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Research Article

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Evaluation of Gynecologist's and Patient's Experience, Anxiety and Pain Perception During Intrauterine Device Insertion Containing Levonorgestrel (ELA 52 Study)

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Abstract

Objective: *To characterize patient's and obstetricians-gynecologist's (ob-gyns) experience in insertion of a 52 mg levonorgestrel-releasing intrauterine device (LNG-IUD).*

Materials and Methods: *A non-interventional, prospective and multicentric study was conducted in 583 patient of reproductive age who had insertion of Levosert® following routine clinical practice. Questionnaires were used to collect information on ob-gyns' and patient's experiences associated with IUD insertion. Pain and anxiety were rated, and possible predictors such as age and parity were evaluated.*

Results: *Before IUD insertion, 50.8% of the participants felt minimal anxiousness and 44.9% predicted moderate pain. Two-hundred and sixteen (37.0%) patient reported mild pain with insertion and 227 (38.9%) reported moderate pain. Ob-gyns were aware of the patient's insertion pain experience and 84.2% considered LNG-IUD insertion "Easy" or "Very Easy". The vast*

majority of patient (88.2%) were also "Satisfied" or "Very Satisfied" with LNG-IUD insertion, considering the procedure less or at least equally painful as they expected.

Conclusions: *Given the strong link between anxiety and expected pain and the lack pain management strategies effectiveness, the implementation of interventions that may mitigate both anxiety and pain during IUD insertion are crucial. LNG-IUD is associated with high satisfaction rates by patient and considered easy to apply by ob-gyns.*

Keywords: Contraception, Intrauterine device, Satisfaction, Pain, Anxiety, Levonorgestrel.

Abbreviation List:

- LNG: Levonorgestrel
- IUD: intrauterine device
- Ob-gyns: Obstetricians-gynecologists.

Introduction

Levonorgestrel-releasing intrauterine device (LNG-IUD) is an effective, well tolerated, reversible and long-lasting method of contraception [1]. Levonorgestrel (LNG) induces cervical mucus thickening, preventing the passage of sperm, and promotes the endometrium thinning, which avoids the egg fixation [2]. Although the amount of LNG that goes into circulation is minimal, ovulation can be inhibited in some cycles [3].

LNG-IUD is associated with good patient satisfaction and therefore a higher willingness to continue using it [4]. A randomized study performed on 200 nulliparous women showed that only 20% of patient discontinued LNG-IUD one year after placement, indicating good acceptability [5]. Similarly, a study performed in adolescents and young adult patient aged between 18 and 22 years-old reported high overall satisfaction (76.8%) and 67.4% would recommend an IUD to a friend [6].

Despite these good indicators, IUDs are less used than oral contraceptives [7]. In fact, several studies report that a significant number of patient experience moderate to severe pain during IUD insertion. Suhonen et al. reported that the pain felt by nulliparous patient during IUD insertion was identified as mild to moderate in 64.9%, severe in 21.3% of the participants and only 13.8% of patient did not experience any pain [5]. Similarly, a non-interventional study showed that 9% nulliparous patients reported no pain and 72% reported moderate pain [8]. Among parous patient, the numbers are less expressive, and women with previous vaginal delivery are less likely to have pain classified as moderate or severe at insertion [9].

Pain is an unpleasant sensory and emotional experience that is perceived in a personal and unique way by each woman. Factors such as nulliparity, not currently breastfeeding and longer time since last pregnancy increases the likelihood of higher pain levels [10]. Additionally, cultural and personal differences, fear of pain and anxiety are also important aspects in pain perception [11, 12]. Patient with higher levels of anticipated pain prior to IUD insertion are more likely to have higher experienced pain during IUD insertion [11, 13]. Of note, the levels of pain are highly correlated with the odds of recommending an IUD to a friend [6]. Similarly, literature suggests that anxiety may also contribute to higher levels of perceived pain [14]. Several pharmacological interventions to reduce pain related to IUD insertion have been tested but there is no clear consensus on which strategy is the most effective [15, 16]. Hence, understanding patients' experiences during the procedure may improve counselling to address pre-procedure anxiety, plan therapy for modifiable aspects and ultimately enhancing health services' quality and acceptance.

This study aimed to assess patient anxiety and pain as perceived by the physician who insert the LNG-IUD (Levosert®, Gedeon Richter, Hungary) and the real anxiety and pain experienced by the patient, before and after placing the IUD. The correlation among several other variables such as age, parity or uterine position were evaluated. In addition, satisfaction of the participant with the IUD insertion procedure was examined.

