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OBSTETRICS

Lidocaine-Prilocaine Cream versus Placebo in Conjunction with Lidocaine Injection for Pain Relief during Episiotomy Repair after Normal Vaginal Delivery

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ABSTRACT

Objectives: To study the efficacy of lidocaine-prilocaine cream versus placebo in conjunction with lidocaine injection in relieving pain during episiotomy repair.

Materials and Methods: Postpartum women who underwent restrictive episiotomy with second-degree perineal tears from August 2023 to February 2024 were randomly allocated into two groups. In the intervention group, lidocaine-prilocaine cream was applied around the episiotomy wound in conjunction with lidocaine injection, while in the control group, placebo cream was applied instead. The primary outcome was pain intensity during episiotomy repair using a 10-cm visual analogue scale (VAS).

Results: Ninety women were randomly assigned into two groups (45 in each group). Pain score during lidocaine injection in the lidocaine-prilocaine cream group was significantly lower compared to the control group (2.45 ± 2.49 vs 3.71 ± 2.73; mean difference (MD) -1.26, 95% confidence interval (CI) -2.07 to -0.46, p = 0.002). Pain scores during perineal muscle repair and perineal skin repair in the lidocaine-prilocaine cream group were significantly lower than the control group (1.95 ± 2.13 vs 3.13 ± 2.34; MD -1.19, 95%CI -2.11 to -0.27, p = 0.012 and 1.87 ± 2.12 vs 3.82 ± 2.86; MD -1.95, 95%CI -2.95 to -0.95, p < 0.001, respectively). Perineal wound complications were not significantly different between groups (p = 0.556). No adverse reactions were found.

Conclusion: Lidocaine-prilocaine cream in conjunction with lidocaine injection effectively reduced pain during lidocaine injection, perineal muscle repair, and perineal skin repair without adverse reaction.

Keywords: Episiotomy, lidocaine-prilocaine cream, pain intensity, perineal repair.

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การศึกษาเปรียบเทียบประสิทธิภาพของครีมยาชาไลโดเคน-พริโลเคนกับยาหลอกที่ให้ร่วมกับการฉีดยาชาไลโดเคนในการลดความเจ็บปวดขณะเย็บแผลฝีเย็บหลังคลอด

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บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาประสิทธิภาพของครีมยาชาไลโดเคน-พริโลเคนเทียบกับยาหลอกที่ให้ร่วมกับการฉีดยาชาไลโดเคนในการลดความเจ็บปวดขณะเย็บแผลฝีเย็บหลังคลอด*

วัสดุและวิธีการ: *สตรีหลังคลอดที่ได้รับการตัดฝีเย็บร่วมกับมีการฉีกขาดของแผลฝีเย็บระดับสอง ระหว่างเดือนสิงหาคม พ.ศ. 2566 ถึงเดือนกุมภาพันธ์ พ.ศ. 2567 ได้ถูกสุ่มแบ่งออกเป็นสองกลุ่ม คือ กลุ่มทดลองซึ่งได้รับการทาครีมยาชาไลโดเคน-พริโลเคนรอบแผลฝีเย็บและกลุ่มควบคุมซึ่งได้รับการทาครีมยาหลอก ร่วมกับการฉีดยาชาไลโดเคน และวัดผลความเจ็บปวดขณะเย็บแผลฝีเย็บโดยใช้มาตรวัดความเจ็บปวดด้วยสายตาความยาว 10 เซนติเมตร*

ผลการศึกษา: *สตรีหลังคลอดจำนวน 90 คนถูกสุ่มออกเป็นสองกลุ่ม กลุ่มละ 45 คน คะแนนความเจ็บปวดขณะฉีดยาชาไลโดเคนในกลุ่มทดลองต่ำกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ (2.45 ± 2.49 vs 3.71 ± 2.73; mean difference (MD) -1.26, 95% confidence interval (CI) -2.07 ถึง -0.46, p = 0.002) คะแนนความเจ็บปวดขณะเย็บกล้ามเนื้อฝีเย็บและเย็บผิวหนังฝีเย็บในกลุ่มทดลองต่ำกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ (1.95 ± 2.13 vs 3.13 ± 2.34; MD -1.19, 95%CI -2.11 ถึง -0.27, p = 0.012 และ 1.87 ± 2.12 vs 3.82 ± 2.86; MD -1.95, 95%CI -2.95 ถึง -0.95, p < 0.001 ตามลำดับ) ภาวะแทรกซ้อนของแผลฝีเย็บในทั้งสองกลุ่มไม่แตกต่างกันและไม่พบผลข้างเคียงที่สัมพันธ์กับการใช้ครีมยาชาไลโดเคน-พริโลเคน*

