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Efficacy of 10% Lidocaine Spray for Relief Postpartum Perineal Wound Pain: A randomized controlled trial

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ABSTRACT

Objectives: To evaluate the effectiveness of 10% lidocaine spray for reducing postpartum perineal wound pain.

Materials and Methods: Postpartum women who had spontaneous delivery with first- or second-degree perineal tears and received wound repair were randomly assigned into two groups. The intervention group received a 10% lidocaine spray, and the control group received a sterile water spray applied to the perineum every 6 hours until reaching 48 hours after delivery. The primary outcome was perineal wound pain using a 10-cm visual analog scale (VAS) 48 hours after delivery. Student t-test and generalized estimating equation (GEE) population-averaged model were used.

Results: Seventy-two women were randomly divided into two groups, 36 women in each group. Perineal wound pain at 24 and 48 hours in the lidocaine spray group was significantly lower than the control group (2.3 ± 0.2 vs 3.5 ± 0.2; mean difference 1.2; 95% confidence interval (CI) 0.4 to 2.0; p = 0.003) and (1.7 ± 0.2 vs 3.1 ± 1.6; mean difference 1.4; 95%CI 0.7 to 2.1; p < 0.001), respectively. Pain intensity in the lidocaine spray group was also significantly lower than the control group (mean difference = -0.4; 95%CI -0.6 to -0.1; p = 0.004). No serious adverse effects were observed in this study.

Conclusion: The 10% lidocaine spray was effective in the reduction of perineal wound pain after spontaneous delivery.

Keywords: perineal wound pain, pain control, lidocaine spray, postpartum.

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การศึกษาประสิทธิภาพของยาชาเฉพาะที่ชนิดพ่น 10% ลิโดเคน เปรียบเทียบกับยาหลอก ในการลดความเจ็บปวดบริเวณแผลฝีเย็บหลังคลอด: การทดลองแบบสุ่มที่มีการควบคุม

อุทัยวรรณ สุวรรณภาพ , ศรัญญา ฉัตรพงศ์ธาดา

บทคัดย่อ

วัตถุประสงค์*: เพื่อศึกษาประสิทธิภาพของยาชาเฉพาะที่ชนิดพ่นลิโดเคนร้อยละ 10 ในการช่วยลดความเจ็บปวดบริเวณฝีเย็บในช่วงหลังคลอด*

วัสดุและวิธีการ*: สตรีหลังคลอดที่คลอดทางช่องคลอดที่มีการบาดเจ็บบริเวณฝีเย็บระดับหนึ่งหรือสองและได้รับการเย็บซ่อม จะถูกแบ่งออกเป็น 2 กลุ่มโดยการสุ่ม คือ กลุ่มที่ได้รับยาชาเฉพาะที่ชนิดพ่นลิโดเคนร้อยละ 10 และกลุ่มที่ได้รับน้ำปลอดเชื้อเป็นกลุ่มควบคุม โดยทั้งสองกลุ่มจะได้รับการพ่นยาบริเวณฝีเย็บทุก 6 ชั่วโมงเป็นเวลา 48 ชั่วโมงหลังคลอดและผลลัพท์หลักเพื่อประเมินความเจ็บปวดบริเวณฝีเย็บ ที่ 48 ชั่วโมงหลังคลอด โดยใช้มาตรวัดความเจ็บปวดด้วยสายตา ขนาดความยาว 10 เซนติเมตร (visual analog scale) โดยใช้ student t-test และ generalized estimating equation (GEE) population-averaged model ในการคำนวน*

ผลการศึกษา*: สตรีหลังคลอด72 คนถูกสุ่มออกเป็นสองกลุ่ม กลุ่มละ 36 คน โดยพบว่ากลุ่มที่ได้รับยาชาเฉพาะที่ชนิดพ่นลิโดเคนร้อยละ 10 มีความเจ็บปวดบริเวณฝีเย็บที่เวลา 24 และ 48 ชั่วโมงลดลงมากกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ (2.3 ± 0.2 vs 3.5 ± 0.2; mean difference 1.2; 95% confidence interval (CI) 0.4 to 2.0; p = 0.003) และ (1.7 ± 0.2 vs 3.1 ± 1.6; mean difference 1.4; 95%CI 0.7 to 2.1; p < 0.001) ตามลำดับ และระดับความรุนแรงของความเจ็บปวดในกลุ่มที่ได้รับยาชาเฉพาะที่ชนิดพ่นลิโดเคนร้อยละ 10 น้อยกว่ากลุ่มควบคุม (mean difference = -0.4; 95%CI -0.6 to -0.1; p = 0.004) และไม่พบผลข้างเคียงรุนแรงจากงานวิจัยนี้*