Materials and Methods

Study Design

This was a non-interventional, prospective and multicentric study approved by an Ethics Committee and conducted in accordance with the Declaration of Helsinki. The study recruited 611 healthy patients, willing to have Levosert® insertion (52 mg of LNG) as part of their normal routine care. No additional diagnostic procedure was applied. Patients who fulfilled all the eligibility criteria were invited by their obstetricians and gynecologists (ob-gyns) to participate in the study and all patient signed a written informed consent form prior to their admission.

Study Population

Patients were eligible to enter the study if they were at least 16 years of age, were of reproductive age and were physically and psychologically able to participate in the study. Patient were excluded if they had any known adverse reactions to the active substance or to any of the excipients, have a known or suspected pregnancy, be affected by a known or suspected uterine or cervical malignant tumour or have current or history of pelvic inflammatory disease. Moreover, patients with lower genital tract infection, abnormal liver function or hepatic tumour, postpartum endometritis, abortion with infection in the last three months, cervicitis, or cervical dysplasia were excluded from the study. Patients with undiagnosed genital bleeding, a known or suspected hormone-dependent tumour; acute malignant diseases affecting the blood (except when in remission), recent trophoblastic disease if human chorionic gonadotropin levels remain elevated were also disqualified. The study also excluded patients with a current or recent history of drug or alcohol abuse, and participants with a serious illness, mental disorder or any other cause that could impact their participation.

Study Assessments and outcome measures

The present study used two questionnaires, one completed by the (ob-gyns) and the other by the patient at the time of LNG-IUD insertion.

The ob-gyn and patient questionnaire were divided into two parts, one to be filled out before IUD insertion and the other afterwards. For the ob-gyn questionnaire the first part identified the reasons for IUD insertion, the use of former contraceptives, the use of pain management strategies and the perception of the patient's anxiety in a four-points scale (0=no anxiety, 1=slightly anxious, 2=very anxious, 3= extremely anxious). The second part provided information about the ease of placement in a five-points scale, the patient's pain and identified the occurrence of uterine perforation, lipothymia or faints.

The patient questionnaire completed before IUD insertion assessed demographic variables including age, level of education, civil status and reproductive history variables such as the number of pregnancies, the use of former contraceptive methods and the reason for LNG-IUD insertion. The patient's predicted pain experience was indicated in a ten-points scale from none (0) to the worst pain possible (10), and to improve data analysis 4 categories were defined: no pain (0), mild pain (1 to 3), moderate pain (4 to 6), severe pain (7 to 9) and the worst pain possible (10). In addition, pre-procedure patient anxiety was described in a four-points scale (0=no anxiety, 1=slightly anxious, 2=very anxious, 3= extremely anxious). After IUD insertion, patients were asked if they felt faint during the procedure, to rate the level of pain they experienced in a ten-points scale from none (zero) to maximum (10) pain, and if insertion was easier or not than expected and patient's satisfaction with the procedure.

Statistical Analysis

Data analysis was performed with SPSS Statistics for Windows, IBM Corp., Version 21.0. (Armonk, NY). Continuous values were presented with mean and standard deviation (SD) and categorical variables were presented with frequencies and percentages. Normality of data distribution was done by Kolmogorov-Smirnov test. Fisher's exact test was used to compare categorical variables between groups and Spearman's rank-order correlation was used to verify correlations. All statistical tests were evaluated with a level of significance of 0.05.

Results

Study population

A total of 611 patients were screened for eligibility of which 583 (95.4%) were enrolled and completed the study. Three patients declined to participate and for the remaining 25 patient and ob-gyns' questionnaires were not pair matched.

A summary of the characteristics of the patients is presented in Table 1. The average age of the sample was 40 ± 7 years old. Half of the patients were aged between 40 and 49 (50.3%), 59.9% had a college degree, 63.1% were married and 64.0% were multiparous. The anteflexed uterine position was determined in 383 (65.7%) patient, 146 (25%) had the uterus in a neutral position and only 54 (9.3%) presented a retroflexed uterine position. The mean body mass index was 25.0 ± 4.6 and only a small percentage of patients (16.5%) were a smoker.

Table 1: Participant's socio-demographic characterization (n(%)).

