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Novelty in Clinical Medicine. 2023; 2(3): 143-148
https://doi.org/10.22034/NCM.2023.405960.1098

Research Article Open Access

Prevalence of Mastalgia and the complications attributed to it following Mirena intrauterine device insertion: A prospective cohort study

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Received: 8 July 2023 **Revised:** 21 August 2023 **Accepted:** 30 August 2023 **e-Published:** 31 August 2023

Abstract

Background: In recent decades, the surge in global population has prompted the adoption of family planning policies. While an intrauterine device (IUD) is among the most effective contraception methods, it may result in complications and issues that necessitate its removal. The aim of this study is to examine mastalgia and related complications stemming from the use of Mirena IUD among women who seek medical care in Yazd, Iran.

Objectives: The objective of this study is to assess the prevalence of mastalgia and associated complications following the use of Mirena IUD among women visiting medical centers in Yazd, Iran.

Methods: In this prospective cohort study, a total of 201 women who were using Mirena IUD and visited the gynecology ward of two hospitals (one public and one private) in Yazd province, Iran were followed up for 6 months (from November 2021 to June 2022). The study data were collected using a questionnaire that included information on age, parity, duration of IUD usage, and any complications arising from the use of IUD.

Results: The study found that after IUD insertion, 36.9% of women (48) reported mild mastalgia, while 3.5% (7) and 6% (12) reported moderate and severe mastalgia, respectively. After 6 months, 37.9% of participants (54) experienced mild mastalgia, while 5% (10) and 6% (12) reported moderate and severe mastalgia, respectively. Menstrual spotting was the most prevalent IUD consequence (57.2%), followed by pelvic discomfort (28.9%), dyspareunia (27.9%), and nausea (17.4%).

Conclusion: This study highlighted mastalgia as the second most frequent complication associated with IUD usage after abnormal uterine bleeding. Interestingly, the age and parity of the participants did not appear to be related to mastalgia. Furthermore, breast complications associated with IUD usage were found to be relatively common, underscoring the need for further investigation into these complications.

Keywords: Mastodynia, Intrauterine devices, Breast.

Introduction

Recent decades have seen the implementation of family planning policies, prompted by the exponential growth of the global population. The utilization of contraceptives, such as the intrauterine device (IUD), has been shown to drastically reduce the incidence of unwanted pregnancies and pregnancy-related mortalities.[1,2] Not only is the IUD cost-effective, but it also boasts extended effectiveness, lasting 5–10 years or longer, depending on the type.[3] Moreover, the IUD has been found to have additional health benefits, including protection against endometrial and cervical cancers, relief of dysmenorrhea, reduction of menstrual bleeding, prevention of anemia, and prevention of endometrial hyperplasia.[4]

At present, two types of IUDs are available: copper and hormonal. Copper IUDs stimulate a strong inflammatory response in the uterus, resulting in the death of spermatozoa.[5] Hormonal IUDs, like the levonorgestrel-

releasing Mirena, have a T-shaped body made of polyethylene. Levonorgestrel is released daily to inactivate the endometrium, effectively preventing pregnancy. Furthermore, studies have revealed that the use of Mirena IUD can provide relief from menorrhagia and anemia, conditions that are more common in developing nations. Additionally, it can alleviate symptoms associated with endometriosis and adenomyosis.[6–8] The therapeutic effects of Mirena on dysmenorrhea, menorrhagia, and contraception have been affirmed in several clinical trials conducted worldwide.[9]

Despite its effectiveness, IUD use can sometimes result in complications, necessitating its removal. The most prevalent reasons for IUD withdrawal are dysmenorrhea and menstrual bleeding, with copper IUD use having a greater prevalence, whereas levonorgestrel IUD considerably decreases dysmenorrhea and anemia by minimizing excessive bleeding and maintaining iron storage.[10–12] Levonorgestrel IUDs are frequently removed due to amenorrhea, although research has demonstrated that participants receiving these IUDs may face additional issues like nausea, headaches, depression, skin problems, and mastalgia.[8,12]

Objectives

IUDs are among the most popular contraceptive methods worldwide, and it is crucial to understand the possible side effects that may limit their safe usage and acceptance by the population over time. Since ongoing research investigates the pros and cons of Mirena IUD, this study aims to investigate the frequency of mastalgia, along with other breast-related complications that may arise following the insertion of Mirena IUD.

Methods

Study design

This prospective cohort study involved an evaluation of women seeking care at two public and private hospitals in the Yazd, Iran between November 2021 and June 2022.