สรุป*: ยาชาเฉพาะที่ชนิดพ่นลิโดเคนร้อยละ 10 มีประสิทธิภาพในการช่วยลดความเจ็บปวดบริเวณแผลฝีเย็บหลังคลอดบุตรทางช่องคลอด*

คำสำคัญ*: แผลฝีเย็บ, การระงับปวด, ยาชาเฉพาะที่ชนิดพ่นลิโดเคนร้อยละ 10, สตรีหลังคลอด*

Introduction

Postpartum perineal pain commonly results from bruising, spontaneous tearing, or trauma such as episiotomy. Perineal pain is common among all postpartum women. The frequency and severity of the pain depend on the degree of perineal tearing[1]. Perineal pain may negatively affect mobility, interfere with breastfeeding, newborn care and self-care activities such as sleeping, resting, urination and bowel movements. It can impact sexual relationships and personal life, causing psychological and emotional problems during the puerperium[2], in which postpartum perineal pain levels are high over several postpartum day, and then declines over time[3]. Many methods have been proposed for postpartum perineal pain relief, for example nonpharmacological methods such as application of heat or cold therapy, warm sit baths, and music therapy, or pharmacological methods such as non-steroidal anti-inflammatory drugs (NSAIDs) and intravenous or epidural analgesia[4]. American College of Obstetricians and Gynecologists (ACOG) suggests the stepwise multimodal approach for management of pain after vaginal delivery, starting with NSAIDs or acetaminophen and using opioids only if necessary[5]. In contrast, Cochrane review does not recommend NSAIDs for breastfeeding women[6]. Moreover, adjunctive therapies such as topical agents for perineal pain, or ice and heat therapy can also support pain management, though evidence for their effectiveness is limited[5]. Harrison et al compared the aerosol formulations of 5% lignocaine, 2% cinchocaine and water spray in a single-dose, and reported that both local anesthetics offered significant relief from the perineal wound pain with the 5% lignocaine spray being more effective than 2% cinchocaine, but over time, the pain increased gradually after receiving local anesthetic spray[7]. Corkill et al reported the efficacy of lignocaine gel in reducing postpartum perineal pain. They found that the pain score in the lidocaine gel group was significantly lower than that of the control group at 48 hours after delivery, whereas the pain score was not significantly different at 24 hours after delivery. There was no difference in the consumption of oral analgesics between groups. This study suggested that lignocaine gel may be effective on the second postpartum day[8]. Abbas et al, who compared the effect of topical lidocaine-prilocaine cream versus rectal meloxicam suppository for relief of post-episiotomy pain. The results of the study showed no difference between groups using the visual analog scale, but the lidocaine-prilocaine group was reported lower scores at 12 hours and 5 days post-episiotomy[9].

Lidocaine is one of the most effective local anesthetic agents commonly used in medical procedures for reducing pain at mucosa or skin. Regarding the pharmacodynamics of lidocaine, it is voltage-gated sodium channel blocker, resulting in an inability to transmit signals of pain or stimulation[10].

Lidocaine spray is a convenient method and is easily used in clinical practice. Obstetric and gynecologic procedures, including first-trimester surgical abortion, intrauterine device insertion, endometrial sampling, and loop electrosurgical excision procedure (LEEP), have been investigated to determine the effectiveness of lidocaine spray in reducing pain[11].

Nowadays, the effectiveness of 10% lidocaine spray in alleviating the pain from perineal wound in the postpartum period remains uncertain due to insufficient evidence. Therefore, this study aimed to evaluate the efficacy of 10% lidocaine spray for relief post episiotomy pain.

Materials and Methods

This randomized controlled study was conducted between September 2023 and May 2024 at the Department of Obstetrics and Gynecology, Khon Kaen Hospital after approved by the Khon Kaen Hospital Institute Review Board in Human Research (KEF66015). The eligibility criteria were set as women aged 18 years old or above who underwent spontaneous vertex delivery with first- or second-degree perineal tear. The exclusion criteria were women who (a) had a postpartum hemorrhage; (b) underwent operative vaginal delivery by forceps or

vacuum extraction; (c) underwent manual placenta removal; (d) had multiple perineal lacerations; (e) had allergy to lidocaine; (f) had renal or hepatic diseases; (g) received epidural anesthesia; (h) had perineal infection (e.g., condyloma, chancroid, etc.); (i) had perineal wound hematoma; or (j) received lidocaine injection > 10 ml.