Variables	Total Sample (N=583)
Mean age in years ± SD	39.8±6.8
Age group	
16-19	1 (0.17)
20-29	42 (7.2)
30-39	218 (37.4)
40-49	293 (50.3)
50-59	28 (4.8)
Level of education	
Elementary School	7 (1.2)
Middle School	132 (22.6)
Secondary School	85 (14.6)
Bachelor / Master's Degree	349 (59.9)
Doctoral Degree	10 (1.7)
Civil Status	
Single	58 (9.5)
Common Law	99 (17.0)
Marriage	368 (63.1)

Divorced	36 (6.2)
Widowed	6 (1.0)
Parity	
Nulliparous	42 (7.2)
Primiparous	160 (27.4)
Multiparous	364 (62.4)
Uterine position	
Anteflexed	383 (65.7)
Neutral Position	146 (25.0)
Retroflexed	54 (9.3)
BMI ± SD (kg/m2)	25.0 ± 4.6
Smokers	96 (16.5)
Previous contraceptive methods	
Combined oral contraceptive	192 (32.9)
IUD	182 (31.7)
Progestogen-only pill	67 (11.5)
Condoms	41 (7.0)
Other	101 (16.9)

In this study, 185 (31.7%) patients already used an IUD as a contraceptive method. The remaining participants' previous contraceptive methods were oral combined contraception (32.9%), progestogen-only pill (11.5%), condoms (7.0%) or other methods (16.9%) varying from natural ones to vaginal rings or transdermic adhesives.

From a physician's point of view, the main reason for IUD insertion was contraception (58.3%) followed by the combination of contraception and abundant menstruation (22.3%). Approximately half of the patient (49.9%) reported physician recommendation as the principal motivation for IUD placement. IUD conveniency (31.0%), efficacy (29.2%) and long-lasting effect (27.6%) were important characteristics pinpointed by patient to opt for this contraceptive method.

Pre-procedure anxiety and pain

Approximately half of the participants (50.8%) felt minimally anxious about the procedure. No anxiety was reported in 23.5% of participants and 4.9% described extreme anxiety. Ob-gyns perceived similar anxiety values with a strong relationship between ob-gyns and patient description (r=0.639, p<0.001) (Figure 1A). Ob-gyns considered that 25.4% of the patient were not anxious, 52.3% were minimally anxious, 18.3% were mildly anxious and 3.9% were extremely anxious.

Moderate pain (defined between 4 and 6 points in a ten-point scale) was predicted by 262 (44.9%) of the participants (Figure 1B). Additionally, 19 (3.3%) participants predicted no pain, 166 (28.5%) expected mild pain and 21 (3.6%) predicted the worst pain possible. Predicted pain levels were strongly positively correlated with patient's anxiety (r=0.508, p<0.001) and were inversely affected by age (r=-0.98, p<0.05).

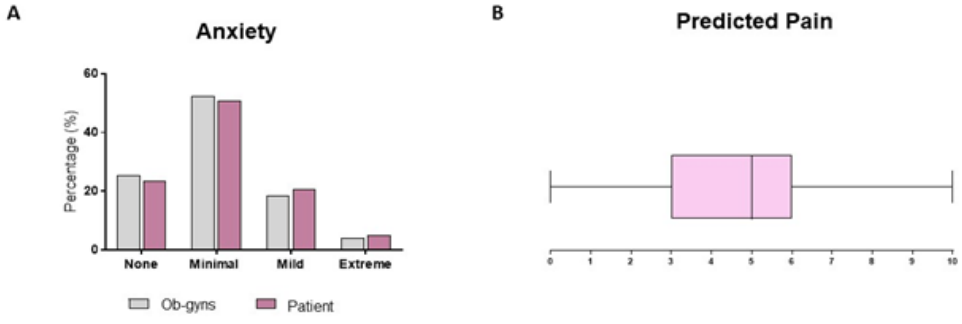

Figure 1: Pre-procedure anxiety reported by patient and ob-gyns. (A) Ob-gyns and patient reported similar values with a strong relationship (r=0.639, p<0.001). (B) Predicted pain was in average 4.76 ± 2.37 and it was heterogeneously distributed along ten-point scale.