Participants

This study followed 201 women using Mirena IUD who had been referred to the gynecology ward of selected hospitals in Yazd, Iran, for a duration of six months. Inclusion criteria were women aged 15 to 49 years, currently using Mirena IUD, and reporting satisfaction with the device. Participants who expressed dissatisfaction were excluded from the study. A census approach was used for sampling, where all women who visited the selected hospitals between April 2017 and March 2017 were eligible to be included in the sample. Women who had a history of mastalgia and those whose mastalgia did not change after receiving the Mirena IUD were excluded from the study.

Study size

The study had a sample size of 201 women, out of which 6 were excluded during the 6-month follow-up, leaving a total of 195 participants to be analyzed. Prior to enrollment, eligible women were informed of the study and provided with study tools, and their voluntary participation and informed consent were obtained before initiating data collection.

Data collection

A questionnaire was used as a data collection instrument, which contained questions related to the participants' age, parity, duration of IUD use, mastalgia, and complications. Participants were followed up after 6 months, and they completed the questionnaire either in person or via phone. During the follow-up, variables such as duration of IUD insertion, parity, breast complications (mass/lump feeling, discharge, and swelling), and other complications including nausea, pelvic pain, menstrual spotting, and dyspareunia were evaluated. The quality of mastalgia was classified based on the classification criteria outlined in Figure 1.

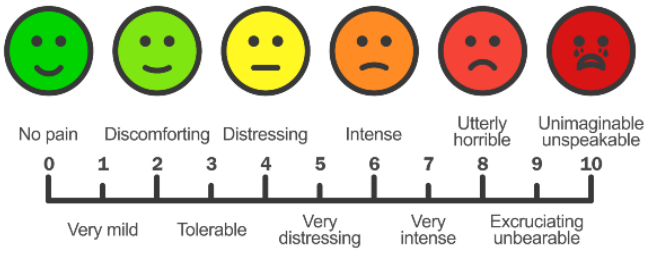

Figure 1. Pain scale for measuring the quality of mastalgia

Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki. Institutional Review Board approval (code: IR.SSU.MEDICINE.REC.1400.319) was

obtained from Shahid Sadoughi University of Medical Sciences. The present study did not interfere with the process of diagnosis and treatment of patients and all participants signed an informed consent form.

Statistical analysis

The continuous variables were expressed as the mean ± SD, and the categorical variables were presented as a percentage and frequency. Descriptive statistics of frequency, percentage, and Chi-square test were used to analyze data. All statistical analyses were performed with SPSS (version 22.0, SPSS Inc, Chicago, IL, USA). A "P-value" less than 0.05 was considered significant.

Results

The study involved 201 individuals who received IUDs, and 195 of them completed a questionnaire after a 6-month follow-up period. Among the participants who were initially enrolled, 29.4% were under the age of 35, while 49.3% were between 36 and 45 years old, and the remaining were over 45 years old. The duration of IUD use varied among the participants, with 8 months being the most common duration of use (11.4%). In terms of pregnancy history, 13 (6.5%) participants had no history of pregnancy, 98 (48.8%) had a history of one or two pregnancies, and 90 (44.8%) had a history of three or more pregnancies. The primary reason for IUD insertion was bleeding in 161 (80.1%) participants, pregnancy prevention in 26 (12.9%) participants, and various other reasons, such as spotting, uterine adhesions, and fibroids, in 14 (7%) participants.

Table 1 shows that for the majority of participants (68.2%), no examination was carried out before the IUD insertion, while 5.5% of participants underwent all examinations, including sonography and mammography.

Table 1. Frequency and percentage of breast examination before IUD insertion

Breast investigation	**Frequency** (%)
None	137 (68.2)
Examination	18 (9)
Examination and sonography	12 (6)
Examination and mammography	5 (2.5)
Sonography	10 (5)
Sonography and mammography	2 (1)
Mammography	3 (1.5)
All procedures	11 (5.5)
Total	201 (100)

At the beginning of the study, 201 participants who received IUDs were evaluated, and among them, 54 (26.9%) reported experiencing mild mastalgia, 9 (4.5%) reported moderate mastalgia, and 11 (5.5%) reported severe mastalgia. The majority of participants (63.2%) did not have mastalgia. Furthermore, 31 (15.4%) of the patients reported a history of mastalgia, which had been aggravated by IUD placement. After six months, 6% of participants still reported severe mastalgia, and only one participant withdrew from the IUD due to mastalgia. During the study period, 30 participants withdrew from the IUD, and among them, 10 had a history of mastalgia. Six participants reported a decreased intensity of mastalgia after IUD removal. There was no significant difference in the frequency of mastalgia between the beginning of the study and after six months ($p = 0.05$), as shown in Table 2.

