

Article

Copper intrauterine device insertion in patients at a teaching hospital: analysis of women's sociodemographic profile and pain assessment during the procedure

Inserção de dispositivo intrauterino de cobre em pacientes de um hospital de ensino: análise do perfil sociodemográfico das mulheres e avaliação da dor no procedimento

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Miranda CS, Caneschi GLT, Souza CR, Lopes LA, Freire NSA, Marzullo Filho U. Copper intrauterine device insertion in patients at a teaching hospital: analysis of women's sociodemographic profile and pain assessment during the procedure / *Inserção de dispositivo intrauterino de cobre em pacientes de um hospital de ensino: análise do perfil sociodemográfico das mulheres e avaliação da dor no procedimento*. Rev Med (São Paulo). 2025 Jan-Feb;104(1):e-227876..

ABSTRACT: Introduction: The intrauterine device (IUD) is one of the most effective contraceptive methods. However, many women have concerns regarding the pain experienced during insertion¹. Studies have associated pain intensity with sociodemographic and clinical variables²⁻⁴. **Objective:** To analyze the relationship between clinical and sociodemographic profiles of women undergoing IUD insertion and their reported pain. **Methods:** This was a cross-sectional observational study approved by the Ethics and Research Committee under number 5,606,733. Data were collected from September 2022 to July 2023 at a public hospital in Juiz de Fora, Brazil. Women of childbearing age with negative Beta HCG were recruited, while those with proven uterine anatomical abnormalities were excluded based on examinations. The participants signed an Informed Consent Form prior to the procedure, and subsequently completed a questionnaire about their clinical and sociodemographic profiles. After insertion, they recorded their perceived pain on a visual analog scale. **Results:** Pain perception among the 52 study participants was associated with marital

status, age at sexual debut, parity, and history of painful procedures. Unmarried women, those who initiated sexual activity between 16 and 18 years old, nulliparous women, or those without prior painful procedures (surgeries and/or childbirths) reported more intense pain. No statistically significant association was observed between pain perception and variables such as age group, ethnicity, income, contraceptive method use, fear of IUD placement, or prior analgesia. Furthermore, there was a statistically significant positive correlation between pain perception and the intensity of cramps, indicating that higher cramp intensity correlated with greater pain perception during IUD insertion. **Conclusion:** The pain intensity experienced during IUD insertion was associated with certain study variables, enabling to characterize patient profiles. However, further studies are needed due to limitations imposed by the small sample size.

KEY WORDS: Intrauterine Devices; Pain; Pain Measurement.

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RESUMO: Introdução: O dispositivo intrauterino (DIU) é um dos métodos contraceptivos mais eficientes. Todavia, muitas mulheres têm receio em relação à dor sentida na inserção¹. Estudos têm associado intensidade da dor com variáveis sociodemográficas e clínicas²⁻⁴.

Objetivos: Analisar a relação entre perfil clínico e sociodemográfico das mulheres submetidas à inserção de DIU e a dor reportada por elas.

Métodos: Estudo observacional transversal aprovado em Comitê de Ética e Pesquisa número 5.606.733. Os dados foram coletados nos meses de setembro de 2022 a julho de 2023 em um hospital público de Juiz de Fora. Foram recrutadas mulheres em idade fértil com Beta HCG negativo e excluídas aquelas com anormalidade anatômica uterina comprovada por exames. Previamente ao procedimento, elas assinaram Termo de Consentimento Livre e Esclarecido e responderam questionário sobre seu perfil clínico e sociodemográfico. Após a inserção, registraram a dor percebida em uma escala visual analógica. **Resultados:** Para as 52 participantes da pesquisa, a percepção de dor mostrou-se associada com as variáveis estado civil, início da vida sexual, gestação e histórico de

procedimentos dolorosos. Mulheres solteiras, com início da vida sexual entre 16 e 18 anos, sem filhos ou histórico de procedimentos dolorosos prévios (cirurgias e/ou partos) relataram dor mais intensa. Para as variáveis faixa etária, etnia, renda, uso de método contraceptivo, receio de colocação do DIU e analgesia prévia não foi observada associação estatisticamente significativa com a dor. Ademais, houve correlação estatisticamente significativa e positiva entre a percepção de dor e a intensidade das cólicas, evidenciando que quanto maior a intensidade das cólicas, maior a percepção de dor no procedimento de inserção do DIU. **Conclusão:** A intensidade da dor sentida durante a inserção do DIU foi associada com algumas variáveis do estudo, permitindo traçar um perfil das pacientes. Porém, novos estudos são necessários, dadas as limitações impostas pelo pequeno tamanho amostral.

