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Comparing the Effects of Lidocaine Cream and Mefenamic Acid on Post Episiotomy Pain

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Abstract

Background: A large number of women were affected from the Post episiotomy pain and the common method for pain relief is use of oral non-steroidal anti-inflammatory drugs.
Objectives: With considering the adverse effects of these drugs, the aim of present study was to compare the effects of lidocaine cream and mefenamic acid capsule on post episiotomy pain.
Patients and Methods: In a clinical trial study, sixty of women with singleton pregnancy and 38-42 weeks of gestation who had episiotomy, were randomized by consecutively numbered sealed envelopes to one of the two study arms that is 2% lidocaine cream (n = 30) or 250 mg mefenamic acid (n = 30). Data collection was performed by questionnaire and visual analogue scale (VAS). The intensity of pain was compared with the first compliant of mother and 6, 12, and 24 hours after the delivery. For data analysis, we used SPSS package, t test and paired t test and $P < 0.05$ was considered significant.
Results: With the first compliant of women, the mean intensity of pain was 4.92 ± 1.9 in lidocaine group and 4.90 ± 1.5 in mefenamic acid group and the difference was not significant ($P = 0.20$). Also there was not a significant difference in mean intensity of post episiotomy pain in the two groups in 6 ($P = 0.05$), 12 ($P = 0.36$) and 24 ($P = 0.98$) after childbirth.
Conclusions: The effect of lidocaine cream and mefenamic acid capsule was similar in the relief of post episiotomy pain and the Lidocaine cream is a good alternative for mefenamic acid that is commonly used to reduce of pain after episiotomy especially in women who are breast feeding and oral analgesic drugs are secreted in their milk.

Keywords: Lidocaine, Mefenamic Acid, Pain

1. Background

Episiotomy is the most common obstetrical surgery that is performed in order to facilitate the second stage of labor. Perineal pain due to episiotomy is severe during the first days after delivery and limit the movement, difficult urination and defecation (1). Episiotomy pain is the major cause of maternal fear of vaginal delivery and cesarean selection. Studies have also shown that the episiotomy pain may also affect the sexual contact (2). For the relief of perineal pain after episiotomy, different pharmacological methods are used such as aspirin-codeine, acetaminophe-codeine, sodium diclofenac, and non-steroidal anti-inflammatory drugs (NSAIDS). Cold and heat; acupressure; acupuncture; relaxation; distraction; and music therapy are the non-medicinal methods for the pain relief (3). Use of oral analgesics is common but their adverse effects including constipation, nausea, abdominal pain and dizziness, limit their use. Because of the adverse effects, topical pain relief methods have been considered, including hot and cold compresses; topical danesthetic and radiation. Lidocaine gel is one of the local anesthetics which are used for pain relief of episiotomy. It blocks the sensory neurons during neuronal membranes by inhibiting sodium; prevent the transmission of nerve messages and the sensation of pain. lidocaine gel 2% has influences on the structures of perineal nerve through the skin or membranes (4). In obstetrics, lidocaine gel is used to anesthetize the perineum during the second stage of labor and its benefits are less systemic absorption and ease of administration (3). About the effect of lidocaine in post episiotomy pain, the studies have reported conflicting results. For example, a study has reported that the severity of perineal pain in the group receiving lignocaine gel in the first 48 hours after childbirth, is less than the group receiving placebo (5), While two studies reported the opposite results (3, 6).

Nonsteroidal anti-inflammatory drugs are analgesic agents that are commonly used throughout the world and their effectiveness has been studied in the treatment of acute pain (7). These inhibit the oxygenase cycle and reduce the production of prostaglandins. Their physiological effects are protecting the gastric mucosa, regulation of renal blood flow and set the tone of vascular endothelial. They also play an important role in inflammation, although less about the mechanism of this action is ex-

plained (8). Mefenamic acid is one of NSAIDS used for the relief of pain after episiotomy. It is more used in the treatment of primary dysmenorrhea, headache, toothache, and postoperative pain. It has been suggested that it should not take more than seven days (9). Its dose is 500 mg three times a day, and this dose is different for children. Mefenamic acid after ingestion of rapidly absorbed and has a short half-life of about 2 hours. A review of four studies that involved a total of 842 people, has reported that the degree of pain experienced after receiving 500 mg of mefenamic acid was reduced in 50% of patients, Whereas he pain reduction was 20% in the group receiving placebo (10).

2. Objectives

Little research has been done comparing lidocaine and mefenamic acid in reducing of perineal pain after episiotomy. In this context and given the fact that so far no study has compared the effect of lidocaine cream and mefenamic acid on post episiotomy pain in primiparous women, this study was carried out to compare the effect of lidocaine cream and mefenamic acid on pain of episiotomy in a teaching hospital in Shahrekord University of Medical Sciences, Shahrekord, IR Iran.