Table 3 displays the incidence and percentage of participants who experienced other breast complications related to IUD insertion. There was no significant difference in the occurrence of breast complications between the beginning of the study and after six months ($p=0.66$).

Table 2. Incidences and percentage of quality of mastalgia in participants at the beginning of the study and after six months

Mastalgia	**Initial Time** (n=201)		**Six months after follow-up** (n=195)		**P value**
	Incidences	percentage	Incidences	percentage	
None	127	63.2	119	59.2	0.05
Mild	54	26.9	54	26.9	
Moderate	9	4.5	10	5	
Severe	11	5.5	12	6	

Table 3. Incidences and percentage of participants in terms of other IUD breast complications

Breast complications	Incidences (%)	P value
Mass/lump feeling	17 (8.5)	0.66
Discharge	2 (1)	
Feeling of swelling	11 (5.5)	
Breast complications after six months	**Incidences** (%)	
Mass/lump feeling	16 (8)	
Discharge	1 (0.5)	
Feeling of swelling	11 (5.5)	

Chi-square test, Intrauterine device (IUD)

Menstrual spotting was reported by the majority of patients (57.2%), followed by pelvic pain (28.9%), dyspareunia (27.9%), and nausea (17.4%) [Table 4].

Table 4. Incidences and percentage of other-non-breast complication reported after IUD insertion

Breast complications	Incidences (%)
Nausea	35 (17.4)
Pelvic pain	58 (28.9)
Menstrual spotting	115 (57.2)
Dyspareunia	56 (27.9)

A total of 36.3% of participants had an IUD insertion duration of less than 6 months, while 43.3% had an IUD duration between 6 and 12 months, and 20.4% had a duration of more than 12 months. Among participants with mastalgia, 14.9% had an IUD insertion period of between 6 and 12 months, which increased to 17.9% six months later. Participants without mastalgia had the highest incidence of IUD duration between 6 and 12 months. However, there was not any significant difference in mastalgia in relation to IUD duration [Table 5].

Table 5. Incidences of mastalgia by duration of IUD insertion

Variable		Initial Time (n=201)		p-value*	Six months after follow-up (n=195)		p-value
		No	Yes		No	Yes	
Duration of IUD insertion	< 6 months	47(23.4)	26(12.9)	0.346	47(23.4)	26(12.9)	0.47
	6-12 months	57(28.4)	30(14.9)		50(24.9)	36(17.9)	
	> 12 months	23(11.4)	18(9)		22(10.9)	14(7)	

Data presented as n (%), Chi-square test, Intrauterine device (IUD)

Discussion

The IUD is a highly effective and safe form of temporary contraception, with a low failure rate, reversibility, and minimal impact on daily activities. However, complications have been reported, which may result in premature withdrawal.[13] Increasing awareness of these complications can help patients make informed decisions regarding their contraceptive choices and increase community acceptance. Notably, this study is the first to specifically investigate breast complications associated with the use of the levonorgestrel IUD.

Menstrual spotting was the most often reported non-breast problem (57.2%), followed by pelvic discomfort (28.9%), dyspareunia (27.9%), and nausea (17.4%).[13] In a study by Makins et al.,[14] complications during insertion were reported in 134 cases out of 36,697 insertions with available data, with heavy bleeding during insertion being the most common (0.14%). No perforations were recorded, which is unsurprising as the immediate postpartum uterus differs significantly from the nonpregnant uterus, which is at a higher risk of perforation during interval insertion.[14] The thick walls of the immediate postpartum uterus make perforation highly unlikely.

During the study period, 30 participants (15%) had their IUDs removed, with 10 of them reporting a history of mastalgia. Of those participants, six reported a decrease in the quality of mastalgia after IUD removal.[13] In a study conducted by Makins et al., in six countries, the expulsion rates ranged from 1.2% in Tanzania to 4.3% in Kenya, while removal rates varied from 2.6% in India and Kenya to 8.3% in Tanzania. Overall, the expulsion and removal rates were 2.6% and 3.7%, respectively, with the most common complaint being persistent vaginal discharge in 6.9% of cases, followed by abdominal pain (4.4%).[14] While the overall expulsion rates were higher than those reported in the literature, the expulsion and removal rates were similar to those published in another study by Pfitzer et

al.[15] It is perceived that the high expulsion rates result from the inability of the inserter to place the IUD high in the uterine fundus.