PALAVRAS-CHAVE: Dispositivos Intrauterinos; Dor; Medição da Dor.

INTRODUCTION

Intrauterine devices (IUDs) are efficient, safe and long-lasting contraceptive methods which can be classified as hormonal or non-hormonal^{1, 5}. These devices can be used at any age during the reproductive period, without the need for daily intervention by the woman and without compromising future fertility². Despite their advantages, only 1.1% of women with steady partners opt for the IUD in Brazil, with tubal ligation surgery being the most commonly used method (40%), followed by birth control pills (20%)¹.

One explanation for the low adherence to IUD use is the fear that most women have regarding the pain felt during the device's insertion⁶. Procedures that can cause pain during IUD insertion are: use of the tenaculum to hold the cervix and change its position, uterine sounding, IUD insertion through the cervical os, and irritation of the endometrial cavity⁷.

Previous studies have shown that sociodemographic and clinical variables have been associated with pain intensity at the time of IUD insertion²⁻⁴. A clinical history of dysmenorrhea was shown to be an important predictor among nulliparous women, increasing the risk of reporting severe pain at the time of the procedure by 36%. Furthermore, considering the patient's clinical history, previous cesarean sections and nulliparity were also related to higher pain scores^{2,5}.

In addition, age and race were identified as relevant predictors regarding the sociodemographic profile. These factors were notably related to greater expression of anticipated pain, which is another important variable that greatly influences studies on the subject. Thus, an increase in anticipated pain is associated with an increase in perceived pain during IUD insertion, especially in black adolescent women⁴.

Similarly, other psychological and behavioral aspects, such as pre-procedure anxiety and negative prior perceptions about the IUD, had a significant impact on the results². According to a review by Lopez et al. (2015)⁷, most women experience mild to moderate discomfort during insertion of the device, but rarely severe pain⁷. However, most studies to date in the literature aim to provide recommendations on pharmacological analgesic and anesthetic interventions.

Nevertheless, there is still an obstacle in determining the main characteristics that influence the intensity of perceived pain during IUD insertion. It is also worth noting that few previously published studies have discussed the association between profile and pain without performing analgesic and anesthetic pharmacological interventions. In view of the above, the objective of this study was to analyze the relationship between the clinical and sociodemographic profile of women undergoing copper IUD insertion and the pain reported during the procedure, performed in a hospital in Juiz de Fora, Brazil.

METHODS

A cross-sectional observational study approved by the Research Ethics Committee under number 5,606,733 was conducted which characterized patients who were candidates for IUD insertion using a clinical and sociodemographic profile form. Data were collected from September 2022 to July 2023 at a public hospital in Juiz de Fora, Brazil. The women selected to participate in the study were patients of this hospital who wanted to have a copper IUD inserted and scheduled the procedure at the family planning outpatient clinic. Candidates for IUD insertion previously underwent Beta-HCG and transvaginal ultrasound to rule out pregnancy and uterine anatomical abnormalities and/or any conditions that contraindicated IUD insertion.

After explaining the study objectives prior to the procedure and reinforcing that participation was free, each participant was given a questionnaire and an Informed Consent Form to sign. The participants answered the questionnaire about their clinical and sociodemographic profile, consisting of 23 multiple-choice questions, namely: age, ethnicity, marital status, monthly family income, education, current professional activity, age at menarche, presence of menstrual cramps, intensity of cramps, age at sexual debut, active sexual life, use of contraceptive method in the last 6 months, contraceptive method used, pregnancy, number of pregnancies, number of normal births, number of cesarean sections, abortion, number of miscarriages, and STIs in the last 12 months. Next, five statements were asked in addition to the questions about the sociodemographic profile using a Likert scale to assess the patient's knowledge about the procedure: "insertion

of the IUD is uncomfortable for the woman”; “the IUD is an abortive contraceptive method”; “a woman has difficulty getting pregnant after removal of the IUD”; “the partner feels the IUD during sexual intercourse”; “the IUD increases the risk of uterine cancer”; and “the IUD causes many unpleasant side effects”.

