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## OBSTETRICS

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# Effectiveness of Topical 2% Lidocaine Gel for Post-episiotomy Pain Relief: A randomized, Double-blind trial

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### ABSTRACT

**Objectives:** To evaluate the effectiveness and safety of topical 2% lidocaine gel versus a placebo for post-episiotomy analgesia, assessed using the numeric rating scale (NRS) pain scores at 6, 12, and 24 hours postpartum.

**Materials and Methods:** This randomized, double-blind, placebo-controlled trial was conducted at a tertiary care hospital in Thailand. A total of 184 women who underwent vaginal delivery with episiotomy were randomized to receive topical 2% lidocaine gel (n = 92) or placebo gel (n = 92), applied as a thin layer to the perineal wound every 4 hours for 12 hours post-repair. Pain was assessed with the NRS at 6, 12, and 24 hours by blinded assessors. Secondary outcomes included rescue-analgesic use within 24 hours, lochia pad count, perineal wound events (hematoma, dehiscence, infection), adverse events and length of hospital stay.

**Results:** Mean NRS pain scores at 6, 12, and 24 hours were not different between groups: mean difference -0.11 (95% confidence interval (CI) -0.5, 0.28), -0.21 (-0.56, 0.15), and -0.21 (-0.51, 0.10), respectively. Rescue-analgesic use was similar in both groups (46.7% vs 56.5%; relative risk (RR) 0.83, 95% CI 0.62, 1.10). No drug-related adverse events or maternal complications were observed. The lidocaine group had a significantly higher lochia pad count ( $p < 0.001$ ), whereas the length of hospital stay was significantly shorter than in the placebo group ( $p = 0.019$ ).

**Conclusion:** Topical 2% lidocaine gel did not provide a statistically significant reduction in post-episiotomy perineal pain during the first 24 hours compared with placebo. Therefore, it should not be recommended as a first-line analgesic in this setting.

**Keywords:** episiotomy wound, postpartum perineal pain, lidocaine gel, topical anesthetics, randomized controlled trial, numerical rating scale.

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## ประสิทธิผลของเจลลิโดเคนร้อยละ 2 ชนิดใช้เฉพาะที่ในการบรรเทาปวดหลังการตัดฝีเย็บ: การทดลองแบบสุ่ม ปกปิดสองทาง

ณัฐกฤษฏี สินตระกูลชัย, โชคชัย โชติบุรณ์, ภูริณัฐ ใจธรรม, เมธา ทรงธรรมวัฒน์

### บทคัดย่อ

**วัตถุประสงค์:** ประเมินประสิทธิผลและความปลอดภัยของเจลลิโดเคนร้อยละ 2 ชนิดใช้เฉพาะที่เมื่อเทียบกับยาหลอกในการบรรเทาปวดหลังการตัดฝีเย็บ โดยวัดด้วยคะแนนความปวดแบบตัวเลข (NRS) ที่ 6, 12 และ 24 ชั่วโมงหลังคลอด

**วัสดุและวิธีการ:** การทดลองแบบสุ่ม ปกปิดสองทาง และมีกลุ่มควบคุมด้วยยาหลอก ดำเนินการที่โรงพยาบาลตติยภูมิในประเทศไทย สตรีที่คลอดทางช่องคลอดร่วมกับการตัดฝีเย็บจำนวน 184 ราย ถูกสุ่มให้ได้รับเจลลิโดเคนร้อยละ 2 ( $n = 92$ ) หรือเจลยาหลอก ( $n = 92$ ) ทาบาง ๆ บริเวณแผลฝีเย็บ ทุก 4 ชั่วโมง นาน 12 ชั่วโมง หลังเย็บซ่อม ประเมินความปวดด้วย NRS ที่ 6, 12 และ 24 ชั่วโมง โดยผู้ประเมินที่ไม่ทราบการจัดกลุ่ม ผลลัพธ์รองได้แก่ การใช้ยาแก้ปวดเพิ่มเติมภายใน 24 ชั่วโมง จำนวนผ้าอนามัยที่ใส่รองน้ำคาวปลา ภาวะแทรกซ้อนที่แผลฝีเย็บ (เลือดคั่ง แผลแยก การติดเชื้อ) อาการไม่พึงประสงค์จากยา และระยะเวลาการนอนโรงพยาบาล

