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

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Abstract

Background: The unprecedented increase in population around the globe has led to considering family planning policies in recent decades. Intrauterine device (IUD) is one of the most effective methods of contraception; yet, this method is associated with complications and problems that cause its removal.

Objectives: This study aims to evaluate mastalgia and the complications attributed to it following Mirena IUD in women referring to medical centers in Yazd.

Methods: In this prospective cohort study, 201 women using Mirena IUD who referred to the Gynecology Ward of two public and private hospitals in Yazd province were followed up for 6 months From November2021 to June 2022. Data were gleaned using a data questionnaire including age, parity, duration of IUD use, and IUD complications.

Results: Of 201 women studied, 48 (36.9%) reported mild mastalgia, 7 (3.5%) had moderate mastalgia, and 12 (6%) reported severe mastalgia after IUD insertion. After 6 months, 54 (37.9%) participants had mild mastalgia, 10 (5%) reported moderate mastalgia, and 12 (6%) reported severe mastalgia. Moreover, among the complications of IUD, menstrual spotting was reported in the majority of participants (57.2%), followed by pelvic pain (28.9%), dyspareunia (27.9%), and nausea (17.4%) as the most common complications, respectively.

Conclusion: According to this study, mastalgia in women using IUD is the most common complication, second to abnormal uterine bleeding, and is not related to the age and parity of the participants. Also, IUD breast complications are relatively common, and more studies are needed to investigate these complications.

Keywords: Mastodynia, Intrauterine devices, Breast.

Introduction

The unprecedented global increase in population has led to family planning policies in recent decades. Using contraceptives can reduce the prevalence of unwanted pregnancies and mortality due to pregnancy complications.[1,2] Intrauterine device (IUD) is one of the most effective contraceptive methods, enjoying the merits of low cost, long action duration, and rapid reversibility after its withdrawal. Its efficacy varies depending on its type from 5-10 yr and even more.[3] In addition to the contraceptive effect, other health benefits have been mentioned for the IUD, including its protective effect against endometrial and cervical cancers, reduction of dysmenorrhea, reduction of menstrual bleeding, prevention of anemia, and prevention of endometrial hyperplasia.[4]

Currently, two types of copper and hormonal IUDs are available. Copper IUDs cause a severe inflammatory reaction in the uterus, killing spermatozoa.[5] The hormonal or levonorgestrel-releasing IUD with the trade name of

Mirena has a T-shaped body of polyethylene. This daily diffusion of levonorgestrel inactivates the endometrium and thus prevents pregnancy. In addition, studies have shown that the use of Minera IUD provides other health benefits, including the treatment of menorrhagia and anemia, which are more prevalent in developing countries, as well as reducing the symptoms associated with endometriosis and adenomyosis.[6-8] Therapeutic effects of Mirena on dysmenorrhea, menorrhagia, and contraception have been confirmed in various clinical trials in other countries.[9]

The use of an IUD also has complications and problems that cause its removal. The most common cause of IUD withdrawal is dysmenorrhea and menstrual bleeding, which has been seen especially with the use of copper IUDs, while levonorgestrel IUD significantly prevents dysmenorrhea and also prevents anemia by maintaining iron storage and preventing excessive bleeding.[10-12] The most common cause of levonorgestrel IUD withdrawal is amenorrhea; however, various studies have shown that in addition to amenorrhea, these participants experience other problems such as nausea, headache, depression, skin problems, and mastalgia.[8,12]

Objectives

Given the importance of the IUD as one of the most widely used contraceptives and the need to recognize the unexpected side-effects that can lead to the limited safe use of this device in the long run and reduce its acceptance by the community, and since studies on the merits and demerits of Mirena IUD are being conducted, the present study was carried out to evaluate the frequency of mastalgia and other breast complications following the Mirena IUD insertion.

Methods

Study design

This prospective cohort study was performed on women who referred to the Gynecology Ward of two public and private hospitals in Yazd province from November 2021 to June 2022.

Participants

201 women using Mirena IUD who referred to the Gynecology Ward of selected hospitals in Yazd, Iran were followed up for 6 months. Inclusion criteria were age of 15-49 yr, having a Mirena IUD, and patient satisfaction. Also, the exclusion criterion was participants' dissatisfaction. Sampling was done by census so that all women referring selected hospitals, during April 2017 to March 2017, formed a sample, and women that qualified for inclusion entered the study. In this, women who receive a Mirena IUD were enrolled. Women with a history of mastalgia, whose intensity of mastalgia did not change after Mirna IUD, were excluded from the study.

Study size

The sample size was 201 women. In the 6-month follow-up, 6 people were excluded from the study, and thus, the data of 195 participants were examined. After observing the inclusion criteria of women, voluntary participation and informed consent were obtained from participants, and study tools were provided to them.