All eligible pregnant women were informed about the study by research assistants during their admission to the labor room. Written informed consent was individually obtained before the enrollment. Standard care was given to all participants during all stages of labor.

Lidocaine infiltration was performed on all women who were considered for the performance of restrictive episiotomy. Criteria for restrictive episiotomy were fetal distress, maternal conditions, history of severe perineal tearing, and larger fetal size. After vaginal delivery, physicians evaluated and sutured the perineal wound, and the severity of the perineal wound tear was checked. All cases received local infiltration anesthesia during perineal wound repair with 10 ml of 1% lidocaine HCL solution without adrenaline and plain catgut 2-0 was used to repair the perineal wound. Perineal repair was performed by an experienced physician or a nurse. After suturing the perineal wound, the participants were allocated randomly into two groups by computer-generated blocks of four and allocation concealment was done by using sealed opaque envelopes. Baseline characteristics were recorded.

The drug (10% lidocaine spray) and placebo (sterile water) which were identical in appearance were prepared in a pack by the pharmacist, under aseptic conditions. Each package was prepared and stored at room temperature. Lidocaine or placebo were applied by (spraying) five times/application onto the perineal wound for relief of pain after vaginal delivery every 6 hours by physician or trained nurse, with the first dose at 2 hours after delivery, with a total of 8 doses given to each participant. As the investigator and outcome assessor were two different people, the participants, the investigator, and the outcome assessor were therefore all blinded.

The intensity of the perineal pain was assessed using a 10-cm visual analog scale (VAS) at 2, 6, 12, 24, and 48 hours after delivery. The pain level on the VAS was identified with 0 representing "painless", and 10 representing "unbearable pain". Participants were asked to mark the point in the sitting position that they thought was related to the pain at that moment. When assessing mild to moderate pain, non-opioid analgesics should be considered first, with acetaminophen or ibuprofen being suitable options, as they are safe for breastfeeding mothers. Acetaminophen is typically recommended first. In this study, if the pain score was more than 4, the healthcare provider provided an analgesic drug (acetaminophen). If the level of pain was still not relieved, the healthcare provider provided NSAIDs (ibuprofen)[12]. Adverse effects were observed and recorded. If serious complications or side effects were presented, the drug was discontinued. Minor side effects such as nausea and vomiting were treated by symptomatic management. At 48 hours postpartum, participants were asked about their satisfaction with the application by using a 5-point Likert scale with the following options: completely satisfied, satisfied, no idea, dissatisfied and completely dissatisfied.

The sample size calculation was based on a pilot study with 20 women per group. The average pain score in the intervention group was 1.88 with a standard deviation (SD) of 1.21, whereas the pain score in the control group was 3.19 with SD of 1.79. With a power of 90%, an alpha error of 5%, and a dropout of 10%. The total participants were 72 women (36 women in each group). The primary outcome was the perineal wound pain score assessed by visual analog scale at 48 hours after delivery. The secondary outcomes were perineal wound pain at 6, 12, and 24 hours, side effects, additional analgesia and participant's satisfaction.

Data was analyzed using STATA version 17.0 based on an intention-to-treat analysis. The student t-test was used to analyze the continuous data. The Fisher's exact test was used to analyze categorical

data. The differences of pain reduction between the intervention group and the control group at different times studied were analyzed by the generalized estimating equation (GEE) population-averaged model. A p value of less than 0.05 was regarded as statistically significant.

Results

Between September 2023 and May 2024, 83 eligible women who underwent spontaneous vertex delivery with first- or second-degree perineal tear were enrolled into the study. Eleven of them were excluded from the study: two because of postpartum hemorrhage, eight because of multiple perineal wounds and one because of manual removal of placenta. Subsequently, a total of 72 eligible women were randomly assigned into two groups: 36 to the intervention group and 36 to the control group. There were no dropouts (Fig. 1).