สรุป: *การใช้ครีมยาชาไลโดเคน-พริโลเคนร่วมกับการฉีดยาชาไลโดเคน มีประสิทธิภาพในการลดความเจ็บปวดขณะฉีดยาชา ขณะเย็บกล้ามเนื้อฝีเย็บและขณะเย็บผิวหนังฝีเย็บ โดยไม่มีผลข้างเคียง*

คำสำคัญ: *การตัดฝีเย็บ, ครีมยาชาไลโดเคน-พริโลเคน, ระดับความเจ็บปวด, การเย็บแผลฝีเย็บ*

Introduction

Perineal trauma is a common consequence of vaginal delivery, occurring in about 85% of postpartum women after vaginal birth[1]. It can result from either spontaneous perineal tears or intentional episiotomy[2]. Episiotomy is an intended incision of the perineum performed to enlarge the vaginal opening for birth and prevent severe perineal trauma in selective use[3]. Today, numerous methods exist to provide anesthesia during episiotomy repair. These methods comprise non-pharmacological methods, such as warm or cold compression and perineal massage, and pharmacological methods such as local or topical anesthetics[4,5]. The most common technique performed is perineal infiltration with local anesthetic. However, the injection itself can cause pain and tissue edema[6]. Moreover, based on the literature review, the pain intensity during perineal repair under lidocaine injection alone is still moderate pain[7–9].

Nowadays, sprays, gels, and creams are topical alternatives to injectable anesthetics[10,11]. The superior advantages of topical anesthesia over local infiltration anesthesia are achievement of local effect without significant systemic absorption, painless application, and avoidance of swelling at surgical sites which can distort wound margins in perineal repair[12].

Lidocaine-prilocaine cream is a widely used topical anesthetic agent, consisting of 5% eutectic mixture with 25 mg/ml of lidocaine and 25 mg/ml of prilocaine in emulsion cream[13]. After application, lidocaine-prilocaine cream acts by releasing lidocaine and prilocaine into the epidermis and dermis, where it blocks pain receptors and nerve conduction. On intact skin, the onset duration of lidocaine-prilocaine cream is 1–2 hours for adequate anesthesia. However, the onset is much shorter when applied to the genital mucosa (5–10 minutes) with a maximum duration of effective anesthesia of about 45 minutes[14,15]. The systemic absorption of lidocaine and prilocaine depends on the duration and the size of the application area. Nevertheless, lidocaine-prilocaine cream has few adverse reactions, such as redness, burning sensation, and edema, and rare complications include allergic and systemic reactions[15,16]. Lidocaine-prilocaine cream is frequently used in various minor procedures in the pediatric, skin, and plastic fields[17–19]. It is also applied in minor gynecological procedures including genital warts removal, vulvar biopsy, minor surgery of genital mucosa, laser therapy for cervical intraepithelial neoplasia (CIN), and hysteroscopy[20].

Many studies have aimed to compare the efficacy of lidocaine-prilocaine cream to lidocaine injection for pain relief during perineal repair. However, they evaluated each method of anesthesia separately, and the pain intensity during perineal repair was still moderate pain[7–9]. We hypothesized that the conjunction of lidocaine-prilocaine cream with lidocaine injection may increase the analgesic effect. Therefore, the objective of this study was to evaluate the efficacy of lidocaine-prilocaine cream versus placebo in conjunction with lidocaine injection for pain relief during episiotomy repair.

Materials and Methods

This randomized control trial was conducted at the Department of Obstetrics and Gynecology, Khon Kaen Hospital between August 2023 and February 2024. The study was started after being approved by the Khon Kaen Hospital Institute Review Board in Human Research (KEF66013).

The eligibility criteria were term singleton pregnant women aged ≥ 18 years old with cephalic presentation who underwent vaginal delivery with restrictive episiotomy with second-degree perineal tears. The exclusion criteria were pregnant women with (a) operative vaginal delivery (forceps or vacuum extraction); (b) manual removal of placenta; (c) perineal wound hematoma; (d) postpartum hemorrhage; (e) previous adverse reaction to local anesthesia; (f) glucose-6-phosphate dehydrogenase deficiency; (g) compromised cardiac and pulmonary systems; (h) hepatic diseases; (i) congenital or idiopathic methemoglobinemia; and (j) difficulty communicating in Thai language.