**ผลการศึกษา:** ค่าคะแนนความปวดเฉลี่ยแบบ NRS ที่ 6, 12 และ 24 ชั่วโมงไม่มีความแตกต่างกันระหว่างกลุ่ม: ผลต่างค่าเฉลี่ย -0.11 (95% Confidence interval (CI) -0.50, 0.28), -0.21 (95% CI -0.56, 0.15), และ -0.21 (95% CI -0.51, 0.10) ตามลำดับ อัตราการใช้ยาแก้ปวดเพิ่มเติมใกล้เคียงกัน (ร้อยละ 46.7 เปรียบเทียบกับ 56.5; relative risk [RR] 0.83, 95% CI 0.62, 1.10) ไม่พบอาการไม่พึงประสงค์ที่เกี่ยวข้องกับยาหรือภาวะแทรกซ้อนในมารดา กลุ่มลิโดเคนมีจำนวนผ้าอนามัยที่ใส่รองน้ำคาวปลามากกว่าอย่างมีนัยสำคัญ ( $p < 0.001$ ) ขณะที่ระยะเวลาการนอนโรงพยาบาลสั้นกว่ากลุ่มยาหลอก ( $p = 0.019$ )

**สรุป:** เจลลิโดเคนร้อยละ 2 ชนิดใช้เฉพาะที่ ไม่ทำให้ความปวดหลังการตัดฝีเย็บลดลงอย่างมีนัยสำคัญในช่วง 24 ชั่วโมงแรก เมื่อเทียบกับยาหลอก จึงไม่ควรแนะนำเป็นยาแก้ปวดหลัก

**คำสำคัญ:** แผลฝีเย็บ, ความปวดฝีเย็บหลังคลอด, เจลลิโดเคน; ยาชาเฉพาะที่, การทดลองแบบสุ่มมีกลุ่มควบคุม, คะแนนความปวดแบบตัวเลข

## Introduction

Episiotomy is a common procedure performed during vaginal delivery. The incision can be made either in a midline or mediolateral direction<sup>(1)</sup>. Primigravid women have a higher likelihood of undergoing episiotomy compared with women who have previously delivered vaginally<sup>(2)</sup>. Although global practice has shifted toward restrictive rather than routine use<sup>(3)</sup>, the high prevalence of episiotomy and subsequent perineal pain remains a significant challenge in Thai obstetric care. Recent studies continue to highlight that postpartum perineal pain is a common and distressing experience, with a substantial number of women reporting moderate to severe pain levels following the procedure<sup>(5)</sup>.

The pathogenesis of post-episiotomy pain involves acute mechanical trauma to the perineal tissues and a subsequent inflammatory cascade. The surgical incision directly stimulates nociceptors and may cause peripheral nerve damage, followed by the release of inflammatory mediators, such as prostaglandins and bradykinin, which sensitize nerve endings and lower the pain threshold at the site of injury<sup>(5,6)</sup>. Postpartum perineal pain following episiotomy is common. Severe pain in the early postpartum period can contribute to maternal fatigue and psychological stress, which may interfere with the mother–infant relationship and the ability to perform routine activities such as sitting, walking, defecation, breastfeeding, and caring for the newborn<sup>(7–9)</sup>.

Various methods have been employed to reduce post-episiotomy perineal pain, including the application of heat or cold, the use of oral analgesics, and the administration of local anesthetics. However, each approach has advantages and limitations. For example, oral analgesics may cause gastrointestinal side effects or maternal drowsiness, whereas the application of heat or cold may provide only modest, short-lived relief<sup>(10,11)</sup>.

Lidocaine is a local anesthetic that acts by inhibiting voltage-gated sodium channels on neuronal cell membranes, thereby blocking the transmission of nerve impulses to the brain and reducing pain

perception at the site of application<sup>(12)</sup>. Through this mechanism, it provides localized analgesia without affecting the central nervous system. Small randomized trials have evaluated topical anesthetics for post-episiotomy pain, including 2% lidocaine gel and lidocaine ointments/sprays, indicating possible benefit but heterogeneity in formulation, dosing, and timing, as well as limited safety reporting<sup>(13–17)</sup>. Therefore, this double-blind randomized controlled trial aimed to evaluate the effectiveness of 2% lidocaine gel for reducing post-episiotomy perineal pain.