The IUD insertion was performed following a standardized protocol to ensure safety and efficacy of the procedure. The steps were conducted by trained professionals in an outpatient setting. The procedure began with a bimanual examination to assess the uterus position and mobility, followed by inserting a vaginal speculum to expose the cervix. After this, the region was aseptically cleaned and the anterior lip of the cervix was clamped with a Pozzi clamp to stabilize and align the cervical canal. Then, the uterine cavity depth was measured using a hystrometer, and the IUD was inserted and positioned in the uterine body to the depth previously determined by hystrometry. Finally, the insertion tube was removed and the threads were cut approximately 2 to 3 centimeters from the cervix. All of the procedure steps were performed in accordance with clinical guidelines and the manufacturer’s recommendations.

The patient received the questionnaire again after the procedure to answer two more questions (whether she had received analgesia prior to the procedure and what medication was used), and to assess the pain felt during insertion using a visual analogue scale (VAS) (“no pain”, “mild”, “moderate” or “severe”). The questionnaire was prepared for this study by the researcher with the aim of verifying the relationship between the women’s profile and pain during the IUD insertion procedure and correlating them with the outcome of the present study.

Statistical analysis

Descriptive statistics were performed using the mean and standard deviation (minimum – maximum) for quantitative variables and frequencies and percentages for categorical variables. The Chi-Squared (χ^2) test was used to test the association between categorical variables. The effect size (ES) was assessed by Cramer’s V, adopting the following classification: small < 0.30; medium < 0.50; large \geq 0.50 (Cohen, 1992). The correlation between pain perception and cramp intensity was assessed by Spearman’s correlation test. The analyses were performed using IBM SPSS software (IBM SPSS Statistics, version 22.0; IBM Corporation). A p-value < 0.05 was adopted for statistical significance⁸.

RESULTS

The sociodemographic characteristics of the sample are presented in Table 1. Most women were between 25 and 34 years old, were single, earned 1 minimum monthly salary and had completed high school. The sample was equally distributed between white, mixed race and black regarding ethnicity. Most women had an employment relationship, with 36.5% having a formal employment contract in the private sector, 9.6% being domestic workers, 7.7% public servants, 5.8% without a formal employment contract in the private sector and 7.7% having other employment relationships; in addition, 17.3% reported being self-employed and 15.4% being unemployed.

TABLE 1 - Sociodemographic characteristics of the sample (n = 52)

Variables	n	%
Age range		
18 to 24 years	10	19.2%
25 to 29 years	18	34.6%
30 to 34 years	14	26.9%
35 to 39 years	8	15.4%
\geq 40 years	2	3.8%
Ethnicity		
White	18	34.6%
Brown	17	32.7%
Black	17	32.7%
Civil status		
Single	29	55.8%
Married	21	40.4%
Divorced/others	2	3.8%
Income		
< 1 minimum monthly salary	2	3.8%
1 minimum monthly salary	27	51.9%
2 to 3 minimum monthly salaries	19	36.5%
4 to 6 minimum monthly salaries	4	7.7%
Education		
Elementary	7	13.5%
High school	27	51.9%
Higher education	18	34.6%

Most patients had their menarche between 10 and 12 years of age and initiated their sexual life between 16 and 18 years of age. Most patients currently had an active sexual life and used some contraceptive method. Patients reported feeling cramps with an average intensity of 4.0 on a scale of 0 to 10

