SD) were calculated; for categorical variables, number and frequencies (percentages) are presented.

Parametric (Student’s two-sample t-test or ANOVA) and non-parametric (Mann–Whitney U-test) tests were used, according to the distribution of the variables. The categorical variables were analysed using the Chi-square or Fisher test, as appropriate.

Spearman correlation was used to analyse the non-linear association between two continuous or ordinal variables. To test statistical differences in overall satisfaction with LNG-IUD by parity and other categorical variables, Wilcoxon’s signs and Bowker test of symmetry were used. All statistical tests were 2-sided and a 5% significance level was assumed. Software package SAS version 9.4. or higher (SAS Institute Inc., Cary, NC) was used.

Results

A total of 704 women from 41 centres (11 public and 30 private gynaecology clinics) across Spain were invited to participate in the study. Among them, 36 did not meet selection criteria. From the 668 women who completed baseline visit, 112 (16.8%) dropped out of the study, and 555 completed the study up to the final visit. At the end of the study, data from 551 women (210 parous and 341 nulliparous) were considered assessable for the primary endpoint and included in the Full Analysis Set. Reasons for excluding these 4 women were: out-of-time basal visit,
expulsion and reinsertion of the LNG-IUD during the course of the study, and the date of the end of observation was previous to the date of the final visit (Figure 1).

Baseline demographic and clinical characteristics of study population

Baseline demographic and clinical characteristics of participants according to parity status are shown in Table 1. The sample included 37.3% parous women (n = 249) and 62.7% nulliparous (n = 418), with a mean age of 25.8 years. Women in the nulliparous group were significantly younger, had a higher education and different working status (more students) than women in the parous group. A lower percentage of women in the parous group used a previous contraceptive method (88.0% in parous vs 97.1% in nulliparous group, p < 0.0001). The most common previous contraceptives were the male condom (46.7%) and the combined contraceptive pill (31.4%), with no differences between groups (Table 1).

Regarding menstrual bleeding pattern at baseline (Table 2), nulliparous population presented more regular bleeding (92.3% nulliparous vs 86.7% of parous women, p = 0.02) and lower incidence of abnormally long menses (7.4% vs 14.9% with >8 days of duration, p = 0.001). No differences regarding the frequency and quantity of menstrual bleeding were observed.

Participants stated that the main reasons to choose a hormonal IUD were their high efficacy (66.9%), safety (61.2%), user-friendliness (60.4%), durability (53.4%) and the absence of risk of forgetting (44.7%) (supplemental Table S1).

Regarding type of IUD, the most frequently chosen LNG-IUD was LNG-IUD 19.5 mg (Kyleena®) (82.2% of total sample; 75.5% of parous and 86.1% of nulliparous women, p < 0.05). LNG-IUD 52 mg (Mirena®) was the second most inserted option in the parous group (20.1% of parous vs 2.2% of nulliparous women, p < 0.05) and LNG-IUD 13.5 mg (Jaydess®) was the second most inserted option in the nulliparous population (3.2% of parous vs 11.7% of nulliparous women, p < 0.05). Only three subjects chose LNG-IUD 52 mg (Levosert®), and all belonged to the parous group.

Ease of insertion and pain during LNG-IUD insertion

Investigators considered that the insertion procedure was ‘easy’ or ‘very easy’ in 93.6% of all cases, without differences by type of device. Regarding the pain experienced during IUD insertion, 79.8% of women stated feeling ‘no pain’ or ‘mild pain’ during LNG-IUD insertion and no differences on pain during procedure according to type of LNG-IUD were observed (p = 0.49) (supplemental Table S2).

Satisfaction with LNG-IUD at one-year visit

One year after LNG-IUD insertion, 92.4% of women were satisfied or very satisfied with the IUD. No significant differences on the degree of satisfaction were found between parity groups (Figure 2(A)), type of IUD chosen (Figure 2(B)) or menstrual bleeding pattern at baseline (Table 3). Similarly, no differences on the degree of satisfaction were observed according to previous contraceptive method used or the reason to choose a LNG-IUD, except for those women who considered the ‘absence of risk of forgetting’ an important reason (95.5% of them reported high satisfaction).

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**Figure 1.** Participant flowchart. AE: adverse event; BAS: Baseline Analysis Set; FAS: Full Analysis Set; IAS: Intermediate Analysis Set. ‘Investigator’s decision’: investigators could chose this as reason of discontinuation when they considered that study discontinuation was the best course of action for a participant, and none of the other reasons were applicable.
satisfaction vs 89.9% of those who did not consider ‘risk of forgetting’ an important reason, \( p = 0.03 \).