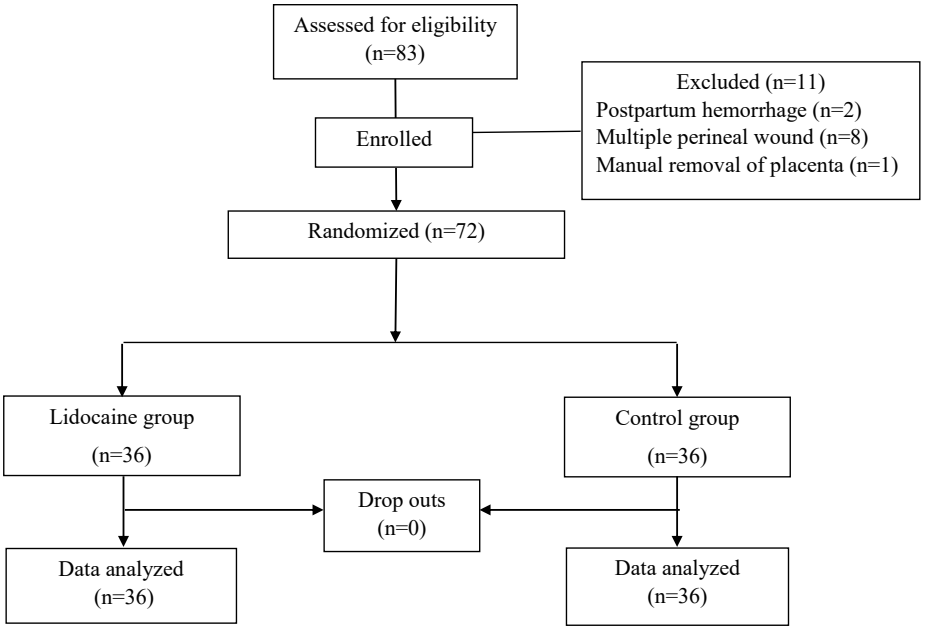

Fig. 1. Study flow diagram

Baseline characteristics (age, gestational age, body mass index, duration of each stage of labor, fetal birth weight, degree of vaginal tear, and duration of suture) were similar between groups, except for parity, in which the intervention group had a small proportion of nulliparous women compared to multiparous women than in the control group (Table 1).

Perineal wound pain at 48 hours of the intervention group (10% lidocaine spray) was significantly lower than that of the control group (1.72 ± 0.21 vs 3.16 ± 1.62; mean difference 1.44; 95%CI 0.75-2.14; p < 0.001) (Table 2).

Perineal wound pain at 24 hours of the intervention group was also significantly lower than that of the control group (2.33 ± 0.26 vs 3.56 ± 0.29; mean difference 1.23; 95%CI 0.45-2.01; p = 0.003). Perineal wound pain at 6 and 12 hours was not statistically significant between groups (3.63 ± 0.36 vs. 3.59 ± 0.37; mean difference 0.04; 95%CI -1.08-0.99; p = 0.934), (3.23 ± 0.3 vs. 3.72 ± 0.33; mean difference 0.49; 95%CI -0.4-1.39; p = 0.278), respectively (Table 3).

In the intervention group, the reduction of pain was significantly greater than that the control group (mean difference = -0.4; 95%CI -0.6 to -0.1; p = 0.004) as indicated by the GEE population-averaged model analysis (Table 4, Fig. 2).

Table 1. Baseline characteristics.

	Lidocaine group (n = 36)	Control group (n = 36)	p value
Maternal age (years), mean ± SD	27.17 ± 4.71	27.08 ± 6.35	0.950[a]
Body mass index (kg/m^2), mean ± SD	27.95 ± 4.71	27.91 ± 5.07	0.968[a]
Gestational age (weeks), mean ± SD	38.29 ± 1.99	38.40 ± 1.33	0.779[a]
Parity			0.173[b]
Nulliparous, n (%)	9 (25.0)	18 (50.0)	
Multiparous, n (%)	27 (75.0)	18 (50.0)	
Duration of first stage of labor (min), mean ± SD	556.25 ± 56.61	654.86 ± 66.35	0.262[a]
Duration of second stage of labor (min), mean ± SD	12.17 ± 1.61	13.94 ± 2.34	0.533[a]
Fetal birth weight (gm), mean ± SD	3,208.89 ± 435.30	2,981.94 ± 375.26	0.206[a]
Perineal wound, n (%)			0.527[b]
Episiotomy	31 (86.1)	29 (80.6)	
No episiotomy	5 (13.9)	7 (19.4)	
Degree of perineal tears			0.691[b]
First degree, n (%)	4 (11.1)	3 (8.3)	
Second degree, n (%)	32 (88.9)	33 (91.7)	
Duration of suture (min), mean ± SD	19.25 ± 9.46	17.83 ± 9.09	0.519[a]

[a] student t-test, [b] Fisher's extract test
SD: standard deviation

Table 2. Primary outcome.