No pharmacological pain management strategy before IUD insertion was given to 430 out of 583 (73.9%) patient who participated in this study (Table 2). The most used (10.6%) pre-procedure medications were non-steroid anti-inflammatory drugs (NSAIDs) followed by misoprostol (9.4%), antibiotics (2.2%), paracetamol (2.1%) and butilescopilamine (1.9%). During the procedure cervical anesthesia was administered to nine patients of which only one had also taken misoprostol. Previous medication mildly influenced the predicted pain ($r=0.172$, $p<0.001$) or patient anxiety ($r=0.122$, $p<0.001$). For patient who received pain relief interventions, the mean predicted pain was superior in comparison with those who did not take any medication (5.42 ± 2.17 versus 4.54 ± 2.39). Similar results were found for anxiety (1.22 ± 0.81 versus 1.02 ± 0.78).

Table 2: Pain management strategies.

No medication	**430 (73.9%)**
NSAIDs	**62 (10.6%)**
Misoprostol	**55 (9.4%)**
Butilescoplamine	**11 (1.9%)**
Antibiotics	**13 (2.2%)**
Paracetamol	**12 (2.1%)**

Experienced pain and associated factors

The mean experienced pain was moderate (6 ± 2). Similar percentages of mild and moderate pain were reported (37.0% and 38.9%, respectively). These values were in line with those predicted by patient ($r=0.372$, $p<0.001$) (Figure 2A) as well as with those assessed by doctors describing patient's pain ($r=0.676$, $p<0.001$) (Figure 2B).

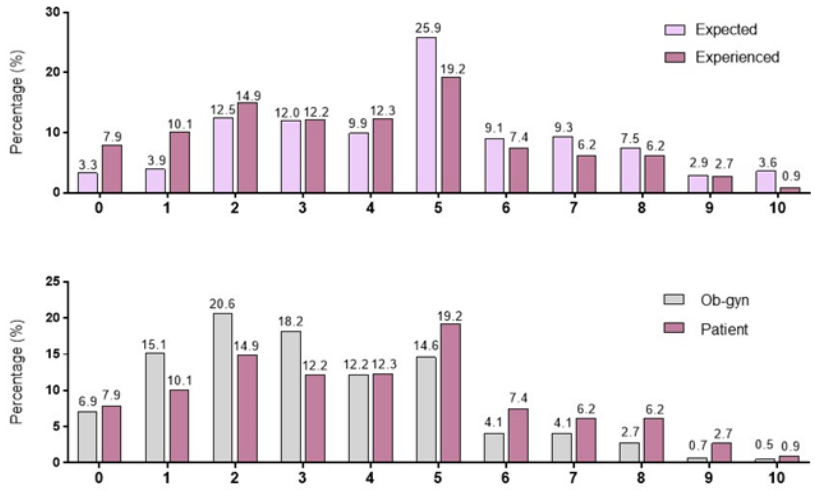

Figure 2: Distribution of experienced pain. Predicted pain scores were similar to (A) those anticipated by patient and (B) with those reported by clinicians.

In this study, anxiety significantly modulated the pain experience ($p<0.001$) with higher levels of anxiety contributing to higher pain levels (Table 3). Parity to a lesser extent, also significantly impacted pain experience ($p=0.034$). Nulliparous patient reported moderate and severe pain more often than parous patient (moderate: 44.5% versus 38.1% and severe: 28.9% versus 13.9%). In contrast, previous medication or IUD insertion and uterine position did not significantly impact the patient's experienced pain (Table 3).

Table 3: Experienced pain rated by patient and its associated factors. Ten-points scale rated pain was stratified into 5 categories: no pain (0), mild (between 1 to 3), moderate (4 to 6), severe (7 to 9) and the worst pain possible (10). Parity and anxiety were determined as important factors for the experienced pain during IUD insertion procedure.