3. Patients and Methods

This study is a randomized controlled trial conducted from February 2011 to December 2011 at antenatal clinic and post-delivery ward in Hajar Hospital, a university hospital and referral center for obstetric care in Shahrekord, Iran. This study has received permissions from deputy of research and also the ethics' board of the Shahrekord University of Medical Sciences. The study also obtained the clinical trial code from Iranian registry of clinical trials (IRCT201104253078N7). Primiparous women, who had a normal vaginal delivery with medio-latertal episiotomy and experiencing perineal pain, were recruited to the study. Exclusion criteria included women who had a postpartum hemmorrhage, manual removal of placenta, severe asthma, gastric or duodenal ulcer, and preeclampsia. Women with a known sensitivity to non-steroidal anti-inflammatory drugs, laceration of perineum, length of episiotomy larger than 5 cm and adverse reaction to local anesthetics were also excluded. The participants received written and verbal information about the study at 37 weeks at antenatal clinic and they were given the same information on admission to the postnatal ward by the ward midwife. All participants who agreed with the study procedures and voluntarily agreed to participate, signed the free and informed consent form. The women were randomized by consecutively numbered sealed envelopes to one of the two study arms, that is 2% lidocaine cream (n = 30) or 250 mg mefenamic acid (n = 30). The study could not be blinded to women and investigators, but it was blinded for analyzer of data. The randomization schedules were prepared by a researcher not involved in patient care, using a computer-generated random number table.

After birth and in the time of post-delivery ward admission, the intensity of perineal pain was assessed with visual analogue scale (VAS) by the ward midwife with the first compliant of women and before the patients taking the first dose of medications in the two groups. Then 250 mg mefenamic acid was administered to patients in first group and the patients in second group received the 5 mL lidocaine cream 2% on the episiotomy line. Lidocaine topical cream mefenamic acid was manufactured by Tehtan Chemie pharmaceutical company. Drugs were available in hospital pharmacy. Sociodemographic information was provided by the patient records. Visual Analogue Scale asked women to score their pain from 0 = no pain to 10 = worst possible pain (9). The primary outcomes were pain scores at 6, 12 and 24 hours after birth with rest. The secondary outcomes relating to pain were the frequency use of medication, use of additional analgesia, time from birth to first analgesia, dosing intervals, and adverse effects of therapeutic medications. Data were analyzed by SPSS version 16 (SPSS Inc., Chicago, IL, USA), Categorical variables were compared using χ^2 and fisher exact tests, compared continuous variables as measured on the visual analogue scale, using student independent samples T test and a P value of less than 0.05 was considered significant with confidence interval of 95%. The analysis was performed blinded to treatment groups.

4. Results

During the study period, a total of 420 women who gave birth at Hajar's Hospital and had perineal trauma requiring reparing during childbirth. A total of 280 gave written informed consent and 118 of them were potentially eligible for taking part in the trial. Of whom, 58 women were excluded the study most commonly that they were not experiencing perineal pain and 60 women provided meeting inclusion criteria, with 30 randomized to receive mefenamic acid and 30 to receive lidocaine cream. The two groups were well balanced for demographic characteristics at trial entry and labour and birth outcomes (Table 1).

Study outcome data were available for 100% of women at 6, 12, and 24 hours after birth. Comparing the mean intensity of pain in the two groups is presented in Table 2 showing that there is no statistically significant differences in the intensity of pain with the first compliant of

Table 1. Demographic Chracteristics of Participants [a]

Demographic Chracterictics	Lidocaine	Mefenamic Acid	P Value
Age, y	23.6 ± 4.6	24.2 ± 3.8	0.56
Height, cm	160 ± 5.2	162 ± 4.4	0.05
Weight, kg	57.9 ± 11.4	57.9 ± 8.6	0.99
Parity, No.	1.4 ± 0.5	1.6 ± 0.8	0.46
Abortion, No.	0.3 ± 0.4	0.2 ± 0.6	0.47
Gestational Age based on LMP, week	39.4 ± 0.59	39 ± 0.89	0.07
Gestational Age based on Sonography, week	39.8 ± 0.48	39.5 ± 1	0.004
Length of episiotomy, cm	3.2 ± 0.8	3.6 ± 0.9	0.10

[a] Data are presented as Mean ± SD for n = 30.

pain at rest between two groups. Also no significant difference was found in the intensity of pain in 6 hours after the childbirth between the two groups. Mean intensity of post episiotomy pain had not a significant difference in 12 hours after the childbirth between the two groups. Also the difference was not significant in 24 hours after the childbirth between the two groups. There was not a significant difference in incidence use of medications during the 24 hours after the delivery, receiving the additional analgesic for pain relief, and time from birth to first additional analgesia (Table 3). No adverse effects of therapeutic drugs were reported in the two groups.