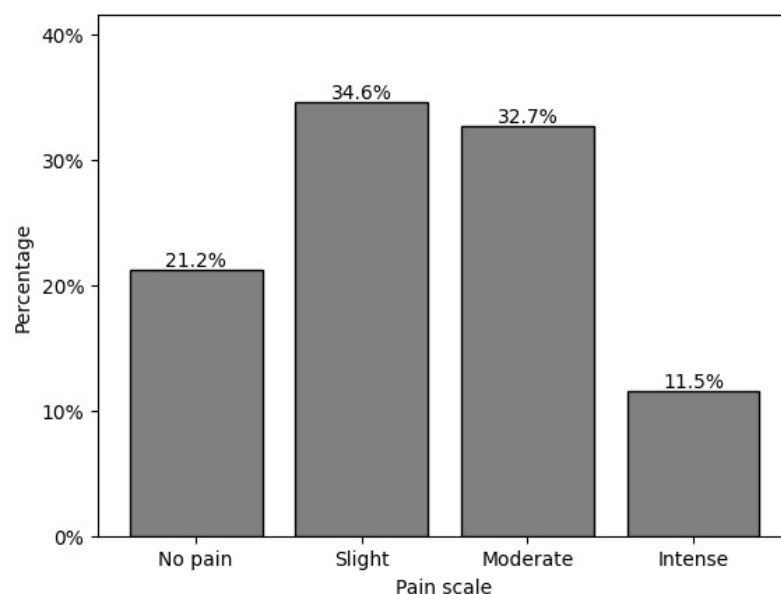
(Table 2). Regarding pregnancy, 40 patients (76.9%) had at least one pregnancy, 67.5% of which had normal delivery and 20.0% of them had miscarriages. One patient reported having had a sexually transmitted infection in the last 12 months and one patient stated that she did not know.

TABLE 2 - Characteristics of the sample in relation to aspects of sexual life (n = 52)

Variables	Mean \pm SD n	Minimum – Maximum %
Age at menarche		
< 10 years	3	5.8%
10 to 12 years	31	59.6%
13 to 15 years	17	32.7%
> 15 years	1	1.9%
Menstrual cramps (intensity)	4.0 \pm 3.0	0.0 – 10.0
Sexual life debut		
< 15 years	18	34.6%
16 to 18 years	27	51.9%
19 to 21 years	6	11.5%
22 to 24 years	1	1.9%
Active sexual life (yes)	49	94.2%
Use of contraceptive method		
None	19	36.5%
Birth control pill	19	36.5%
Injectable contraceptive	6	11.5%
Condom	4	7.7%
IUD	3	5.8%
More than one method	1	1.9%

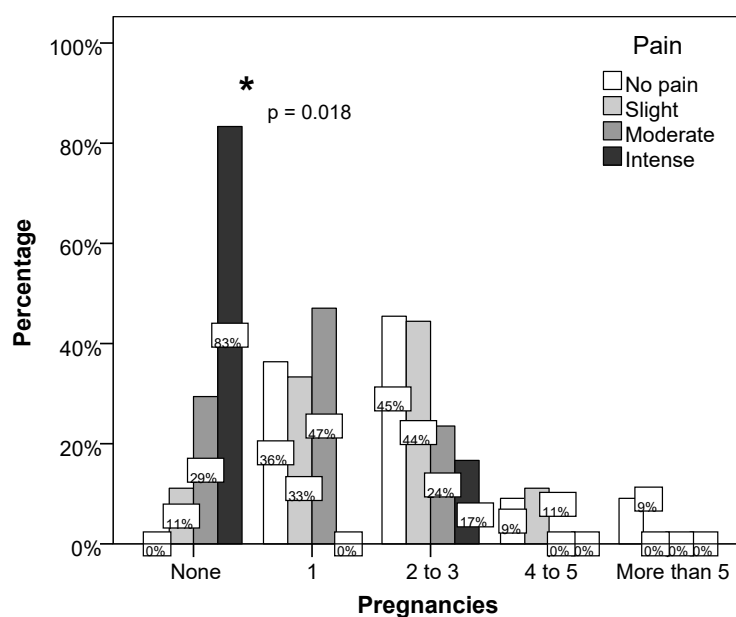
Figure 1 shows that approximately 8 out of 10 women felt some pain after the IUD insertion procedure. A statistically significant association was found between pain perception and the number of pregnancies ($\chi^2 = 24.439$; $p = 0.018$; $V = 0.40$) (Figure 2). Most of the women who reported intense pain did not have pregnancies. From a clinical point of view, the observed

effect size was moderate. In addition, a positive and statistically significant correlation was found between pain perception and cramping intensity ($r = 0.29$; $p = 0.036$; $n = 52$). This means that the greater the cramping intensity, the greater the pain perception during the IUD insertion procedure. From a clinical point of view, the effect size of this correlation was small.