	Experienced Pain					
	No (0)	Mild (1-3)	Moderate (4-6)	Severe (7-9)	Worst Pain Possible (10)	p-value*
Previous Medication						
Yes	11 (7.2)	49 (11.4)	65 (42.8)	26 (17.1)	1 (0.9)	0.532
No	36 (8.4)	167 (38.7)	162 (37.6)	62 (14.4)	4 (0.2)	
Parity						
Nulliparous	1 (2.2)	11 (24.4)	20 (44.5)	13 (28.9)	0 (0)	0.034
Primiparous	12 (7.3)	64 (38.8)	56 (33.9)	31 (18.8)	2 (1.2)	
Multiparous	33 (8.8)	142 (38.1)	151 (40.5)	44 (12.0)	5 (0.8)	
Uterine position+						
Anteflexed	27 (7.4)	131 (36.1)	139 (38.3)	62 (17.1)	4 (1.1)	0.056
Neutral Position	14 (9.6)	66 (45.2)	51 (34.9)	15 (10.3)	0 (0)	
Retroflexed	5 (8.2)	14 (23.0)	32 (52.5)	9 (14.8)	1 (1.6)	
Anxiety						
None	25 (18.2)	59 (43.1)	33 (24.1)	19 (13.9)	1 (0.7)	<0.001
Mild	19 (6.4)	113 (38.2)	132 (44.6)	31 (10.5)	1 (0.3)	
Moderate	1 (0.8)	34 (28.1)	54 (44.6)	32 (26.4)	0 (0)	
Extreme	1 (3.4)	11 (37.6)	8 (27.6)	6 (20.7)	3 (13.3)	
Previous IUD insertion						
Yes	32 (8.0)	148 (37.2)	161 (40.5)	56 (14.1)	1 (0.25)	0.135
No	14 (7.6)	69 (37.3)	66 (35.7)	32 (17.3)	4 (2.2)	

*p-value obtained by Fisher-exact test. +Thirteen answered were missing.

After IUD insertion, 253 (43.3%) of the patients described that the procedure was easier than expected, 232 (39.9%) that the procedure corresponded to that expected and the remaining 98 (16.9%) felt that the procedure was more painful than expected. During IUD insertion, ob-gyns described 14 situations of fainting while 33 patients reported light-headedness during or immediately after the procedure.

Overall satisfaction

Ob-gyns were asked to describe the ease of application of LNG-IUD. The vast majority of ob-gyns considered both IUD insertion and cervix passage (84.2% and 85.3%, respectively) as an "Easy" or "Very easy" procedure (Figure 3). Only 15.8% and 14.7% considered the procedure "Hard" or "Extremely Hard", respectively. The correct IUD insertion intrauterine position was only verified by ultrasound in 490 (84.0%). In the remaining 16% of patients no ultrasound was performed. Only one uterine perforation was reported.

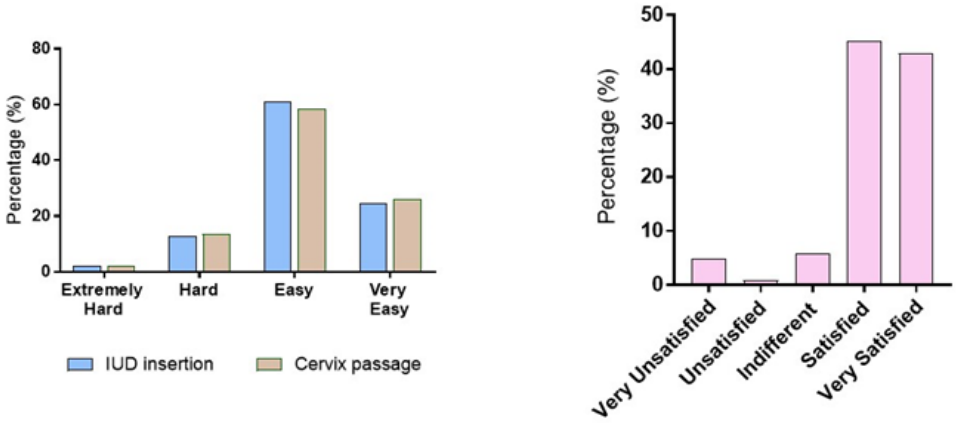

Figure 3: Overall Satisfaction. (A) Obstetricians-gynecologists reported that LNG-IUD was easy or very easy to insert and (B) patient reported elevated levels of satisfaction.

A very expressive number of patient (514, 88.2%) was also "Satisfied" or "Very Satisfied" with the placement of the LNG-IUD. Only 6% were "Unsatisfied" or "Very Unsatisfied". Interestingly, higher satisfaction levels were supported by lower experienced pain levels ($r=-0.261$, $p<0.001$) and with lower pain expectation associated with IUD insertion ($r=0.241$, $p<0.001$) (Table 4).

Table 4: Higher satisfaction levels are associated with LNG-IUD. Satisfaction with IUD was deeply correlated with experienced pain and pain expectation.