All eligible pregnant women were informed about the study, and their consent was obtained by

the research assistants before enrollment. During vaginal delivery, the restrictive episiotomy was performed among those with fetal indication (shoulder dystocia, fetal distress) or when the operator considered that episiotomy might prevent birth canal trauma. Before performing the episiotomy, 1% lidocaine with epinephrine 10 ml was injected at the incision site via a 23-gauge needle. After vaginal delivery and examination of the perineal wound, participants who met the eligibility criteria were randomly allocated into two groups (the lidocaine-prilocaine cream group and the placebo cream group) by computer-generated randomization using a block of four with sealed opaque envelopes. The unaware nurse opened the envelopes which contained a 5 g container of lidocaine-prilocaine cream or the placebo cream (made from cream base) identical in appearance as prepared by a pharmacist. Then, the 5 g of cream was applied around the perineal wound edge by the blinded operator who performed the episiotomy repair. After 5 minutes of application, the cream was removed, and 1% lidocaine with epinephrine 10 ml was injected into the wound. In the case of active bleeding, gauze packing was applied to control the bleeding. All episiotomy repairs were performed by an experienced doctor or nurse using plain catgut 2-0 with a 30 mm needle starting at 2 minutes after the lidocaine injection. An anchor stitch was placed above the wound apex to begin continuous with lock suture to close the vaginal epithelium and deeper tissues and reapproximate the hymenal ring. A transition stitch redirected suturing from vagina to perineum. The superficial transverse perineal and bulbospongiosus muscles were reapproximated using a continuous, non-locking technique. After that, the continuous suture was carried upward as a subcuticular stitch. The final knot was tied proximal to the hymenal ring.

During lidocaine injection before repairing the perineal wound and at each step of perineal repair, the participants were asked by another unaware doctor or nurse to report their pain intensity at the perineal wound using a 10-centimeter visual analogue scale (VAS), in which 0 points represents “no pain” and 10 points represents “the greatest pain possible.” Vertical lines across the VAS were marked by participants in order to indicate their pain levels at each step (during lidocaine injection, vaginal mucosa repair, perineal muscle repair, perineal skin repair, and 1 hour after perineal repair). When patients had moderate pain (VAS > 4) or requested additional anesthesia, 1% lidocaine with epinephrine 5 ml was provided and recorded.

Before being transferred from the delivery room, the patients were asked to rate their satisfaction with the application on a 5-point Likert scale offering the following options: completely satisfied, satisfied, neutral, dissatisfied, and completely dissatisfied. All participants received the same postpartum care including observation of uterine contraction, vaginal bleeding and voiding, promotion of breastfeeding and ambulation, and pain control. Adverse reactions to the lidocaine-prilocaine cream, such as rash, erythema, itching, allergy, and anaphylactic reactions (urticaria, angioedema, bronchospasm, and shock), or methemoglobinemia (cyanotic skin discoloration and/or abnormal coloration of the blood) were recorded if present.

At discharge, the symptoms checklist of perineal wound infection including pain, fever, abnormal discharge, and perineal edema was provided and explained to the participants. They were advised to report and return to the hospital before their postpartum appointment if abnormal symptoms were experienced. In addition, all participants were asked by phone about the symptoms of perineal wound infection at 1 week after delivery. Baseline characteristics were recorded: age, gestational age, body mass index (BMI), parity, duration of second stage of labor, duration of perineal repair, neonatal birth weight, operators, estimated blood loss, and length of stay after delivery.

The primary outcome of the study was the pain score during perineal skin repair. The sample size calculation was based on a pilot study with a power of 80%, at a 5% level of significance, and a dropout rate of 10%. Ninety participants (45 in each group)

were thus required. The secondary outcomes were (a) pain score during lidocaine injection, (b) pain score during vaginal mucosa repair, (c) pain score during perineal muscle repair, (d) pain score 1 hour after perineal repair, (e) additional anesthesia, (f) patient satisfaction, and (g) perineal wound complications. Data were analyzed using STATA version 17 based on intention-to-treat analysis. The student t-test and the Mann-Whitney U test were used to analyze continuous data, while the chi-squared test and Fisher's exact test were used to analyze categorical data. A p value of < 0.05 was considered statistically significant.

Results

Between August 2023 and February 2024, 128 eligible term singleton pregnant women with cephalic presentation who planned vaginal delivery were enrolled. Thirty-eight were excluded due to delivery without episiotomy (n = 17), indicated cesarean delivery (n = 14), vacuum extraction (n = 4), third-degree perineal tear (n = 1), postpartum hemorrhage (n = 1), and manual removal of placenta (n = 1). Therefore, a total of 90 eligible women were randomly assigned into two groups: 45 to the lidocaine-prilocaine cream group and 45 to the placebo group. There was no dropout, and the data of the 90 participants were analyzed. Fig. 1 presents the consort flow diagram. Baseline characteristics were similar between groups, which included maternal age, gestational age, current BMI, parity, duration of second stage of labor, duration of perineal repair, neonatal birth weight, operators, estimated blood loss and length of stay after delivery (Table 1).