FIGURE 1 - Classification of pain perception after IUD insertion procedure (n = 52)

When stratifying the sample according to pain level, it was found that pain perception was associated with the following variables: marital status, sexual activity debut and history of painful procedures (Table 3). Women who reported some pain during the IUD insertion procedure were single, had started their sexual activity between 16 and 18 years of age, and

had no history of previous painful procedures. From a clinical point of view, the effect size observed for this association was moderate. No association was observed between pain and the other variables, namely: age, ethnicity, active sexual activity, type of delivery, abortion, age at menarche, use of contraceptive method, fear of IUD insertion and previous analgesia ($p > 0.05$).

FIGURE 2 - Association between number of pregnancies and pain perception after IUD insertion procedure (n = 52)**TABLE 3** - Variables associated with pain during copper IUD insertion

Explanatory variables	Pain		p-value	ES
	No pain (n = 11)	Pain (n = 41)		
Civil status			0.037*	0.40
Single	4 (36.4%)	25 (61.0%)		
Married	5 (45.5%)	16 (39.0%)		
Divorced	1 (9.1%)	0 (0.0%)		
Others	1 (9.1%)	0 (0.0%)		
Sexual life debut			0.048*	0.39
< 15 years	6 (54.5%)	12 (29.3%)		
16 to 18 years	2 (18.2%)	25 (61.0%)		
19 to 21 years	3 (27.3%)	3 (7.3%)		
22 to 24 years	0 (0.0%)	1 (2.4%)		
History of painful procedures			0.012*	0.46
None	3 (27.3%)	23 (56.1%)		
Surgery	3 (27.3%)	4 (9.8%)		
Childbirth	3 (27.3%)	14 (34.1%)		
Surgery and Childbirth	2 (18.2%)	0 (0.0%)		
Fear of IUD insertion			0.25	0.16
Yes	3 (27.3%)	19 (46.3%)		
No	8 (72.7%)	22 (53.7%)		
Prior analgesia			0.84	0.03
Yes	5 (45.5%)	20 (48.8%)		
No	6 (54.5%)	21 (51.2%)		

ES: effect size assessed by Cramer's V; *represents p-values <0.05 by the Chi-Squared test

DISCUSSION

Most of the participants in the present study characterized the pain as mild or moderate. These results are similar to those observed in a study which compared the participants' experience with the impressions of the professionals who performed the procedure⁹. Mild pain and minimal or no discomfort were reported by most women. However, this and other analyses identified a flaw in the professionals' perception of the pain felt by their patients, who saw it as being of lesser intensity than was actually reported^{9,10}. These results should be considered by physicians before, during, and after IUD insertion, influencing how they will deal with factors such as patient anxiety and pre-procedure fear⁹. In contrast, all of the participants in an analysis performed with 165 nulliparous women reported pain during insertion, the majority of which was severe¹⁰. These results are related to the findings of our study, which identified nulliparity as one of the main variables related to pain. Previous studies have associated nulliparity with higher pain scores¹¹⁻¹⁵. Furthermore, being nulliparous increased the risk of a woman experiencing moderate/severe pain by 3 times¹⁵.

Our analyses regarding the delivery mode do not resemble most of the results found in previous studies. Cesarean section was associated with higher levels of pain², and vaginal delivery with lower levels^{5,16}. Pain was reported as more intense⁵ even among women who had a cesarean section who had gone into labor and had some level of cervical dilation. In contrast, our study showed no statistically significant difference in the discomfort felt by women who had a cesarean section and those who had a vaginal delivery. These differences may be related to the small sample size used in our investigation. However, a clinical trial which aimed to evaluate pain during insertion of the levonorgestrel-releasing intrauterine system (LNG-IUS) and its relationship with parity and delivery type showed no significant difference in the mean score between nulliparous and multiparous women and women with and without cesarean section. However, as the LNG-IUS was used, this may have influenced the result.