Satisfaction with LNG-IUD significantly correlated with satisfaction with menstrual bleeding pattern at 12 months (Spearman correlation coefficient = 0.7356, \( p < 0.0001 \)). No significant differences on the degree of satisfaction with the menstrual bleeding pattern were found between parity groups (\( p = 0.38 \)). However, differences on the degree of satisfaction with LNG-IUD were observed among women with different menstrual bleeding pattern 12 months after device insertion. Women who reported a higher degree of satisfaction with LNG-IUD significantly presented a more regular, shorter, less abundant and less frequent menstrual bleeding that caused less pain and less daily interference than women who reported lower satisfaction with the device (Table 4 and supplemental Table S3).

In agreement with the high level of satisfaction reported, almost all women (93.8%) stated at the final visit that they would recommend LNG-IUD to peers, regardless of parity status (91.9% parous vs. 95.0% nulliparous women; \( p = 0.14 \)).

### Satisfaction with LNG-IUD at intermediate visit at 4 to 12 weeks

Following common clinical practice of each centre, 583 out of the 667 initial women attended to a follow-up visit at 4–12 weeks after LNG-IUD insertion, and satisfaction at short-term was evaluated. At that point, 81.7% of women were satisfied or very satisfied with the LNG-IUD vs the 92.4% of women at final visit (\( p < 0.0001 \)).

No significant differences on the degree of satisfaction at intermediate visit were observed between women who had experienced no pain or mild pain and women who had experienced moderate and severe pain during the device insertion.

| Table 1. Demographic and clinical characteristics of included women according to parity status. |
|---------------------------------------------------------------|
|                                                     | Parous | Nulliparous | Total | \( p \)-Value |
| Age (years), mean (SD) | 27.29 (3.15) | 24.86 (3.37) | 25.8 (3.5) | \(< 0.0001^*\) |
| Place of birth          |                                                   |                                                   |       |              |
| Spain                   | 182 (73.1%) | 372 (89.0%) | 554 (83.1%) |              |
| Rest of Europe          | 11 (4.4%)  | 10 (2.4%)  | 21 (3.1%)  | \( < 0.0001^*\) |
| South/Central America   | 50 (20.1%) | 31 (7.4%)  | 81 (12.1%) |              |
| North America           | 1 (0.4%)  | 5 (1.2%)   | 6 (0.9%)   | \( < 0.0001^*\) |
| Asia                    | 1 (0.4%)  | 0 (0.0%)   | 1 (0.1%)   | \( < 0.0001^*\) |
| Africa                  | 4 (1.6%)  | 0 (0.0%)   | 4 (0.6%)   | \( < 0.0001^*\) |
| Level of studies†       |                                                   |                                                   |       |              |
| No studies/Incomplete primary studies | 5 (2.0%) | 0 (0.0%) | 5 (0.8%) | \( < 0.0001^*\) |
| Primary studies         | 32 (12.9%) | 16 (3.8%) | 48 (7.2%) | \( < 0.0001^*\) |
| Secondary studies       | 119 (47.8%) | 133 (32.0%) | 252 (37.9%) | \( < 0.0001^*\) |
| University studies      | 93 (37.3%) | 267 (64.2%) | 360 (54.1%) | \( < 0.0001^*\) |
| Working status†         |                                                   |                                                   |       |              |
| Active                  | 164 (66.1%) | 250 (60.2%) | 414 (62.4%) | \( < 0.0001^*\) |
| Unemployed              | 23 (9.3%)  | 16 (3.9%)  | 39 (5.9%)  | \( < 0.0001^*\) |
| Unpaid workhouse        | 45 (18.1%) | 3 (0.7%)   | 48 (7.2%)  | \( < 0.0001^*\) |
| Student                 | 16 (6.5%)  | 146 (35.2%) | 162 (24.4%) | \( < 0.0001^*\) |
| Use of contraceptive method previous to IUD |                                                   |                                                   |       |              |
| No                      | 30 (12.0%) | 12 (2.9%)  | 42 (6.3%)  | \( < 0.0001^*\) |
| Yes                     | 219 (88.0%) | 406 (97.1%) | 625 (93.7%) |              |
| Type of contraceptive method used previous to IUD |                                                   |                                                   |       | \( 0.002^*\) |
| Male condom             | 102 (46.6%) | 190 (46.8%) | 292 (46.7%) | \( < 0.0001\) |
| Female condom           | 3 (1.4%)  | 5 (1.2%)   | 8 (1.3%)   | \( < 0.0001\) |
| Combined contraceptive pill (Pill) | 69 (31.5%) | 127 (31.3%) | 196 (31.4%) | \( < 0.0001\) |
| Progestogen-only pill (mini-pill) | 10 (4.6%) | 11 (2.7%) | 21 (3.4%) | \( < 0.0001\) |
| Vaginal ring            | 13 (5.9%)  | 55 (13.5%) | 68 (10.9%) | \( < 0.0001\) |
| Contraceptive patch     | 3 (1.4%)  | 3 (0.7%)   | 6 (1.0%)   | \( < 0.0001\) |
| Implants                | 6 (2.7%)  | 2 (0.5%)   | 8 (1.3%)   | \( < 0.0001\) |
| Injectable              | 2 (0.9%)  | 0 (0.0%)   | 2 (0.3%)   | \( < 0.0001\) |
| Dual method             | 0 (0.0%)  | 3 (0.7%)   | 3 (0.5%)   | \( < 0.0001\) |
| Withdrawal              | 6 (2.7%)  | 8 (2.0%)   | 14 (2.2%)  | \( < 0.0001\) |
| Fertility awareness     | 4 (1.8%)  | 0 (0.0%)   | 4 (0.6%)   | \( < 0.0001\) |
| methods of contraception (Ogino method, cervical mucus, basal temperature) |                                                   |                                                   |       |              |
| Chemical methods of contraception (spermicide, eggs, suppositories, creams, gels) | 1 (0.5%) | 0 (0.0%) | 1 (0.2%) | \( < 0.0001\) |

