

Comparing EMLA Cream and Ibuprofen on Pain after Insertion of Copper Intrauterine Device

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Abstract

Background and Objective: IUD is a safe, effective, and reversible method throughout the world, particularly in areas where population growth is too much. One of the main barriers to use IUD is the fear and pain of its insertion. Therefore, it is necessary to take measures to reduce the pain, and this study was conducted to investigate the effect of EMLA cream and ibuprofen on pain during IUD insertion. **Materials and Methods:** This randomized controlled clinical trial study was conducted on 120 women who admitted to Imam Javad health center in Zahedan in 2015-2016 for insertion of IUD. Women who admitted to this center were randomly assigned into 3 groups of EMLA group (n = 40), ibuprofen (n = 40), and control or placebo (n = 40). These women have no problem to insert IUD. Demographic data and pain level were recorded in a questionnaire based on Johnson's Visual analog scale of pain at 3 stages of IUD insertion, and all IUDs were inserted by a midwife and then data were analyzed by SPSS software. **Findings:** The results of this research show that the lowest level of pain severity at three stages of insertion related to the EMLA cream ($P < 0.01$), while the maximum level of pain in the 3 groups related to Tenaculum. **Conclusion:** The results of the study showed that, compared to ibuprofen and placebo, EMLA cream is a safe method in reducing pain caused by IUD insertion in all stages of IUD insertion.

Keywords

EMLA Cream, Ibuprofen, Women-Pain Severity, IUD

1. Introduction

IUD is used as an effective, reversible, and long-term contraceptive method over the world for 30 years. It is effective for 12 - 10 years and its effect is similar to tubal ligation so that annually more than 150 million women in the world use IUD, most of whom are living in developing countries of Southeast Asia and the

Middle East, and European countries at lowest level. One of the reasons for lack of using IUD is wrong scientific information about it [1]. Scientific information indicates that the IUD is an effective method for 12 years and IUD, as a reversible procedure, does not jeopardize fertility and reproduction. IUD does not increase breast and cervical complications and female genital tract cancers. In addition, it also reduces the risk of endometrial cancer, and IUD is suggested as emergency contraception in cases that one of them has no protection [2]. One of the obstacles to use this method of contraception is the fear and the pain caused by its insertion [3]. Female genital tract mucous membranes is very sensitive to pain, and many of small procedures in this area are conducted without analgesia [4] [5] IUD, as some of the methods of diagnosis and surgery in some individuals, may be associated with high anxiety and pain, and it can make the insertion of the IUD difficult [6]. Studies have shown that about half of the people suffer moderate to severe pain during the insertion of IUD [7]. This feeling varies from low pain and discomfort to severe cramps, along with nausea and weakness [3]. As the number of nerve endings in the cervix area and internal cervical hole is more than that in the corpus of the uterus [8], the insertion of IUD can be followed by pain and discomfort through the use of Tenaculum to keep the cervix, right off the path to Tenaculum, entering Hysterometer, and the entering of IUD canola into uterus. The factors that cause increased pain during IUD insertion include being nullipara by the person, the age of more than 30 years, long time distance from the last menstruation or pregnancy and breastfeeding, and lack of natural childbirth, history of inserting IUD [9]. In the case of non-relieving of the pain, these factors increase the risk of shock and vasovagal and dangerous cardiac arrhythmia [10] [11]. In many of the clinics, ibuprofen and preparations, non-steroidal drugs, anti-inflammatory drugs, and cervical emollient drugs (misoprostol) and a topical anesthetics to alleviate the pain during the IUD insertion are used [5] [7] [10]. One a local anesthetic drugs is EMLA cream 5% that each gram of this cream contains lidocaine 25 mg and prilocaine 25 mg [12]. The analgesics application of this cream is topical on the cervix made to perform laser surgery procedures, hysteroscopy, and Hysterosalpingography [13] [14] [15]. As the insertion of IUD is a painful process and currently in the global standard method and health instructions, pain medication is prescribed to reduce the pain caused by IUD insertion, this study was conducted to compare the effect of ibuprofen and EMLA cream in reducing the pain caused by IUD insertion.

2. Materials and Methods

This clinical controlled trial study was conducted on women admitted to Imam Sajjad health center of Zahedan to insert the IUD in 2015-2016. To determine the sample size on the basis of Allen *et al.* [16] study, the number of samples was considered 32 people for each group and 40 people in each group considering the drop out possibility of the samples, using $M = 3.6$ and $SD = 1.1$ and considering $\alpha = 0.05$ and power = 90% for diagnosis of at least reduction in pain level.