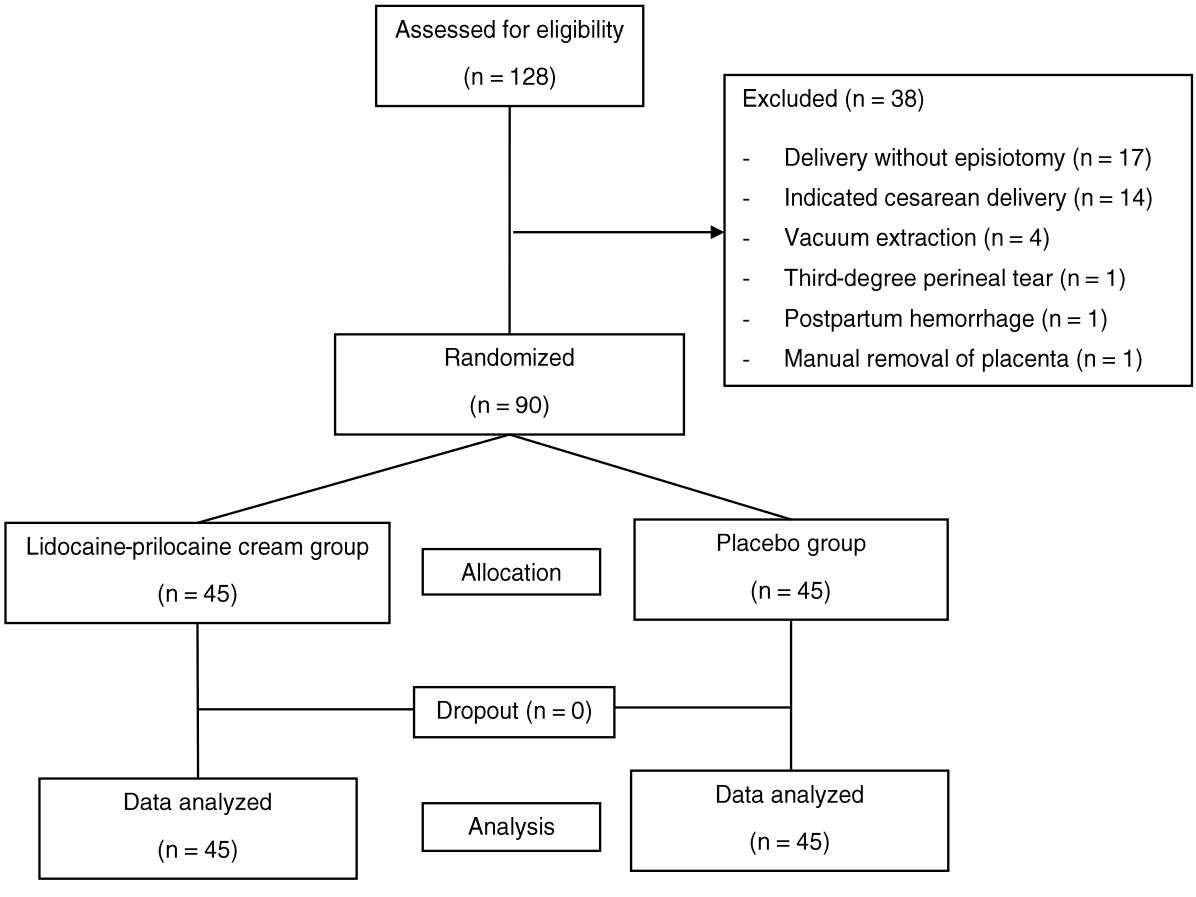

Fig. 1. Consort flow diagram.

Table 1. Baseline characteristics of participants.