†There are missing values (level of studies: two missing values; working status: four missing values).

IUD: intrauterine device; SD: standard deviation.

Fisher test. \( p \)-Value tested equality of distribution of characteristics in nulliparous and parous women.

Chi-squared test. \( p \)-Value tested equality of distribution of characteristics in nulliparous and parous women.

Mann–Whitney U-test.

\( p \)-values in bold indicate statistical significance.
Changes in menstrual bleeding pattern and satisfaction with it one year after LNG-IUD insertion

One year after LNG-IUD insertion, menstrual bleeding pattern had changed in a significant percentage of women. At the final visit, more women stated that their menstrual bleeding was less frequent (37.4% had amenorrhea), had lower quantity and duration, caused less pain, and interfered less with daily activities, despite a higher percentage of women experiencing irregular and intermenstrual bleeding compared to baseline (7.3% vs. 30.4%, respectively) \( (p < 0.0001) \) (Table 5).

Up to 88.7% of women were satisfied or very satisfied with their menstrual bleeding pattern at 12 months after insertion in comparison to 41.5% at baseline \( (p < 0.001) \), with no differences between nulliparous and parous women \( (p = 0.83) \) (Figure 3(A)) or between LNG-IUD chosen \( (p = 0.60) \) (Figure 3(B)). The percentage of women who were highly satisfied with their menstrual bleeding pattern at 12 months after insertion was higher in women who presented amenorrhea (96.1% of women highly satisfied) than in women with noticeable bleeding (84.3%, \( p = 0.0001) \).

Adverse events and discontinuation

Overall, 99 women notified AE during the study, and 68 of these were considered related to LNG-IUD (supplemental Table S4). The most common AEs were pain during the IUD insertion (24.2%), intermenstrual bleeding (18.2%) and pelvic pain (10.1%). Only 14 women (2.2%) discontinued due to AEs without relationship with parity, and there were 5 (0.7%) spontaneous expulsions. No uterine perforations were reported. The AEs reported that led to discontinuation were intermenstrual bleeding (6 women), dysmenorrhea (2 women), pelvic inflammatory disease (2 women), pelvic pain (1 woman), hemoperitoneum related to luteus haemorrhage (1 woman), acne (1 woman) and vasovagal syndrome (1 woman). Also, a serious AE (pregnancy with contraceptive device) was reported, although the physician indicated that the woman was probably pregnant prior to the LNG-IUD insertion.

Discussion

Findings and interpretation

This study reports high satisfaction rates with LNG-IUD among young Spanish women 12 months after insertion. This satisfaction is additionally supported by the fact that almost all participants would recommend IUD to peers. Satisfaction with LNG-IUD is not dependent on parity status, type of LNG-IUD used or menstrual bleeding pattern at baseline in women using LNG-IUD for contraception. Similarly, previous contraceptive method used and reason to choose an IUD do not seem to explain the level of satisfaction with IUD, except for women who highlighted the ‘risk of forgetting’ as the reason to choose a LNG-IUD. In contrast, satisfaction with LNG-IUD correlates with satisfaction with menstrual bleeding pattern 12 months after insertion.