According to IUD insertion instructions, the admitted women had no problem to insert the IUD. The prohibited use of IUD included pregnancy, genital infection, the risk of pelvic infections or sexually transmitted disease (in the current conditions or within the last three months), cervical or endometrial cancer, or undiagnosed genital bleeding, uterine abnormalities and fibroid tumors caused uterine cavity deformation, allergy to copper and Wilson disease [3]. Exclusion criteria included no-use of pain relief drugs in 6 hours, the lack of a history of severe stress, allergy to EMLA cream, withdrawal of the person to participate in research, and uterine depth less than 6 or 9 cm. It is worth mentioning that IUDs of 3 groups were inserted by a midwife at menstruation. People were randomly assigned in three groups in terms of receiving EMLA cream 7 minutes before insertion, receiving two ibuprofen tablets 400 mg, and 45 - 60 minutes before insertion, receiving the placebo (lubricant gel) 7 minutes before insertion. Based on previous studies, the intervention variables, which had the greatest confounding effect on the pain level such as lesions cervical of history, the history of inserting IUD, age, parity, type of childbirth, and breast-feeding in groups were homogenized. Data collection tool was researcher-made questionnaire used to record the individual information and history of midwifery and the checklist of researcher observations, and 10 cm visual analog scale (VAS). The score zero was considered as no pain, score 3 - 1 was considered as mild pain, score 6 - 4 was considered as moderate pain, and the score 9 - 7 was considered as severe pain and score 10 was considered as very severe pain. This tool was the standard scale that its validity and reliability have been proven during different studies [7] [15] [17]. To determine the validity of the midwifery questionnaire, content validity method was used. The used EMLA cream is 50 mg cream that contains 25 mg lidocaine and 25mg prilocaine manufactured by the pharmaceutical company in Sweden with production series of 003021. The used Ibuprofen tablet included 400 mg ibuprofen tablets manufactured by Aria pharmaceutical company, which two tablets were used before IUD insertion. After selecting the samples, sufficient explanations were provided about the goals and the groups for samples and their written consent was obtained. The vagina and cervix of people in the EMLA cream and lubricant gel groups were evaluated in terms of inflammation and unnatural findings and discharges after being exposed at the lithotomy position of external genitalia tract. Then, the uterine was examined by two hands and uterine size and position were determined. After 2 times of washing of the vagina and cervix with betadine, 5 g of EMLA were placed by cotton swap on cervix environment and external hole of cervix. It lasted 7 minutes to begin the anesthetic effect of cream. Then, the pain level was assessed at three stages of IUD insertion using visual analog scale. In the control or placebo group, lubricant gel was used instead of EMLA cream. Ibuprofen group subjects received 400 mg ibuprofen tablet 45 - 60 minutes prior to insertion. Data were analyzed using SPSS 20 software by using descriptive statistics and kendallk's tau-b, chi-square, and Friedman tests. In interpreting the results, p values less 0.05 were considered significant.

3. Findings

The findings of this research showed that the mean age of the women who participated in this research was 26.75 ± 6.33 . To determine the correlation between the severity of pain in any of the stages and confounding variables, Kendall's tau-b s test was used. This test showed significant difference between the variable of maternal education and employment and the history of inserting the IUD and type of delivery and the pain severity of Tenaculum applying ($p < 0.001$). In addition, the test showed a significant difference between education, method of delivery, the severity of pain in the stage of entering the hystrometer ($P < 0.000$). In addition, this test showed there is significant difference between the education, the history of inserting IUD, and type of delivery at the stage of IUD insertion ($p = 0.003$). **Figure 1** showed the trends of pain in three groups of participants in various stages. In all stages, controls had the highest level of pain and EMLA had the lowest levels of pain.

Friedman's Non-parametric test used to measure the pain severity at three stages of insertion in the EMLA group showed that EMLA cream reduced significantly the pain from the stage of applying the Tenaculum (3.23 ± 0.78), to the stages of Hyetometer entering (2.43 ± 0.82), and the insertion of IUD (1.75 ± 0.74). In addition, Friedman's Non-parametric test used to measure the pain severity at three stages of insertion in the ibuprofen group showed that taking the ibuprofen reduced the pain from the stage of applying the Tenaculum (5.80 ± 0.82), to the stages of Hyetometer entering (4.55 ± 0.82), and the insertion of IUD (4.33 ± 0.74). In addition, Friedman's Non-parametric test used to measure the pain severity at three stages of insertion in the placebo group showed that pain severity reduced from the stage of applying the Tenaculum (6.38 ± 0.99), to the stages of Hyetometer entering (5.05 ± 0.94), and the insertion of IUD (4.75 ± 0.89) ($p < 0.001$) (**Table 1**).