Data collection

The data collection instrument was a questionnaire entailing information such as participants age, parity, duration of IUD use, complications, and mastalgia chart questions. Subsequently, 6 months after the start of the study, participants were followed up and participants completed the questionnaire by phone or in person. In the follow-up, variables such as mastalgia, duration of IUD insertion, parity, breast complications (Mass/lump feeling, Discharge and Feeling of swelling) and other complications such as nausea, pelvic pain, menstrual spotting and dyspareunia were questioned. The quality of mastalgia was done according to the following classification (Figure 1).

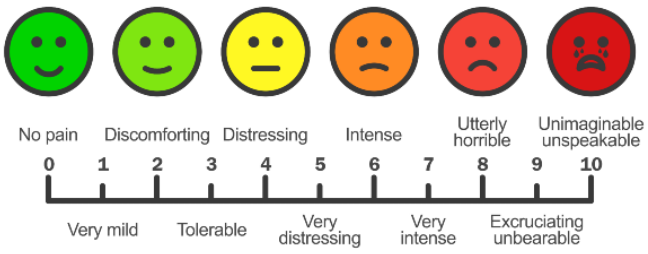

Figure 1. Pain scale for measuring the quality of mastalgia

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

This study was performed on 201 individuals for whom IUDs were inserted. They were followed up for 6 months, and 195 people completed the questionnaire after 6 months. Out of 201 participants studied at the beginning of the study, 29.4% were < 35 yr of age, 49.3% were between 36-45 yr old, and the rest were > 45 yr old. The duration of IUD uses in participants ranged from 1-18 months, among which 8-month use was the most common (11.4%). Besides, 13 (6.5%) participants had no history of pregnancy, 98 (48.8%) participants had a history of one or two pregnancies, and 90 (44.8%) participants had a history of three or more pregnancies. Indication for IUD insertion was bleeding in 161 (80.1%) participants, pregnancy prevention in 26 (12.9%) participants, and miscellaneous causes (Spotting, uterine adhesions, fibroids) in 14 (7%) participants.

For the majority of participants (68.2%), no examination was performed before the IUD was inserted, and in 5.5% of participants, all examinations, sonography, and mammography were performed (Table 1).

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)

Among 201 participants studied at the beginning of the study after IUD insertion, 54 (26.9%) reported mild mastalgia, 9 (4.5%) moderate mastalgia, and 11 (5.5%) severe mastalgia. Besides, 127 participants (63.2%) did not have mastalgia. 31 (15.4%) participants reported a history of mastalgia, which was exacerbated by IUD insertion. The rate of mastalgia in participants after six months also showed that 6% of participants still reported severe mastalgia. IUD withdrawal due to mastalgia was reported in only one participant. During the study period, IUD withdrawal was seen in 30 participants, 10 of whom had a history of mastalgia. 6 participants reported that the quality of mastalgia decreased after the IUD was removed. No significant difference was observed in the quality of mastalgia in participants at the beginning of the study and after six months (p=0.05) (Table 2).

Incidences and percentage of participants in terms of other IUD breast complications are shown in Table 3. There was no significant difference in the incidences of Breast complications at the beginning 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 in most participants (57.2%). After that, pelvic pain (28.9%), dyspareunia (27.9%), and nausea (17.4%) were the most common, respectively (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)

IUD insertion duration was less than six months in 36.3% of participants, between 6 and 12 months in 43.3%, and more than 12 months in 20.4%. Additionally, 14.9% of participants with mastalgia had an IUD insertion period between 6 and 12 months, which rose to 17.9% six months later. On the other hand, the highest incidences of IUD duration in participants who did not have mastalgia was 612 months. The results of this study did not suggest any significant difference in mastalgia in terms of 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

IUD is one of the safe and temporary methods of contraception. It has attracted attention for its high performance, low failure rate, reversibility, and no significant impact on the consumer's daily activities. Numerous complications have been reported for the IUD, sometimes leading to premature withdrawal.[13] Recognition of its complications can help patients choose it correctly and increase its acceptance in the community. This was the first study to have investigated specifically breast complication of IUD (levonorgestrel).

In other-non-breast complication reported after IUD insertion, menstrual spotting was reported in most participants (57.2%). After that, pelvic pain (28.9%), dyspareunia (27.9%), and nausea (17.4%) were the most common, respectively. In study by Makins (2018) Complications during insertion were reported in 134 cases out of a total of 36 697 insertions with data available. The most common complication was heavy bleeding at the time of insertion (0.14%). No perforations were recorded.[14] This is to be expected as the immediate postpartum uterus differs greatly from the nonpregnant uterus which is at known risk of perforation during interval insertion. The large, thick walls of the immediate postpartum uterus make perforation highly unlikely.