Dysmenorrhea was an important variable investigated in our study. The perception of pain during the IUD insertion procedure was greater among patients with a history of dysmenorrhea, which is similar to findings from previous studies¹⁰⁻¹². A randomized controlled clinical trial demonstrated that this variable was an important predictor of the outcome, especially among nulliparous women, increasing the risk of reporting severe pain by 36%. However, it was performed with an LNG-IUS, while our study used a copper IUD. This factor may have influenced the results found. Dysmenorrhea was also described as the only predictor of intolerable pain in one of the studies analyzed.¹⁰

Also corroborating our findings which showed no statistical difference between fear of IUD insertion and increased pain, a randomized controlled clinical trial⁹ observed no significant differences between anxiety before the procedure and the painful sensation described later. In a prospective cohort², women undergoing cesarean sections who presented pre-procedure anxiety and a negative perception of the IUD felt

more pain during insertion. However, the presence of negative perceptions about the IUD appeared to be the most significant predictor of pain for other authors, so that inaccurate knowledge, myths and misperceptions regarding this contraceptive method may affect the results¹².

In an attempt to evaluate the relationship between prior information and reported pain, another study sought to increase patients' understanding before IUD insertion through video-assisted information. As a result, pain levels measured by VAS after this intervention were significantly lower in the group which had access to the information, although no reducing effect on anxiety was observed¹⁷.

Our study did not find a statistically significant relationship with pain for the variables age and education, as described in the literature^{11-14,17,18}. It is suggested that women of all reproductive ages seem to tolerate the IUD equally¹³. Sociodemographic factors such as race and age have previously been described as having little influence on the results¹⁹, which was also verified in our study.

The present analysis also evaluated the relationship between the use of pre-procedure analgesic medication and pain intensity. Some of the participants used non-steroidal anti-inflammatory drugs (NSAIDs), and no statistically significant difference was found in reduction of discomfort. Similarly, existing research to date indicates little influence of pre-procedure pharmacological measures in reducing pain^{7,14,15,16,20}. Published results^{7,15} showed that non-steroidal anti-inflammatory drugs, misoprostol and 2% lidocaine are not effective for this purpose. These conclusions may reveal the multifactorial nature of the pain experienced during the procedure¹⁷. Individual tolerance, anatomical differences, genetics, subjective perceptions, and the professional's skills in inserting an IUD may be important variables for such analysis²¹.

For some authors, there is still no evidence that prophylactic use of any analgesic is necessary²¹. In this same study, prophylactic ibuprofen did not affect the pain level. Furthermore, not even paracervical block was able to present significant results in this regard¹⁴. These conclusions point to the need to research effective measures to relieve the painful sensation during the IUD insertion procedure in order to provide more comfort and greater adherence to this method.

Despite the results being consistent with the literature, our study had some limitations. The small sample size may have influenced the results and their applicability. In addition, different professionals were responsible for inserting the IUD, so the technique, skill, and experience of the physician may have interfered with the patient's pain perception. Furthermore, our results, obtained from the experience with copper IUDs, were also compared with the results of LNG-IUS users, which may lead to less accurate interpretation of the results. According to some authors, less pain was associated with the copper IUD than with the LNG-IUS, which may be related to the different insertion methods between these devices and the larger diameter of the LNG-IUS^{11,12}.

CONCLUSION

In conclusion, our study showed that most women

reported some pain level during insertion, with mild to moderate pain being the most common. Dysmenorrhea and nulliparity were the variables most strongly associated with greater pain intensity. Furthermore, the perception of some pain level was positively associated with marital status, sexual initiation and

history of painful procedures. Given this scenario, knowing the profile of patients most prone to discomfort during IUD insertion can help to consider different strategies for conducting the procedure and researching more effective alternatives for pain relief.

Authors' participation in the text: The authors of this publication contributed in the following ways: Carolina Silva Miranda: research planning, search for sources in the scientific literature, data collection from research participants (questionnaire application) and writing the article. Gian Lucas Teixeira Caneschi: research planning, search for sources in the scientific literature, data collection from participants (questionnaire application) and writing the article. Clarice Rocha de Souza: research planning, search for sources in the scientific literature, data collection from research participants (questionnaire application) and writing the article. Luan Almeida Lopes: Data collection from research participants (questionnaire application). Nathalia de Souza Abreu Freire: acted as advisor in the research planning, search for sources in the scientific literature and writing of the article, in addition to reviewing the article. Umberto Marzullo Filho: acted as co-advisor, assisting in the research planning and reviewing the article.

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Received: 2024, August 28

Accepted: 2025, February 25