Table 2. Pain Intensity With the First Complaint and 6, 12 and 24 Hours After Birth in the Two Groups [a]

Group Treatment	Lidocaine	Mefenamic Acid	P Value
With the first complaint of pain	4.92 ± 1.9	4.90 ± 1.5	0.20
6 hours after birth	3.26 ± 1.3	3.10 ± 1.6	0.05
12 hours after birth	2.26 ± 1.7	2.86 ± 1.4	0.36
24 hours after birth	1.46 ± 1.2	1.49 ± 1.2	0.98

[a] Data are presented as Mean ± SD.

Table 3. Secondry Outcomes Measures [a]

Use of Additional Analgesia	Lidocaine	Mefenamic Acid	P value
Additional analgesia prior to discharge	11 (36)	12 (40)	0.35
Time from birth to first additional analgesia, hour	5.2 ± 1.1	4.9 ± 0.9	0.19
Frequency use of therapeutic drugs, 24 hours	3	3	084

[a] Data are presented as Mean ± SD or No. (%) for n = 30.

The mean birth weight was 3071 ± 439 grams in receiving lidocaine group and 3016 ± 419 g in receiving mefenamic acid group and the difference was not significant (P = 0.62). No significant difference was found in Apgar score in 1 minute and admission to neonatal intensive care unit (NICU). Mean frequency of drug use was 3.20 ± 1.9 in lidocaine group and 3.22 ± 1.7 in mefenamic acid group and the difference was not significant (P = 0.40). No adverse effects of drugs were reported.

5. Discussion

The findings of present study showed that although lidocaine cream and mefenamic acid have been able to reduce the severity of pain after episiotomy over time, but there was not a significant difference in pain intensity between the two groups. The studies have been conducted to compare the effects of two sedative pains after episiotomy, are very limited. In this regard, only one study conducted in Ireland reported that the effect of mefenamic acid and lignocaine is similar on severity of pain after episiotomy (11) that is consistent with our findings. Another study has reported that the lidocaine gel reduced pain intensity at 6 and 12 hours after administration (12). Another study has shown that lidocaine cream has been able to reduce the severity of pain after episiotomy in 15 minutes after delivery, but this effect is not present in 30, 60 and 90 minutes after birth (13). In another study, although the recipients of lignocaine gel, have reported less pain than placebo recipients, but this difference was significant only at 48 hours after delivery (5). Another study reported that the lidocaine gel and diclofenac suppository have the same effect on episiotomy pain relief during the first day postpartum (14). The studies which have examined the effect of mefenamic acid on dysmenorrhea, reported that this drug reduces the pain in primary of dysmenorrhea (15, 16). In a study conducted in regarding of reducing acute pain after surgery using mefenamic acid, the recipients reported at least 50% pain reduction with 500 mg mefenamic acid after 6 hours, while this rate was 4% for placebo and need to get additional analgesic in the groups receiving mefenamic acid, was lower than the placebo group (8). Moll et al. also reported that administration of 500 mg mefenamic acid is effective in relieving of moderate to severe pain after surgery (9).

Mode of delivery (normal delivery, forceps or vacuum) can affect the pain of episiotomy, however, in present study there was not a significant difference in mode of delivery between the two groups. One study from has reported when the forceps is used for delivery, There is a greater need to use an analgesic reducing pain after episiotomy (17). Type of episiotomy can also be effective in reducing

pain. Since in the present study we only used the mediolateral episiotomy, this confounder variable did not affect the results. Also the effect of analgesic drugs were used during labor and could be continued until after giving birth was the factor that could affect the outcome of the study that in this regard, there was not a significant difference between the two groups. Although the study found no significant difference between the effects of lidocaine cream and mefenamic acid on pain of episiotomy and the lidocaine cream is a good alternative for mefenamic acid, but it should be noted that the patient's desire to get other forms of drug is important and some of patients may be prefer the oral form of drug to local form (18). Although the study did not report any adverse effects of drugs, but the side effects of these drugs should also be noted and provide the necessary care.

The strengths of the study were randomly assigned to study groups of samples and measuring the side effects of medications. Small sample size and inability to follow the patients and assessing their pain intensity at 48 hours and during the first week after the delivery were also the limitations of the present study. The effect of lidocaine cream and mefenamic acid was similar in the relief of post episiotomy pain and the Lidocaine cream is a good alternative for mefenamic acid that is commonly used to reduce of pain after episiotomy espicially in women who are breast feeding and oral analgesic drugs are secreted in their milk.

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