Table 2. Characteristics of menstrual bleeding pattern at baseline according to parity status.

|                                | Parous | Nulliparous | Total | p-Value* |
|--------------------------------|--------|-------------|-------|----------|
| **Frequency of menstrual bleeding** |        |             |       |          |
| Frequent (<24 days)             | 16 (6.4%) | 29 (6.9%)   | 45 (6.7%) | 0.51**   |
| Normal (between 24 and 38 days) | 218 (87.6%) | 372 (89.0%) | 590 (88.5%) |          |
| Infrequent (>38 days)           | 15 (6.0%)  | 17 (4.1%)   | 32 (4.8%)  |          |
| **Regularity of menstrual bleeding** |        |             |       | 0.02**   |
| Regular                         | 216 (86.7%) | 386 (92.3%) | 602 (90.3%) |          |
| Irregular                       | 33 (13.3%)  | 32 (7.7%)   | 65 (9.7%)   |          |
| **Quantity of menstrual bleeding** |        |             |       | 0.05**   |
| Abundant‡                       | 59 (23.7%)  | 85 (20.3%)  | 144 (21.6%) |          |
| Normal                          | 171 (68.7%) | 276 (66.0%) | 447 (67.0%) |          |
| Low                             | 19 (7.6%)   | 57 (13.6%)  | 76 (11.4%)  |          |
| **Duration of menstrual bleeding** |        |             |       | 0.001**  |
| Extended (>8 days)              | 37 (14.9%)  | 31 (7.4%)   | 68 (10.2%)  |          |
| Normal (4–8 days)               | 179 (71.9%) | 299 (71.5%) | 478 (71.7%) |          |
| Short (<4 days)                 | 33 (13.3%)  | 88 (21.1%)  | 121 (18.1%) |          |
| **Menstrual pain**              |          |             |       | 0.13**   |
| No pain                         | 81 (32.5%)  | 109 (26.1%) | 190 (28.5%) |          |
| Mild pain                       | 104 (41.8%) | 173 (41.4%) | 277 (41.5%) |          |
| Moderate pain                   | 37 (14.9%)  | 86 (20.6%)  | 123 (18.4%) |          |
| Intense pain§                   | 22 (8.8%)   | 46 (11.0%)  | 68 (10.2%)  |          |
| Very intense pain‡              | 5 (2.0%)    | 4 (1.0%)    | 9 (1.3%)    |          |
| **Presence of intermenstrual bleeding** |     |           |    | 0.07**   |
| Yes                             | 23 (9.2%)   | 23 (5.5%)   | 46 (6.9%)   |          |
| No                              | 226 (90.8%) | 395 (94.5%) | 621 (93.1%) |          |
| **Interference with daily activities** |      |           |    | 0.74**   |
| Not at all                      | 139 (55.8%) | 219 (52.4%) | 358 (53.7%) |          |
| Slightly                        | 77 (30.9%)  | 137 (32.8%) | 214 (32.1%) |          |
| Moderately                      | 28 (11.2%)  | 49 (11.7%)  | 77 (11.3%)  |          |
| To a large extent               | 5 (2.0%)    | 13 (3.1%)   | 18 (2.7%)   |          |

*Those women who stated her quantity of menstrual bleeding as ‘abundant’ but had not been diagnosed with HMB met selection criteria.

‡Those women who stated her menstrual pain as ‘intense pain’ or ‘very intense pain’ but did not present a clinical history of severe dysmenorrhea, met selection criteria.

**Chi-squared test.

*p-Value tested equality of distribution of characteristics (i.e., frequency, regularity, quantity, and duration of menstrual bleeding; menstrual pain; presence of intermenstrual bleeding; and interference with daily activities at baseline) in nulliparous and parous women.

p-values in bold indicate statistically significance.
device insertion. Those women who present a more regular, shorter, less abundant and less frequent menstrual bleeding that causes less pain and daily interference show higher degrees of satisfaction with the device at 12 months, which was to be expected. Moreover, the percentage of women satisfied with their menstrual bleeding pattern after 12 months of using LNG-IUD was more than twice higher than at baseline (88.7% vs 41.5%). In this line, results from a multinational European survey showed that around 60% of women would like to reduce their bleeding frequency [27]. This high satisfaction with menstrual bleeding pattern was noticeable as soon as 4–12 weeks after LNG-IUD insertion. Finally, both women with noticeable menstrual bleeding and amenorrhoea reported to be highly satisfied with their menstrual bleeding pattern at 12 months after LNG-IUD insertion. This is remarkable since the intended use of the device was for contraceptive purpose, although menstrual bleeding changes are usually reported.

The drop-out rate in our study (16.8%) is similar to the previously reported by Stovall et al. (18.6%) [12], and was mainly caused by ‘loss to follow-up’ and ‘closure of the site’. AEs leading to discontinuation were uncommon (2.2% of women) and were not related to age or parity status, in agreement with previous studies [12]. Spontaneous expulsions in our study were very rare (0.7%), and no cases of uterine perforations were reported [28–30]. These findings show that LNG-IUD devices were well tolerated and safe for young women in our study.