Baseline characteristics	Lidocaine-prilocaine cream (n = 45)	Placebo (n = 45)	p value
Maternal age (years), mean ± SD	26.62 ± 5.41	27.13 ± 5.51	0.658[a]
Gestational age (weeks), mean ± SD	38.78 ± 1.13	38.56 ± 0.92	0.308[a]
Body mass index (kg/m²), mean ± SD	26.55 ± 3.81	27.84 ± 4.42	0.144[a]
Parity, n (%)			0.202[b]
Nulliparous	29 (64.4)	22 (48.9)	
Multiparous	16 (35.6)	23 (51.1)	
Duration of second stage of labor (min), mean ± SD	14.82 ± 11.13	15.02 ± 14.11	0.941[a]
Duration of perineal repair (min), mean ± SD	22.24 ± 11.83	21.22 ± 8.13	0.633[a]
Neonatal birth weight (kg), mean ± SD	3.00 ± 0.26	3.10 ± 0.33	0.105[a]
Operators, n (%)			0.962[c]
Staff	5 (11.1)	6 (13.3)	
Resident 3	4 (8.9)	2 (4.4)	
Resident 2	9 (20.0)	10 (22.2)	
Resident 1	21 (46.7)	22 (49.0)	
Nurses	6 (13.3)	5 (11.1)	
Estimated blood loss (ml), median (IQR)	100 (100 - 150)	100 (100 - 130)	0.529[d]
Maternal length of stay (hours), mean ± SD	56.76 ± 9.51	58.13 ± 14.47	0.595[a]

[a] student t-test, [b] chi-square test, [c] Fisher's Exact test, [d] Mann-Whitney U test
SD: standard deviation, IQR: interquartile range

The primary and secondary outcomes are presented in Table 2. The mean pain scores in the lidocaine-prilocaine cream group were significantly lower compared to those of the placebo group during lidocaine injection (2.45 ± 2.49 vs 3.71 ± 2.73; 95% confidence interval (CI) -2.07 to -0.46, p = 0.002), perineal muscle repair (1.95 ± 2.13 vs 3.13 ± 2.34; 95%CI -2.11 to -0.27, p = 0.012) and perineal skin repair (1.87 ± 2.12 vs 3.82 ± 2.86; 95%CI -2.95 to -0.95, p < 0.001). The mean pain scores during vaginal mucosa repair (p = 0.064) and at 1 hour after episiotomy repair (p = 0.176) were not significantly different between groups.

The need for additional anesthesia was not significantly different between groups (13.3% vs 11.1%; p = 0.747). According to the data, 97.8% of patients in the lidocaine-prilocaine cream group were satisfied or completely satisfied with pain control compared to 93.4% of patients in the placebo group. To sum up, the patient satisfaction was not different between groups. Two participants in the lidocaine-prilocaine cream group were diagnosed with episiotomy wound infection, and one participant in the placebo group had episiotomy wound infection and dehiscence. However, perineal wound complications between groups were not significantly different (4.4% vs 2.2%; p = 0.556). No adverse reactions related to lidocaine-prilocaine cream were found.

Table 2. Outcomes.

Outcomes	Lidocaine-prilocaine cream (n = 45)	Placebo (n = 45)	mean difference (95% CI)	p value
Pain scores, mean ± SD				
Lidocaine injection	2.45 ± 2.49	3.71 ± 2.73	-1.26 (-2.07, -0.46)	0.002 [a]
Vaginal mucosa repair	2.26 ± 2.10	3.07 ± 2.51	-0.81 (-1.66, 0.05)	0.064 [a]
Perineal muscle repair	1.95 ± 2.13	3.13 ± 2.34	-1.19 (-2.11, -0.27)	0.012 [a]
Perineal skin repair	1.87 ± 2.12	3.82 ± 2.86	-1.95 (-2.95, -0.95)	< 0.001 [a]
1 hour after perineal repair	1.54 ± 1.68	2.29 ± 1.73	-0.75 (-1.84, 0.34)	0.176 [a]
Need for additional anesthesia, n (%)	6 (13.3)	5 (11.1)		0.747 [b]
Patient satisfaction, n (%)				0.745 [c]
Completely satisfied	25 (55.6)	26 (57.8)		
Satisfied	19 (42.2)	16 (35.6)		
Neutral	1 (2.2)	2 (4.4)		
Dissatisfied	0 (0.0)	1 (2.2)		
Completely dissatisfied	0 (0.0)	0 (0.0)		
Perineal wound complications, n (%)	2 (4.4)	1 (2.2)		0.556 [c]
Infection	2 (4.4)	1 (2.2)		
Dehiscence	0 (0.0)	1 (2.2)		

[a] student t-test, [b] chi-square test, [c] Fisher's Exact test, [d] Mann-Whitney U test
SD: standard deviation, CI: confidence interval