Perineal wound pain	Lidocaine group (n = 36)	Control group (n = 36)	mean difference	95%CI	p value
At 48 hr. after delivery, mean ± SD	1.72 ± 0.21	3.16 ± 1.62	1.44	0.75 to 2.14	< 0.001[a]

[a] student t-test
SD: standard deviation, CI: confidence interval

Table 3. Secondary outcomes.

Perineal wound pain, mean ± SD	Lidocaine group (n = 36)	Control group (n = 36)	mean difference	95%CI	p value
2 hr. (baseline)	3.29 ± 0.39	3.34 ± 0.32	0.06	-0.95 to 1.06	0.912[a]
6 hr.	3.63 ± 0.36	3.59 ± 0.37	0.04	-1.08 to 0.99	0.934[a]
12 hr.	3.23 ± 0.30	3.72 ± 0.33	0.49	-0.40 to 1.39	0.278[a]
24 hr.	2.33 ± 0.26	3.56 ± 0.29	1.23	0.45 to 2.01	0.003[a]

[a] student t-test
SD: standard deviation, CI: confidence interval

Table 4. Comparison of perineal pain between the intervention and control groups.

Perineal wound pain, mean ± SD	Lidocaine group (n = 36)	Control group (n = 36)	mean difference	95%CI	p value
2 hr. (baseline)	3.29 ± 0.39	3.34 ± 0.32	0.06	-0.95 to 1.06	0.912[a]
6 hr.	3.63 ± 0.36	3.59 ± 0.37	0.04	-1.08 to 0.99	0.934[a]
12 hr.	3.23 ± 0.30	3.72 ± 0.33	0.49	-0.40 to 1.39	0.278[a]
24 hr.	2.33 ± 0.26	3.56 ± 0.29	1.23	0.45 to 2.01	0.003[a]
48 hr.	1.72±0.21	3.16±1.62	-0.4	-0.6 to -0.1	0.004[c]

[c] generalized estimating equation population-averaged model
SD: standard deviation, CI: confidence interval

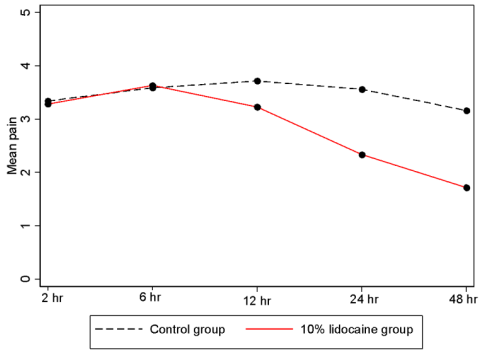

Fig. 1. Perineal wound pain during 48 hours after delivery.

Women in the intervention group were more completely satisfied with higher statistical significance than the women in the control group (75% vs 36.1%, p < 0.001). There was no significant difference in the need for additional analgesia with acetaminophen (16.7% vs 25 %, p = 0.384) or ibuprofen (27.8% vs 22.2%, p = 0.586) (Table 5).

Table 5. Additional analgesia and participant's satisfaction.

	Lidocaine group (n = 36)	Control group (n = 36)	p value
Post-episiotomy participant's satisfaction			
Completely satisfied, n (%)	27 (75.0)	13 (36.1)	0.001 [b]
Satisfied, n (%)	7 (19.4)	19 (52.8)	0.003 [b]
No idea, n (%)	2 (5.6)	4 (11.1)	0.394 [b]
Dissatisfied, n (%)	0	0	0
Completely dissatisfied, n (%)	0	0	0
The need for additional analgesia			
Ibuprofen (400), n (%)	10 (27.8)	8 (22.2)	0.586 [b]
Acetaminophen (500), n (%)	6 (16.7)	9 (25.0)	0.384 [b]

[b] Fisher's extract test. SD: standard deviation, CI: confidence interval

In this study, no adverse effects of the drug (burning sensation, bradycardia, hypotension, allergic reaction) or complications of the perineal wounds were found.