Historically, IUDs have been underutilised in young population. According to ‘Survey on Contraception in
Spain, less than 50% of women <30 years old have been informed and offered the possibility to use LARCs, such as LNG-IUD, cooper IUD or implants, and among the youngest group (15–19 years old) the figure remains much lower (34.0%) [15], which suggests a lack of awareness of updated clinical guidelines that recommend first line option in adolescents [5,8]. Although between 2016 and 2020 the number of young women in Spain being

| Baseline menstrual bleeding pattern | High satisfaction $N = 509$ | Neutral satisfaction $N = 25$ | Low satisfaction $N = 17$ | p-Value* |
|------------------------------------|-------------------------------|-------------------------------|---------------------------|----------|
| Frequency of menstrual bleeding    |                               |                               |                           |          |
| Frequent (<24 days)               | 35 (6.9%)                     | 1 (4.0%)                      | 2 (11.8%)                 | 0.65**   |
| Normal (between 24 and 38 days)   | 448 (88.0%)                   | 22 (88.0%)                    | 14 (82.4%)                |          |
| Infrequent (>38 days)             | 26 (5.1%)                     | 2 (8.0%)                      | 1 (5.9%)                  |          |
| Regularity of menstrual bleeding  |                               |                               |                           |          |
| Regular                            | 459 (90.2%)                   | 22 (88.0%)                    | 14 (82.4%)                | 0.38**   |
| Irregular                          | 50 (9.8%)                     | 3 (12.0%)                     | 3 (17.6%)                 |          |
| Quantity of menstrual bleeding    |                               |                               |                           |          |
| Abundant                           | 108 (21.2%)                   | 5 (20.0%)                     | 2 (11.8%)                 |          |
| Normal                             | 341 (67.0%)                   | 18 (72.0%)                    | 14 (82.4%)                |          |
| Low                                | 60 (11.8%)                    | 2 (8.0%)                      | 1 (5.9%)                  |          |
| Duration of menstrual bleeding     |                               |                               |                           |          |
| Extended (>8 days)                | 50 (9.8%)                     | 2 (8.0%)                      | 1 (5.9%)                  | 0.89**   |
| Normal (4–8 days)                 | 363 (71.3%)                   | 20 (80.0%)                    | 14 (82.4%)                |          |
| Short (<4 days)                   | 96 (18.9%)                    | 3 (12.0%)                     | 2 (11.8%)                 |          |
| Menstrual pain                     |                               |                               |                           |          |
| No pain                            | 147 (28.9%)                   | 6 (24.0%)                     | 3 (17.6%)                 | 0.098**  |
| Mild pain                          | 224 (44.0%)                   | 7 (28.0%)                     | 5 (29.4%)                 |          |
| Moderate pain                      | 86 (16.9%)                    | 9 (36.0%)                     | 7 (41.2%)                 |          |
| Intense pain                       | 43 (8.4%)                     | 3 (12.0%)                     | 2 (11.8%)                 |          |
| Very intense pain                  | 9 (1.8%)                      | 0 (0.0%)                      | 0 (0.0%)                  |          |
| Presence of intermenstrual bleeding | 34 (6.7%)                      | 3 (12.0%)                     | 3 (17.6%)                 | 0.09**   |
| Not at all                         | 475 (93.3%)                   | 22 (88.0%)                    | 14 (82.4%)                |          |
| Slightly                           | 168 (33.0%)                   | 6 (24.0%)                     | 7 (41.2%)                 |          |
| Moderately                         | 50 (9.8%)                     | 4 (16.0%)                     | 2 (11.8%)                 |          |
| To a large extent                  | 14 (2.8%)                     | 1 (4.0%)                      | 0 (0.0%)                  |          |

**Chi-squared test.
*p-Value tested equality of distribution of characteristics (i.e., frequency, regularity, quantity and duration of menstrual bleeding; menstrual pain; presence of intermenstrual bleeding; and interference with daily activities) at baseline across the three levels of satisfaction.

Table 4. Satisfaction with LNG-IUD at 12 months according to menstrual bleeding pattern at 12 months.