Discussion

The results of the current study found that lidocaine-prilocaine cream in conjunction with lidocaine injection was more effective than placebo for pain relief during episiotomy repair. The pain score during lidocaine injection in the lidocaine-prilocaine cream group was significantly lower when compared to that of the control group (2.45 ± 2.49 vs 3.71 ± 2.73; mean difference (MD) -1.26, 95%CI -2.07 to -0.46, p = 0.002). It could be explained that the lidocaine-prilocaine cream numbed the tissues at the injection site before the lidocaine injection. Additionally, pain scores during perineal muscle repair and perineal skin repair in the lidocaine-prilocaine cream group were significantly lower than those in the control group (1.95 ± 2.13 vs 3.13 ± 2.34; MD -1.19, 95%CI -2.11 to -0.27, p = 0.012 and 1.87 ± 2.12 vs 3.82 ± 2.86; MD -1.95, 95%CI -2.95 to -0.95, p < 0.001, respectively). This might be due to the synergistic effect of anesthesia of the lidocaine-prilocaine cream and lidocaine injection. However, although the pain score was statistically significant between groups, the difference was 1-2 points of the VAS. Therefore, the difference in pain scores might not be clinically significant. The pain score during vaginal mucosa repair in the study group was not different from that of the placebo group (2.26 ± 2.10 vs 3.07 ± 2.51; MD -0.81, 95%CI -1.66 to 0.05, p = 0.064), which might be due to fewer free nerve endings supply at the vaginal mucosa, especially at the posterior wall, resulting in less pain[21].

There has been no previous study about lidocaine-prilocaine cream in conjunction with

lidocaine injection in pain relief during episiotomy repair. Mostly, many studies compared lidocaine-prilocaine cream versus local infiltration anesthesia. Kargar et al conducted a study on primiparous women comparing the efficacy of lidocaine-prilocaine cream applied at the episiotomy area for an hour before estimated delivery time and before repair of episiotomy wounds with conventional lidocaine injection for pain reduction during episiotomy repair. The mean pain score was 4.1 in the lidocaine-prilocaine cream group and 4.3 in the lidocaine infiltration group with 15% and 22% of participants in each group needing further anesthesia[7]. Duhan et al also evaluated the efficacy in pain relief of lidocaine-prilocaine cream compared with lidocaine injection during episiotomy repair in primiparous women. Based on the results, the mean pain score and need for additional anesthesia in both groups were comparable (4.30 vs 4.14 and 26% vs 18%, respectively)[8]. Similarly, Moradi et al assessed the lidocaine-prilocaine cream and lidocaine injection effectiveness during episiotomy repair in primiparous and multiparous women. The mean pain score was 4.06 in the first group and 4.19 in the latter group[9]. Consistently, the authors of these three studies mentioned all concluded that the pain intensity difference between the lidocaine-prilocaine cream group and the lidocaine injection group was insignificant. Furthermore, the need for additional anesthesia was not significantly different between groups. However, according to the study of Abbas et al, the analgesic effect of lidocaine-prilocaine cream was significantly lower than that of the lidocaine infiltration group during the repair of spontaneous perineal tears after vaginal birth (3.86 ± 1.59 vs 5.99 ± 1.47; p = 0.001)[22]. Moreover, the mean pain intensity in the study was higher than that found in the studies of Kargar et al, Moradi et al, and Duhan et al. This might have resulted from different amounts of anesthesia, as in the study on episiotomy repair, patients were given lidocaine infiltration or lidocaine-prilocaine cream application before undergoing episiotomy, and before perineal repair, patients were given another repeated dose of anesthesia.

In our study, the mean pain score during perineal skin repair in the placebo group, in which patients received 1% lidocaine with epinephrine 10 ml before episiotomy and then another 10 ml before episiotomy repair was performed, was 3.82, correlating with the mean pain scores during episiotomy repair of previous studies. The mean pain score during perineal skin repair in the lidocaine-prilocaine cream group was 1.87, significantly lower than that of the placebo group. Moreover, the pain score during lidocaine injection was significantly lower in the study group. Lidocaine-prilocaine cream alone provided maximal duration of analgesia for 45 minutes[15,16]. In conjunction with lidocaine injection, the pain scores at 1 hour after episiotomy repair were not significantly different between groups, as mild intensity pain persisted in both groups. This might be explained by the diminishing effect of lidocaine-prilocaine cream. The need for additional anesthesia in our study was 11.1% in the lidocaine-prilocaine cream group and 13.3% in the control group without statistical significance. Nevertheless, when compared to Kargar et al and Duhan et al, the need for additional anesthesia in the patients who received lidocaine-prilocaine cream in conjunction with lidocaine injection was lower than that found in the use of conventional lidocaine injection alone[7, 8].