Mastalgia was observed in 33% of participants in this study, alongside other breast complications such as feelings of mass, swelling, and discharge. A review study also listed mastalgia as a short-term complication of IUD use.[13] In a study that compared reported complications between hormonal-type IUDs (Levonorgestrel) and copper IUDs, mastalgia rates were 6.6% and 2%, respectively.[16] Although the hormonal type had a higher rate of mastalgia, the difference between the two groups was insignificant. It should be noted that in this study, mastalgia was not evaluated based on the type of IUD used.

Previously conducted studies have reported abnormal uterine bleeding as the most commonly reported complication with IUD use. Similar to these findings, menstrual spotting was reported in 57% of patients in this study. A study conducted in seven countries that examined women with IUDs for over three years found that abnormal bleeding was the primary reason for IUD removal. Other commonly reported complications included dyspareunia, pelvic pain, and nausea.[12] Notably, this aligns with the present study, where pelvic pain was observed in 50% of patients, and a similar study reported dyspareunia in 41.1% of patients.[12,17]

The present study had limitations such as a low sample size, short-term follow-up of patients, and a lack of comparison between the types of IUDs used in terms of complications. To provide a more comprehensive understanding of the incidence of mastalgia after IUD insertion and the types of IUDs that may be associated with this complication, a prospective study with a larger sample size is recommended. Additionally, long-term follow-up studies are necessary to identify whether mastalgia is a short-term or long-term complication. Although mastalgia following abnormal uterine bleeding is the most common complication in women using IUDs, this has not been previously considered. Notably, the development of mastalgia after IUD insertion was found to be unrelated to the participant's age and parity number in this research.

Conclusions

The study findings indicate that breast complications associated with IUD use are relatively common, highlighting the need for further investigation into these complications. To reduce the likelihood of unnecessary costs and complications, it is advisable to develop a national guideline or protocol for the insertion of Mirena IUD. In addition, before inserting a Mirena IUD, it is suggested that a breast examination and investigation be performed, along with other necessary examinations.

Acknowledgment

The authors would like to express their gratitude to all participants involved in this study. Hereby, we would like to thank the Research Administration of Shahid Sadoughi University of Medical Sciences, Yazd, Iran. The present study was supported by Shahid Sadoughi University of Medical Sciences, Yazd, Iran (grant No. 12024).

Competing interests

The authors declare that they have no competing interests.

Abbreviations

Intrauterine device: IUD.

Authors' contributions

All authors read and approved the final manuscript. All authors take responsibility for the integrity of the data and the accuracy of the data analysis.

Funding

None.

Role of the funding source

None.

Availability of data and materials

The data used in this study are available from the corresponding author on request.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki. Institutional Review Board approval (code: IR.RUMS.REC.1396.119) was obtained (April 2020). The present study did not interfere with the process of

diagnosis and treatment of patients and all participants signed an informed consent form.

Consent for publication

By submitting this document, the authors declare their consent for the final accepted version of the manuscript to be considered for publication.