Discussion

In the current study, it was found that perineal wound pain at 48 hours in the 10% lidocaine spray group was significantly lower than that of the control. Additionally, this study found that the perineal wound pain at 24 hours of the 10% lidocaine spray group was also significantly lower than that of the control group. Moreover, the comparison of the reduction of pain between the intervention group and the control group using the GEE population-averaged model indicated that in the intervention group, pain reduction was more significant than that of the control group. Although the pain scores at 24 and 48 hours were less than 4 and the differences in scores were 1-2 points between groups, this current study found that there was a statistically significant difference; however, it may not be a clinically significant difference. Thus, further research on clinical factors, such as quality of breastfeeding, resting, urination, psychological and emotional conditions, and cost effectiveness, may be required. Even though the decrease in pain is only slight, it may increase the overall quality of life.

The results of this research were consistent with the findings of Harrison et al, which showed that lidocaine spray significantly reduced perineal pain. In addition, Corkill et al found that the efficacy of lignocaine gel in reducing postpartum perineal pain was more effective when administered continuously. Additionally, there was no difference in the consumption of oral analgesics between groups. These results aligned with our study, which showed that continuous local anesthesia at the perineal area reduced pain for 48 hours postpartum, without the differences of additional drugs used. However, our study found a reduction in pain during 24 hours after delivery. This may be attributed to differences in the current study, such as the higher concentration of the drug and the regular administration, which could prolong pain relief and provide a statistically significant reduction in pain during the 48 hours after delivery.

In comparison with the research of Chaichanalap et al [13], both studies included a variety of approaches in the management of postpartum pain. The research on music therapy demonstrated a significant reduction in immediate postpartum episiotomy pain, while our study on lidocaine spray showed effective pain relief compared to placebo for perineal wounds after vaginal delivery. Both methods were effective in reducing postpartum perineal pain but may serve different patient needs. Music therapy may be particularly beneficial for those seeking alternatives to medications, whereas lidocaine spray may be appropriate for patients needing immediate, localized pain relief. Harasai et al[14] studied the efficacy of a single dose of ibuprofen and acetaminophen compared to acetaminophen alone. The research demonstrated that the combination significantly reduces perineal pain after childbirth, similar to the current study, which showed effective pain relief for postpartum perineal wound pain. The combination of ibuprofen and acetaminophen offers analgesic effects through different mechanisms with ibuprofen as a non-steroidal anti-inflammatory drug (NSAID) and acetaminophen as an analgesic. In contrast, the lidocaine spray serves as a local anesthetic, directly targeting the site of the pain. Furthermore, Pattarasiriwong et al[15] found no significant differences in the efficacy of the pain reduction of acetaminophen/tramadol rectal suppositories compared to placebo in postpartum women following normal vaginal delivery. This contrasted with our study, which demonstrated that lidocaine spray provided effective pain relief for perineal wounds. This difference may suggest that while systemic analgesics such as acetaminophen and tramadol are beneficial in some contexts, they may not be as effective as local anesthetics in managing postpartum perineal pain.

Although the need for additional analgesia was not different, it remains consistent with the research of Corkill et al, which may be due to some women undergoing additional procedures after delivery such as postpartum sterilization in cases of multiparity. These women might require additional analgesics

(such as paracetamol or ibuprofen) to manage pain. In future studies, this confounding factor may need to be eliminated, or additional data may need to be collected for statistical analysis in this section. However, when comparing the satisfaction of using the drug and placebo, it was found that postpartum women were more completely satisfied with the use of the drug than placebo. Perineal wound pain reduction during the first few postpartum days may help postpartum women have a better quality of life, increase mobility, improve breastfeeding.

Although 10% lidocaine spray is a potential drug of choice for reducing the pain of perineal wounds during 48 hours postpartum, future research should focus on the other daily life activities, e.g. urination and defecation, lactation, psychosocial activities, other procedures after delivery, and the long-term side effects, and should also take into account the cost-effectiveness, operative vaginal delivery, third- or fourth-degree perineal tears, long-term outcomes and other confounding factors.

The key strengths of this study were that it was a randomized, double-blinded, placebo-controlled trial and it assessed the participant satisfaction. The limitations were the lack of analysis regarding the procedures such as postpartum tubal resection, which include the use of analgesics to control pain following the procedure.

The implication for practice was consideration of the application of 10% lidocaine for perineal pain relief during postpartum or its combination with other pain killers.

Conclusion

The 10% lidocaine spray effectively reduced perineal wound pain at 24 and, 48 hours after delivery without serious adverse effect.

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Potential conflicts of interest

The author declares no conflicts of interest.

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