In our study, 97.8% of patients in the lidocaine-prilocaine cream group were satisfied or completely satisfied with the pain control compared to 93.4% of patients in the control group. Thus, patient satisfaction was not different between groups. The perineal wound complication was also not significantly different between groups. In addition, even though the combination of lidocaine-prilocaine cream and lidocaine injection increased the dose of lidocaine given to the patients, there were no adverse effects such as allergy, erythema, itching, rash, or systemic reaction found in the study. Therefore, lidocaine-prilocaine cream can be safely used in conjunction with lidocaine injection for pain relief during the repair of second-degree perineal tears after normal vaginal delivery with restrictive episiotomy.

There were several previous research studies that examined the pain control of postpartum perineal pain, using both non-pharmacological and pharmacological methods. Harasai et al investigated the efficacy of single-dose administration of ibuprofen and acetaminophen in comparison with acetaminophen for postpartum perineal pain relief given immediately after episiotomy repair and found that the ibuprofen plus acetaminophen combination was more effective for perineal pain relief than acetaminophen alone at 1 and 2 hours after treatment. The median pain score at 1 hour after perineal repair was 3 vs 4, respectively[23]. Chaichanalap et al evaluated the efficacy of music therapy in alleviating postpartum episiotomy pain. They concluded that the pain score was significantly lower in the music group at 2 hours (24.0 vs 36.5 millimeters, $p < 0.001$) and 6 hours (12.0 vs 22.0 millimeters, $p < 0.001$) after episiotomy repair[24]. Abbas et al compared the analgesic effect of topical lidocaine-prilocaine cream and rectal meloxicam suppository given once immediately after episiotomy repair on postpartum episiotomy pain in primiparous women. The study found no immediate differences in mean pain scores (8.54 ± 1.35 vs 8.33 ± 1.50, $p = 0.419$) nor at 6 hours post-episiotomy (1.24 ± 0.56 vs 1.23 ± 0.55, $p = 0.859$) but lower mean pain scores in the lidocaine-prilocaine cream group were found at 12 hours (1.20 ± 0.50 vs 5.65 ± 1.65, $p < 0.001$) and 5 days post-episiotomy (1.19 ± 0.49 vs 2.64 ± 1.73, $p < 0.001$)[25]. In our study, the mean pain scores at 1 hour after perineal repair in the lidocaine-prilocaine cream group and placebo group were 1.54 and 2.29, respectively. In comparison, it seemed like patients who received lidocaine-prilocaine cream had lower pain scores immediately after perineal repair than those who received other methods of pain relief in those previous studies.

The strengths of the current study were first, it was a double-blind, randomized, placebo-controlled trial. Second, no patients dropped out. Finally, this was the first study that compared lidocaine-prilocaine cream in conjunction with conventional lidocaine injection. The limitations of this study were that we included only patients who have undergone episiotomy with second-degree perineal tears and in the current study, the cost-effectiveness of conjunctional lidocaine-prilocaine cream was not analyzed. Further research should focus on patients who tend to have more pain intensity, such as postpartum women with operative delivery, third- or fourth-degree perineal tears, or spontaneous perineal tears because they would not be given anesthesia at perineum before delivery as in the case of those with episiotomy. This would allow more benefits from the use of conjunctional lidocaine-prilocaine cream to be revealed. Moreover, research on the effectiveness of lidocaine-prilocaine cream compared with other oral analgesics such as non-steroidal anti-inflammatory drugs should be considered in the future.

Conclusion

Lidocaine-prilocaine cream in conjunction with lidocaine injection more effectively reduced pain during lidocaine injection, perineal muscle repair, and perineal skin repair than placebo without adverse reaction.

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Potential conflicts of interest

The authors declare no conflicts of interest.

References

1. McCandlish R, Bowler U, van Asten H, Berridge G, Winter C, Sames L, et al. A randomised controlled trial of care of the perineum during second stage of normal labour. BJOG 1998;105:1262-72.
2. Thiagamoorthy G, Johnson A, Thakar R, Sultan AH. National survey of perineal trauma and its subsequent management in the United Kingdom. Int Urogynecol