| Menstrual bleeding pattern at 12 months | High satisfaction $N = 309 (100%)$ | Neutral satisfaction $N = 23 (100%)$ | Low satisfaction $N = 13 (100%)$ | p-Value* |
|-----------------------------------------|-------------------------------------|-------------------------------|---------------------------|----------|
| Frequency of menstrual bleeding         |                                     |                               |                           |          |
| Frequent (<24 days)                     | 15 (4.9%)                           | 4 (17.4%)                     | 3 (23.1%)                 | 0.02**   |
| Normal (between 24 and 38 days)         | 218 (70.6%)                         | 12 (52.2%)                    | 8 (61.5%)                 |          |
| Infrequent (>38 days)                   | 76 (24.6%)                          | 7 (30.4%)                     | 2 (15.4%)                 | <0.0001**|
| Regularity of menstrual bleeding        |                                     |                               |                           |          |
| Regular                                | 248 (80.3%)                         | 9 (39.1%)                     | 6 (46.2%)                 |          |
| Irregular                              | 61 (19.7%)                          | 14 (60.9%)                    | 7 (53.8%)                 |          |
| Quantity of menstrual bleeding          |                                     |                               |                           | 0.04**   |
| Abundant                                | 5 (1.6%)                            | 3 (13.0%)                     | 0 (0.0%)                  |          |
| Normal                                  | 40 (12.9%)                          | 6 (26.1%)                     | 4 (30.8%)                 |          |
| Low                                     | 264 (85.4%)                         | 14 (60.9%)                    | 9 (69.2%)                 |          |
| Duration of menstrual bleeding          |                                     |                               |                           | <0.0001**|
| Extended (>8 days)                      | 20 (6.5%)                           | 11 (47.8%)                    | 2 (15.4%)                 |          |
| Normal (4–8 days)                      | 77 (24.9%)                          | 6 (26.1%)                     | 6 (46.2%)                 |          |
| Short (<4 days)                         | 212 (68.6%)                         | 6 (26.1%)                     | 5 (38.5%)                 |          |
| Menstrual pain                          |                                     |                               |                           | <0.0001**|
| No pain                                 | 200 (64.7%)                         | 6 (26.1%)                     | 5 (38.5%)                 |          |
| Mild pain                               | 84 (27.2%)                          | 7 (30.4%)                     | 2 (15.4%)                 |          |
| Moderate pain                           | 21 (6.8%)                           | 6 (26.1%)                     | 5 (38.5%)                 |          |
| Intense pain                            | 4 (1.3%)                            | 3 (13.0%)                     | 1 (7.7%)                  |          |
| Very intense pain                       | 0 (0.0%)                            | 1 (4.3%)                      | 0 (0.0%)                  |          |
| Presence of intermenstrual bleeding     |                                     |                               |                           | 0.001**   |
| Yes                                     | 84 (27.2%)                          | 14 (60.9%)                    | 7 (53.8%)                 |          |
| No                                      | 225 (72.8%)                         | 9 (39.1%)                     | 6 (46.2%)                 |          |
| Interference with daily activities      |                                     |                               |                           | <0.0001**|
| Not at all                              | 278 (90.0%)                         | 7 (30.4%)                     | 5 (38.5%)                 |          |
| Slightly                                | 30 (9.7%)                           | 10 (43.5%)                    | 5 (38.5%)                 |          |
| Moderately                              | 1 (0.3%)                            | 5 (21.7%)                     | 2 (15.4%)                 |          |
| To a large extent                       | 0 (0.0%)                            | 1 (4.3%)                      | 1 (7.7%)                  |          |

**Chi-squared.
*p-Value tested equality of distribution of characteristics (i.e., frequency, regularity, quantity and duration of menstrual bleeding; menstrual pain; presence of intermenstrual bleeding; and interference with daily activities) at 12 months across the three levels of satisfaction with LNG-IUD.
p-values in bold indicates statistically significance.
offered a LARC increased significantly, 0% of women <25 years old reported being current users of LNG-IUD [15,31]. In Spain, the use of long lasting contraceptive methods is associated with both age and having children, with the higher number of users observed among women between 40 and 44 years old (9.2%) [15,32]. The observed low use in young women suggests that LARCs are more intended to limit pregnancies rather than delay or space them. Despite this low use in young population, data from the Contraceptive CHOICE Project indicated that dissatisfaction rates are not higher in this group than in other age groups, and that continuation rates of LARC also involves economic advantages. LARC methods of use results in lower costs to Spanish National Health System (SNHS), along with preventing a significant number of unintended pregnancies. Among LARC methods available in Spain, LNG-IUD and copper IUD are the most economic option [37].

Apart from clinical, social and reproductive benefits, use of LARC also involves economic advantages. LARC methods use results in lower costs to Spanish National Health System (SNHS), along with preventing a significant number of unintended pregnancies. Among LARC methods available in Spain, LNG-IUD and copper IUD are the most economic option [37].

### Strengths and weaknesses

As this is a real-world, non-interventional study, visits were conducted according to common clinical practice and women freely chose a LNG-IUD for contraception (after being adequately counselled by their physician). To ensure sample representativeness and reduce bias, centres were selected across Spain, and women were consecutively recruited.