References

1. Peipert JF, Zhao Q, Schreiber CA, Teal S, Turok DK, Natavio M, et al. Intrauterine device use, sexually transmitted infections, and fertility: a prospective cohort study. Am J Obstet Gynecol. 2021; 225 (2):157-9. doi:10.1016/j.ajog.2021.03.011 PMid:33716075
2. Wheeler LJ, Desanto K, Teal SB, Sheeder J, Guntupalli SR. Intrauterine device use and ovarian cancer risk: a systematic review and meta-analysis. Obstet Gynecol. 2019; 134 (4): 791-800. doi:10.1097/AOG.0000000000003463 PMid:31503144
3. Averbach SH, Ermias Y, Jeng G, Curtis KM, Whiteman MK, Berry-Bibee E, et al. Expulsion of intrauterine devices after postpartum placement by timing of placement, delivery type, and intrauterine device type: a systematic review and meta-analysis. Am J Obstet Gynecol. 2020;223(2):177-88. doi:10.1016/j.ajog.2020.02.045 PMid:32142826 PMCid:PMC7395881
4. Ti AJ, Roe AH, Whitehouse KC, Smith RA, Gaffield ME, Curtis KM. Effectiveness and safety of extending intrauterine device duration: a systematic review. Am J Obstet Gynecol. 2020;223(1): 24-35. doi:10.1016/j.ajog.2020.01.014 PMid:31954154
5. Yüksel İT, Erdem B, Çetin BA, Köroğlu ND, Dansuk R. Effect of the Levonorgestrel-Releasing Intrauterine System on the Uterine Artery, Uterine Volume, and Endometrium in Endometrial Hyperplasia without Atypia. J Acad Res Med. 2019 ;9(Special Issue):15. doi:10.5152/jarem.2019.2470
6. Achilles SL, Chen BA, Lee JK, Gariepy AM, Creinin MD. Acceptability of randomization to levonorgestrel versus copper intrauterine device among women requesting IUD insertion for contraception. Contraception. 2015;92(6):572-4. doi:10.1016/j.contraception.2015.08.009 PMid:26297203 PMCid:PMC4654647
7. Bilgehan F, Dilbaz B, Karadag B, Deveci CD. Comparison of copper intrauterine device with levonorgestrel-bearing intrauterine system for post-abortion contraception. J Obstet Gynecol Res. 2015;41(9):1426-32. doi:10.1111/jog.12747 PMid:26180028
8. Miranda MT, Simó PA. Ethical Aspects of the Use of Mirena (r) Iud in the Treatment of Heavy Menstrual Bleeding. Cuadernos de bioetica: revista oficial de la Asociacion Espanola de Bioetica y Etica Medica. 2018;29(96):159-76.
9. Goldstuck ND, Cheung TS. The efficacy of intrauterine devices for emergency contraception and beyond: a systematic review update. Int J Women's Health. 2019;11:471. doi:10.2147/IJWH.S213815 PMid:31686919 PMCid:PMC6709799
10. Hubacher D, Schreiber CA, Turok DK, Jensen JT, Creinin MD, Nanda K, et al. Continuation rates of two different-sized copper intrauterine devices among nulliparous women: Interim 12-month results of a single-blind, randomised, multicentre trial. E Clin Med. 2022; 51:1-12. doi:10.1016/j.eclinm.2022.101554 PMid:35865736 PMCid:PMC9294241
11. Wemrell M, Gunnarsson L. Claims in the clinic: Tensions in healthcare communication about perceived side effects of the copper IUD. InFutures Ahead-Translations and collaborations between medicine, social science and the humanities, Linköping, Sweden, June 15-17, 2022 2022 (pp. 97-98). Linköping University.
12. Bahamondes L, Brache V, Meirik O, Ali M, Habib N, Landoulsi S, et al. A 3-year multicentre randomized controlled trial of etonogestrel-and levonorgestrel-releasing contraceptive implants, with non-randomized matched copper-intrauterine device controls. Hum Reprod. 2015;30(11):2527-38. doi:10.1093/humrep/dev221 PMid:26409014
13. Moray KV, Chaurasia H, Sachin O, Joshi B. A systematic review on clinical effectiveness, side-effect profile and meta-analysis on continuation rate of etonogestrel contraceptive implant. Reprod Health. 2021;18(1):1-24. doi:10.1186/s12978-020-01054-y PMid:33407632 PMCid:PMC7788930
14. Makins A, Taghinejadi N, Sethi M, Machiyama K, Munganyizi P, Odongo E, et al. FIGO postpartum intrauterine device initiative: Complication rates across six countries. Int J Obstet Gynecol. 2018;143:20-7. doi:10.1002/ijgo.12600 PMid:30225873
15. Pfitzer A, Mackenzie D, Blanchard H, Hyjazi Y, Kumar S, Lisanework Kassa S, et al. A facility birth can be the time to start family planning: postpartum intrauterine device experiences from six countries. Int J Gynecol Obstet. 2015;130:S54-S61. doi:10.1016/j.ijgo.2015.03.008 PMid:26115859
16. López-Farfan JA, Hernandez-Gonzalez A, Vélez-Machorro IJ, Vázquez-Estrada LA. A comparative, randomized study of levonorgestrel intrauterine system (LNG-IUS) vs Copper T 380 A intrauterine device applied during cesarean section. Open J Obstet Gynecol. 2012;2(2):151-5. doi:10.4236/ojog.2012.22029
17. Sakinci M, Ercan CM, Olgan S, Coksuer H, Karasahin KE, Kuru O. Comparative analysis of copper intrauterine device impact on female sexual dysfunction subtypes. Taiwan J Obstet Gynecol. 2016; 55(1):30-4. doi:10.1016/j.tjog.2014.12.011 PMid:26927244

Cite this article as:
Paksima F, Jafari Nudoshan J, Shiryazdi SM, Shamsi F. Prevalence of Mastalgia and the complications attributed to it following Mirena intrauterine device insertion: A prospective cohort study. Novel Clin Med. 2023;2(3):143-148. doi: 10.22034/NCM.2023.405960.1098