J 2014;25:1621-7.
3. Lappen JR, Gossett DR. Changes in episiotomy practice: evidence-based medicine in action. Expert Rev Obstet Gynecol 2010;5:301-9.
4. Sanders J, Peters TJ, Campbell R. Techniques to reduce perineal pain during spontaneous vaginal delivery and perineal suturing: a UK survey of midwifery practice. Midwifery 2005;21:154-60.
5. Dahlen HG, Homer CSE, Cooke M, Upton AM, Nunn RA, Brodrick BS. "Soothing the ring of fire": Australian women's and midwives' experiences of using perineal warm packs in the second stage of labour. Midwiferyq 2009;25:e39-48.
6. Eshkevari L, Trout KK, Damore J. Management of postpartum pain. J Midwifery Womens Health 2013;58:622-31.
7. Kargar R, Aghazadeh-Nainie A, Khoddami-Vishteh HR. Comparison of the effects of lidocaine prilocaine cream (EMLA) and lidocaine injection on reduction of perineal pain during perineum repair in normal vaginal delivery. J Fam Reprod Health 2016;10:21-6.
8. Duhan N, Nandal R. Topical lidocaine-prilocaine cream versus lignocaine infiltration for episiotomy repair: a randomized clinical trial. J Clin Res 2013;2:43-6.
9. Moradi Z, Kokabi R, Ahrari F. Comparison of the effects of lidocaine-prilocaine cream and lidocaine injection on the reduction of perineal pain while doing and repairing episiotomy in natural vaginal delivery: randomized clinical trial. Anesthesiol Pain Med 2019;9:e90207.
10. Jorge LL, Feres CC, Teles VE. Topical preparations for pain relief: efficacy and patient adherence. J Pain Res 2010;4:11-24.
11. Walker SM. Neonatal pain. Paediatr Anaesth 2014;24:39-48.
12. Franchi M, Cromi A, Scarperi S, Gaudino F, Siesto G, Ghezzi F. Comparison between lidocaine-prilocaine cream (EMLA) and mepivacaine infiltration for pain relief during perineal repair after childbirth: a randomized trial. Am J Obstet Gynecol 2009;201:186.e1-5.
13. Friedman PM, Mafong EA, Friedman ES, Geronemus RG. Topical anesthetics update: EMLA and beyond. Dermatol Surg 2001;27:1019-26.
14. van der Burght M, Schønemann NK, Laursen JK, Arendt-Nielsen L, Bjerring P. Duration of analgesia following application of eutectic mixture of local anaesthetics (EMLA) on genital mucosa. Acta Derm Venereol 1993;73:456-8.
15. Drugs.com [Internet]. EMLA: package insert/prescribing information [cited 2024 Sep 12]. Available from: https://www.drugs.com/pro/emla.html
16. Buckley MM, Benfield P. Eutectic lidocaine/prilocaine cream. A review of the topical anaesthetic/analgesic efficacy of a eutectic mixture of local anaesthetics (EMLA). Drugs 1993;46:126-51.
17. Lüllmann B, Leonhardt J, Metzelder M, Hoy L, Gerr H, Linderkamp C, et al. Pain reduction in children during port-à-cath catheter puncture using local anaesthesia with EMLATM. Eur J Pediatr 2010;169:1465-9.
18. Shavit I, Hadash A, Knaani-Levinz H, Shachor-Meyouhas Y, Kassis I. Lidocaine-based topical anesthetic with disinfectant (LidoDin) versus EMLA for venipuncture: a randomized controlled trial. Clin J Pain 2009;25:711-4.
19. Greveling K, Prens EP, Liu L, van Doorn MB. Non-invasive anaesthetic methods for dermatological laser procedures: a systematic review. J Eur Acad Dermatol Venereol 2017;31:1096-110.
20. Zilbert A. Topical anesthesia for minor gynecological procedures: a review. Obstet Gynecol Surv 2002;57:171-8.
21. Hilliges M. Nociception in mucosa of sexual organs. In: Gebhart GF, Schmidt RF, editors. Encyclopedia of Pain. Berlin: Springer 2013:2171-2.
22. Abbas A, Hafiz H, Abdelhafez A, Michael A, Ismail A. Topical lidocaine-prilocaine cream versus lidocaine infiltration for pain relief during repair of perineal tears after vaginal delivery: randomized clinical trial. J Matern Fetal Neonatal Med 2018;32:1-181.
23. Harasai P, Pattanapanyasat N. Efficacy of a single dose administration of ibuprofen and acetaminophen in comparison with acetaminophen for the relief of perineal pain after childbirth: a randomized controlled trial. Thai J Obstet Gynaecol 2020;28:24-33.
24. Chaichanalap R, Laosooksathit W, Kongsomboon K, Hanprasertpong T. Efficacy of music therapy on immediate postpartum episiotomy pain: a randomized controlled trial. Thai J Obstet Gynaecol 2018;26:158-65.
25. Abbas AM, Magdy F, Salem MN, Bahloul M, Mitwaly ABA, Ahmed AGM, et al. Topical lidocaine-prilocaine cream versus rectal meloxicam suppository for relief of post-episiotomy pain in primigravidae: a randomized clinical trial. J Gynecol Obstet Hum Reprod 2020;49:101722.