Table 1. Friedman's Non-parametric test to measure pain severity at three stages IUD inserting.

groups	pain stage	Mean	SD	Mean rank	Chi-Square	<i>p</i>
Emla	First stage	3.23	0.78	2.39	49.24	<0.001
	Second stage	2.43	0.82	1.95		
	Third stage	1.75	0.74	1.66		
Ibuprofen	First stage	5.80	0.82	2.50	37.46	<0.001
	Second stage	4.55	0.77	1.83		
	Third stage	4.33	0.74	1.68		
Control	First stage	6.38	0.99	2.48	35.52	<0.001
	Second stage	5.05	0.94	1.84		
	Third stage	4.75	0.89	1.69		

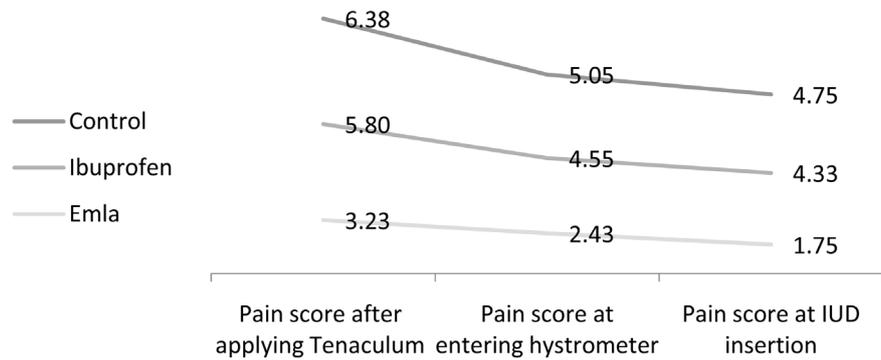


Figure 1. Pain reduction pattern of IUD inserting in three groups of participants.

4. Discussion

As IUD is an effective and acceptable method of contraception, several studies have been conducted about reducing the pain during insertion of IUD. Most of the studies conducted in this regard have examined the effect of chemical drugs like ibuprofen, naproxen, vitamin B1, misoprostol and herbal drugs such as lavender and a few of studies have been conducted on the effect of using topical and regional anesthesia on pain at the time of IUD insertion. In a study conducted by Alizadeh *et al.* (2010) and Nicholas *et al.* (2012) which entitled the effect of lidocaine gel on the pain caused by insertion of IUD, significant difference was not observed between lidocaine gel and placebo [7] [18]. Some of the reasons that can be involved in these results include the use of low concentration of anesthetic material, low durability of cream on cervix before procedure (1 minute), and lack of anesthetic material diversity. In the current study, the effect of EMLA cream on cervix at three stages of insertion of IUD was examined. Results showed that applying Tenaculum on the cervix that is the most painful stage, reduced the pain of people who received EMLA cream compared to the ibuprofen and placebo groups ($p < 0.001$). The findings of the current study are in line with results of study conducted by Liberty *et al.* (2007) to examine the effect of EMLA cream on Hysterosalpingography pain [15] and with the results of the study conducted by Stigliano *et al.* (1997) that examined the EMLA cream effect in Hysteroscopy pain [19]. In addition, they were consistent with the study conducted by Zibert (2002) that examined the effect of EMLA cream on the pain caused by cervix area laser [13]. Additionally, the current study results are in line with the result of the study conducted by Ttavakollian *et al.* (2013) entitled as investigation of EMLA cream effect on the pain caused during the insertion of copper IUD [20]. Therefore, any manipulation of the cervix causes severe pain in uterine and the transfer of the pain from uterine and cervix is conducted through two paths. Sensory fibers move from the body of the uterus through the eleventh and twelfth thoracic nerve roots to the central nervous system, while the sensory nerves of the cervix transfer to the second or the third and fourth sacral nerves through the pelvic nerves. The possible mechanism of EMLA cream lies in blocking the pain transferred from the second, third and fourth sacral nerves. In addition, study conducted by Hubacher *et al.* (2006) on the pain

caused by insertion of IUD with taking ibuprofen [9] as well as the research conducted by Bednarek *et al.* (2010) on the pain caused by insertion of IUD with taking prophylactic ibuprofen [21] indicated that taking ibuprofen did not reduce the pain caused by IUD. These results are not in line with the findings of the current study. In addition, in a study conducted by Jafari *et al.* (2013) entitled the effect of Vitamin B1 on the pain caused by IUD, it was found that taking B1 reduced the pain caused by insertion of IUD and it increased the satisfaction of the users [22], which it is in line with our study. Investigations show that all IUDs stimulate the formation of prostaglandins in the uterus and they cause smooth muscle contraction. Therefore, the procedure of IUD insertion is painful and its insertion makes the cervix environment and channel involved. Using EMLA cream on cervix environment can reduce the pain in this area significantly with the mechanism of probably blocking of the second, third, and fourth sacral nerves.

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