To date, there are no satisfaction studies conducted with young women (18–25 years old) with all available type of LNG-IUD. Thus, the results of our study help to elucidate the factors that have an impact on satisfaction of young women with LNG-IUD, and can be useful for the gynaecologist to improve clinical counselling and help women to choose a contraceptive method. Receiving adequate counselling on contraception improves user satisfaction and continuation of the contraceptive method, in particular in

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**Table 5.** Characteristics of menstrual bleeding pattern at baseline, and 4–12 weeks and 1 year after IUD insertion.

| Presence of menstrual bleeding | Baseline N = 551 (100%) | 4–12 weeks after IUD insertion N = 507 (100%) | 12 months after IUD insertion N = 551 (100%) | p-Value* |
|--------------------------------|-------------------------|-----------------------------------------------|---------------------------------------------|----------|
| Amenorrhoea                    | 0 (0.0%)                | 96 (18.9%)                                    | 206 (37.4%)                                 | -        |
| Noticeable menstrual bleeding  | 551 (100.0%)            | 411 (81.1%)                                   | 345 (62.6%)                                 | 0.0001** |
| Frequency of menstrual bleeding|                          |                                               |                                             |          |
| Frequent (<24 days)            | 38 (6.9%)               | 80 (15.9%)                                    | 22 (4.6%)                                   | 0.0001** |
| Normal (between 24 and 38 days)| 484 (87.8%)             | 275 (66.9%)                                   | 238 (46.0%)                                 |          |
| Infrequent (>38 days)          | 29 (5.3%)               | 56 (13.6%)                                    | 85 (16.4%)                                  |          |
| Regularity of menstrual bleeding|                          |                                               |                                             |          |
| Regular                        | 495 (89.8%)             | 268 (65.2%)                                   | 263 (47.2%)                                 |          |
| Irregular                      | 56 (10.2%)              | 143 (34.8%)                                   | 82 (23.8%)                                  |          |
| Quantity of menstrual bleeding |                          |                                               |                                             |          |
| Abundant                       | 115 (20.9%)             | 9 (2.2%)                                      | 8 (2.3%)                                    |          |
| Normal                         | 373 (67.7%)             | 127 (30.9%)                                   | 50 (14.5%)                                  |          |
| Low                            | 63 (11.4%)              | 275 (66.9%)                                   | 287 (82.3%)                                 |          |
| Duration of menstrual bleeding |                          |                                               |                                             |          |
| Extended (>8 days)             | 53 (9.6%)               | 82 (20.0%)                                    | 33 (9.6%)                                   |          |
| Normal (4–8 days)              | 397 (72.1%)             | 153 (37.2%)                                   | 89 (25.8%)                                  |          |
| Short (<4 days)                | 101 (18.3%)             | 176 (42.8%)                                   | 223 (64.6%)                                 |          |
| Menstrual pain                 |                          |                                               |                                             | 0.001**  |
| No pain                        | 156 (28.3%)             | 242 (58.9%)                                   | 211 (61.2%)                                 |          |
| Mild pain                      | 236 (42.8%)             | 126 (30.7%)                                   | 93 (27.0%)                                  |          |
| Moderate pain                  | 102 (18.5%)             | 31 (7.5%)                                     | 32 (9.3%)                                   |          |
| Intense pain                   | 48 (8.7%)               | 8 (1.9%)                                      | 8 (2.3%)                                    |          |
| Very intense pain              | 9 (1.6%)                | 4 (1.0%)                                      | 1 (0.3%)                                    |          |
| Presence of intermenstrual bleeding |          |                                               |                                             |          |
| Yes                            | 40 (7.3%)               | 198 (48.2%)                                   | 105 (30.4%)                                 |          |
| No                             | 511 (92.7%)             | 213 (51.8%)                                   | 240 (69.6%)                                 |          |
| Interference with daily activities |                        |                                               |                                             | 0.001**  |
| Not at all                     | 299 (54.3%)             | 300 (73.0%)                                   | 290 (84.1%)                                 |          |
| Slightly                       | 181 (32.8%)             | 90 (21.9%)                                    | 45 (13.0%)                                  |          |
| Moderately                     | 56 (10.2%)              | 18 (4.4%)                                     | 8 (2.3%)                                    |          |
| To a large extent              | 15 (2.7%)               | 3 (0.7%)                                      | 2 (0.6%)                                    |          |

IUD: intrauterine device.

*Chi-squared.

*p-Value tested equality of distribution of characteristics (i.e., frequency, regularity, quantity and duration of menstrual bleeding; menstrual pain; presence of intermenstrual bleeding; and interference with daily activities) at baseline, at 4–12 weeks and at 12 months after LNG-IUD insertion.

p-values in bold indicates statistically significance.

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young women, since they may prefer to better understand benefits and side effects of their birth control outside of pregnancy prevention [38].