	Satisfaction					
	Very Unsatisfied	**Unsatisfied**	**Indifferent**	**Satisfied**	**Very Satisfied**	**p-value***
Pain expectation						
Easier	15 (5.9)	0 (0)	10 (3.9)	89 (35.2)	139 (54.9)	<0.001
Equal	9 (3.9)	0 (0)	8 (3.4)	119 (51.2)	96 (41.4)	
Harder	7 (7.1)	3 (3.1)	16 (16.3)	56 (53.1)	16 (20.4)	
Experienced Pain						
None	5 (10.9)	0	0	5 (10.9)	36 (76.1)	<0.001
Mild	13 (6.0)	0	5 (2.3)	90 (41.5)	109 (50.2)	
Moderate	7 (3.1)	0	15 (6.6)	119 (52.4)	86 (37.9)	
Severe	6 (6.8)	3 (3.4)	13 (14.8)	48 (54.5)	18 (20.4)	
Worst Pain Possible	0	0	1 (20)	2 (40)	2 (40)	

*p-value obtained by Fisher-exact test.

Discussion

IUD use is low among patient, in part due to fear of pain and discomfort associated with the insertion procedure [6, 17]. Although pain control is essential for increasing the quality of health care, little effective options exist regarding pain management in IUD insertion. Thus, characterizing ob-gyns and patient experience in IUD insertion will enable better strategies to mitigate both anxiety and pain to be developed and implemented.

In this study, most patient reported mild to moderate pain associated with IUD insertion regardless of the use of pre-procedure medication. Patient who experienced higher pain levels according to their pain scores described elevated pre-procedure anxiety and predicted pain. A large project which analysed 1,149 patient receiving an IUD also reported that for each increasing point in the level of anticipated pain on a 10-point scale, the likelihood of experiencing significant pain during the procedure was 19% greater [11].

Previous painful examinations, feedbacks and knowledge of IUDs may actually influence a patient's reaction [18, 19]. Although in this study patient with previous IUD use did not report lower pain levels, parity was significantly correlated with pain levels. The correlation found was weak which may derive from the large representation of parous patient in comparison with nulliparous. Other clinical studies have strongly correlated parity and pain scores [12]. Similarly, our sample was largely composed of highly educated and adult patient rather than adolescents or young adults which may hinder possible relationships among these variables.

Interestingly, uterine position seems to be related with pain scores. Although not statistically significant, patient with neutral uterine position were less likely to rate their pain as moderate and none scored their experienced pain as the "worst pain possible". A previous study also failed to relate pain and uterine position [20]. However, the assessment of uterine position prior to IUD insertion is always recommended so that pain may be minimized [21].

In contrast with previous studies, ob-gyns were accurate in their anxiety and pain observations [22, 23]. They were sensitive to the patients' experience and did not underestimate the degree of experienced pain during IUD insertion procedures. Of note, participants reporting higher pain levels were counselled by ob-gyns to take pre-procedure medication. Due to the lack of orientations and effectiveness of pharmacological pain management strategies, proper counselling before IUD insertion may have benefits for both patient and clinician. Psychological preparation, a clear description of what is to be expected during IUD insertion and demystification of some associated ideas should reduce the patient's expectation of pain. Additionally, ob-gyns should assess a patient's needs and decide appropriate pre-procedure interventions, such as anxiolytic medication if warranted.

The patient who participated in this study were in their majority "Satisfied" or "Very Satisfied" about the insertion which reinforces the high acceptability of LNG-IUD (Levosert®). Furthermore, this study showed that patient satisfaction was intimately supported by the experienced pain levels and pain expectation. Ob-gyns considered LNG-IUD (Levosert®) application easy or very easy, highlighting the feasibility of insertion.

The strengths of our study include matching ob-gyns and patient questionnaires before and after IUD insertion, avoiding recall bias and constraints. However, this was an overall 40-year-old population with high educational levels and parous patient, limiting the association of possible predictors. Only 52 mg LNG-IUD (Levosert®) was studied and therefore anxiety and pain levels may not be generalizable to other IUD types.

Conclusion

Expected pain and pre-procedural anxiety strongly affected experienced pain during IUD insertion. Ob-gyns are aware of patient's pain levels; however, the lack of effective pain management strategies hinders the possibility to minimize that. High overall satisfaction with the LNG-IUD insertion was verified both for physician and patient, validating the use of this device as a long-acting, reversible contraceptive or for the treatment of heavy menstrual bleeding. Future research should evaluate other interventions to improve the IUD insertion experience.

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Conflict of interest statement

Daniel Pereira da Silva is a Medical Advisor of Gedeon Richter Portugal. The remaining authors have no conflict of interest in relation to this article to disclose.

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