During the study period, IUD withdrawal was seen in 30 participants (15 %), 10 of whom had a history of mastalgia. 6 participants reported that the quality of mastalgia decreased after the IUD was removed. In the study conducted by Makins et al (2018) in 6 countries, expulsion rates varied from 1.2% in Tanzania to 4.3% in Kenya. Removal rates also varied from 2.6% in India and Kenya to 8.3% in Tanzania. Overall expulsion and removal rates were 2.6% and 3.7%. The most common complaint was persistent vaginal discharge in 6.9% of cases and the second most common was abdominal pain (4.4%).[14] Overall expulsion rates were higher than those recorded in the literature. However, expulsion and removal rates are

similar to those published by Pfitzer et al.[15] There is a general perception that high expulsion rates are a consequence of the inability of the inserter to place the IUD high at the uterine fundus.

In this study, mastalgia was observed in 33% of participants. Other breast complications seen in these participants included feelings of mass, feeling of swelling, and discharge. A review study listed mastalgia as a short-term complication of IUD use.[13] In a study,[16] the reported complications were compared between hormonal type IUD (Levonorgestrel) and copper type. Mastalgia was reported to be 6.6% for hormonal IUD and 2% for copper IUD. Although the amount of mastalgia in the hormonal type was higher, the difference between the two groups was insignificant. In this study, mastalgia was not studied according to the type of IUD.

Among the complications reported for IUDs, abnormal uterine bleeding was the most common in previous studies. In this study, in line with other studies, menstrual spotting was reported in 57% of patients. A study in seven country[12] examined women with IUDs >3 yr. According to the results of the study, abnormal bleeding was the most common reason for IUD removal. Other common reported complications of this study were dyspareunia, pelvic pain, and nausea. Consistent with the present study, in another study,[12] pelvic pain was seen in 50% of patients, and in similar study,[17] dyspareunia was observed in 41.1% of patients.

Limitations of the present study included low sample size, short-term follow-up of patients, and lack of comparison of the type of IUD used in patients in terms of complications. It is suggested that a prospective study with a greater sample size be designed to examine mastalgia after IUD insertion and the incidence of mastalgia in the types of IUDs used. Further studies with long-term follow-up are required to classify mastalgia as a short-term or long-term complication. According to this research, mastalgia in women using IUDs after abnormal uterine bleeding is the most common complication. However, this complication had not been considered yet. Mastalgia developed after IUD insertion is unrelated to the participant's age and parity number.

Conclusions

According to the results of this study, IUD breast complications are relatively common, and more studies are needed to investigate these complications. It is recommended that a national guideline or protocol for the insertion of Mirena IUD be prepared in the country so that participants would not incur unnecessary costs and complications. Also, before insertion of Mirena IUD, breast examination and investigation should be performed in addition to other necessary examinations.

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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.

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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. American Journal of Obstetrics and Gynecology. 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. Obstetrics & Gynecology. 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. American journal of obstetrics and gynecology. 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. American journal of obstetrics and gynecology. 2020;223(1):24-35. doi:10.1016/j.ajog.2020.01.014 PMid:31954154
5. Temel Yüksel İ, Erdem B, Aslan Çetin B, Duğan Köroğlu N, Dansuk R. Effect of the levonorgestrel-releasing intrauterine system on the uterine artery, uterine volume, and endometrium in endometrial hyperplasia without atypia. Endometrial Hyperplasia without Atipia. 2019; 9(1):15-8. 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. Journal of Obstetrics and Gynaecology Research. 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. International journal of 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 Clinical Medicine. 2022; 51:1-12. doi:10.1016/j.eclinm.2022.101554 PMid:35865736 PMCid:PMC9294241
11. Wemrell M, Gunnarsson L, editors. Claims in the clinic: tensions in healthcare communication about perceived side effects of the copper IUD. Futures Ahead-Translations and collaborations between medicine, social science and the humanities; 2022.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. Human Reproduction. 2015;30(11):2527-38. doi:10.1093/humrep/dev221 PMid:26409014
12. 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. Reproductive Health. 2021;18(1):1-24. doi:10.1186/s12978-020-01054-y PMid:33407632 PMCid:PMC7788930
13. Makins A, Taghinejadi N, Sethi M, Machiyama K, Munganyizi P, Odongo E, et al. FIGO postpartum intrauterine device initiative: Complication rates across six countries. International Journal of Gynecology & Obstetrics. 2018;143:20-7. doi:10.1002/ijgo.12600 PMid:30225873
14. 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. International Journal of Gynecology & Obstetrics. 2015;130:S54-S61. doi:10.1016/j.ijgo.2015.03.008 PMid:26115859
15. 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 Journal of Obstetrics and Gynecology. 2012;2(2):151-5. doi:10.4236/ojog.2012.22029
16. Sakinci M, Ercan CM, Olgan S, Coksuer H, Karasahin KE, Kuru O. Comparative analysis of copper intrauterine device impact on female sexual dysfunction subtypes. Taiwanese Journal of Obstetrics and Gynecology. 2016;55(1):30-4. doi:10.1016/j.tjog.2014.12.011 PMid:26927244

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