On the other hand, our study has some limitations that have to be taken into account. The most chosen LNG-IUD (82.2%) in both nulliparous (86.1%) and parous (75.5%) women was LNG-IUD 19.5 mg (Kyleena®). Currently, there are no specific recommendations for the contraceptive use of high- or low-dose LNG-IUD in different women populations, and studies that assess physicians’ and/or women preferences among different LNG-IUD devices are scarce [39,40]. Interestingly, a recent real-world prospective cohort study showed that women who were prescribed low-dose LNG-IUD (13.5 and 19.5 mg) were significantly younger, thinner, nulliparous and had lower number of vaginal deliveries and C-section than women who were prescribed high-dose LNG-IUD (52 mg) [40]. In our study, women were rather young, and most of them were nulliparous (62.7%). We hypothesise that physicians may have favoured the use of a LNG-IUD with small size (insert diameter 3.8 mm) in such a population because of ease of insertion. Moreover, women in our study may have preferred a LNG-IUD with a low hormonal dose, due to the perception that side-effects and influence on the bleeding pattern may be more limited with this device. In this sense, a multinational European survey investigating the reasons for choosing a contraceptive method found that absence of side effects, no influence on the cycle and absence or low concentration of hormones were considered important factors among women [39]. The longer duration of LNG-IUD 19.5 mg (5 years) as compared to LNG-IUD 13.5 mg can explain the unbalance of the sample distribution among the available low-dose LNG-IUD. Lastly, the lower use of LNG-IUD 52 mg (Mirena®) may be
explained because women with HMB and/or with a clinical history of severe dysmenorrhea had been excluded from the study per protocol. Regarding the use of LNG-IUD 52 mg (Levosert®), only three participants chose it because it was launched when study sample was almost completely recruited.

Our data show a high degree of satisfaction among young women irrespective of the type of IUD chosen; however, this result should be interpreted with caution. As discussed above, the vast majority of women, parous or nulliparous, chose for Kyleena® instead of for Mirena®, Jaydess® or Levonorsert®. This imbalance in group sizes hinders an accurate comparison between devices. Future studies that include more women for each type of IUD are needed to adequately compare satisfaction with different IUD.

The study is observational and does not allow causal relationships to be inferred. Besides, there might be confounding variables that might have not been taken into account. Finally, the primary outcome was based on a subjective opinion and personal experience that might be subjected to bias. However, use of validated scales (5-point Likert scale) ensures validity of the measurement.

Similarities and differences in relation to other studies

At 12 months, both nulliparous and parous participants showed a high rate of satisfaction with LNG-IUD without significant differences. In this line, high levels of user satisfaction regardless of parity status have been previously reported. Overall, 92.4% of women were satisfied or very satisfied with the LNG-IUD in our study. Previous publications have reported high satisfaction rates with similar figures, when LNG-IUD is used for contraception in different populations [11,12,29,41–45]. The rate of AEs (expulsions) are also comparable to those previously reported [12,29]. Finally, women reported high rates of satisfaction with menstrual bleeding pattern at 12 months with similar figures than those obtained in previous publications [22]. It should be noted that at 4–12 weeks after LNG-IUD insertion, up to 81.7% of women were satisfied/very satisfied with the device, a higher rate than those previously reported [12]. Specifically, satisfaction with LNG-IUD correlates with satisfaction of menstrual bleeding pattern 12 months after device insertion, specifically in those with amenorrhea (shorter, less abundant and less frequent menstrual bleeding). Thus, amenorrhea was mostly considered to be a positive menstrual change, as previously reported [46].

A real-world prospective study comparing satisfaction between different doses of LNG-IUD in Italy has been recently published [40]. Bastianelli et al. reported differences in menstrual bleeding pattern at last visit (mean time of approximately 9 months) between women using low-dose (13.5 and 19.5 mg) and high-dose (52 mg) LNG-IUD, with more amenorrhea in those using the high-dose LNG-IUD [40]. In our study, we observed similar satisfaction rates in women using low-dose and high-dose LNG-IUD, with both menstrual bleeding pattern at 12 months after insertion and with LNG-IUD contraceptive method. Similarly, Bastianelli et al. reported high and similar satisfaction rates with all LNG-IUD devices, irrespective of differences in final bleeding patterns [40].

Open questions and future research

This study shows that both satisfaction with LNG-IUD and satisfaction with menstrual bleeding pattern 12 months after IUD insertion in young women were high and independent of parity status. Discontinuation due to undesirable changes of menstrual bleeding or to adverse events was very low. These data can have an impact on counseling, and increase women preference for IUD, especially in young and nulliparous women. However, additional research to investigate the potential mid/long-term satisfaction should be conducted. It is important for the clinician to know which variables have more weight when evaluating long-term women’s satisfaction with the IUD in order to be able to give better advice.

Conclusions

This study shows that after 12 months of LNG-IUD use, young women reported high satisfaction rates with the device and good tolerability irrespective of parity status. Furthermore, women confirmed high rates of satisfaction with menstrual bleeding characteristics 12 months after LNG-IUD insertion. Finally, a correlation between satisfaction with LNG-IUD and satisfaction with menstrual bleeding pattern 12 months after device insertion was observed. The data obtained in the BERTA study provides further support for the suitability of LNG-IUD in nulliparous and young women.

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