## Materials and Methods

This randomized, double-blind, placebo-controlled, parallel-group trial was conducted at Udon Thani Hospital, a tertiary care center in Thailand. The study protocol was approved by the Udon Thani Hospital Ethics Committee in Human Research (approval no.4/2568) and was prospectively registered with the Thai Clinical Trials Registry (TCTR20250310001).

The inclusion criteria were postpartum women with singleton pregnancies who underwent vaginal delivery with episiotomy at Udon Thani Hospital, with a gestational age between 37 and 41 weeks, aged 18 years or older, and who provided written informed consent. The exclusion criteria were (i) known hypersensitivity/allergy to lidocaine, other amide-type local anesthetics or gel excipients; (ii) obstetric anal sphincter injury (third- or fourth-degree tear) or perineal hematoma; (iii) postpartum hemorrhage (more than 500 cc); (iv) admission to the intensive care unit or endotracheal intubation after delivery.

Postpartum women who had a vaginal delivery with episiotomy were screened for eligibility. Eligible women received detailed study information in the labor room and, if willing, provided written informed consent before any study procedures. Eligible women were randomized into two groups. Group 1 received 5 mL of topical 2% lidocaine gel applied to the episiotomy wound every 4 hours for 12 hours (four scheduled applications at 4, 8, 12, and 16 hours postpartum). Group 2 received 5 mL of matching placebo gel on the same schedule.

The first application was performed 4 hours after delivery, following the completion of the episiotomy wound repair, by trained nurses, using a standardized technique. The 5 mL dose was uniformly applied as a continuous coating, approximately 1–2 mm in thickness, sufficient to cover the entire length of the incision to both the external perineal skin and the internal vaginal mucosal edge of the episiotomy incision, after gentle cleansing and drying of the area. Both groups received identical standard intrapartum and postpartum care. All participants underwent a mediolateral episiotomy; local anesthetic infiltration with 1% lidocaine (Xylocaine®) was performed prior to the incision. Episiotomies were repaired with chromic catgut using a standardized three-layer technique: continuous non-locking sutures for the vaginal mucosa and interrupted sutures for the perineal musculature and skin to ensure anatomical apposition.

Pain was assessed using the numerical rating scale (NRS; 0–10, higher scores = more pain) at 6, 12, and 24 hours postpartum by blinded assessors. Additional outcomes included the proportion of participants requiring rescue analgesia and the cumulative 24-hour dose (paracetamol, non-steroidal anti-inflammatory drugs, or opioids), length of hospital stay, and episiotomy wound infection. Lochia pad count (number of sanitary pads used) was recorded as a control variable.

Participants were scheduled for a 6-week postpartum follow-up in the clinic or, if unavailable, via telephone interview to assess for episiotomy-wound complications (dehiscence or infection). All data were recorded and subsequently analyzed.

Randomization (1:1) used a computer-generated sequence, and allocation concealment was maintained with sequentially numbered, sealed, opaque envelopes. At enrollment, authorized study staff opened the next envelope to obtain the study code and dispensed the corresponding gel. A hospital pharmacist prepared the 2% lidocaine gel and matching placebo gel (K-Y gel) to be identical in appearance and packaging, labeled only with a study

code. Participants, care providers, and outcome assessors were blinded to group assignment. Blinding was maintained throughout the study; emergency unblinding was permitted only for patient safety.

The primary outcome of this study was the comparison of mean  $\pm$  standard deviation (SD) NRS pain scores between the two groups at 6, 12, and 24 hours postpartum. The secondary outcomes included the proportion of participants requiring rescue analgesia and the cumulative 24-hour dose of analgesics (paracetamol, nonsteroidal anti-inflammatory drugs, or opioids), length of hospital stay, and episiotomy wound infection. Additionally, adverse events related to topical application (stinging/burning, pruritus, erythema, edema, and dermatitis) and systemic lidocaine-related symptoms (dizziness, perioral numbness, tinnitus, metallic taste, and palpitations), as well as allergic reactions and serious adverse events, were recorded until discharge.

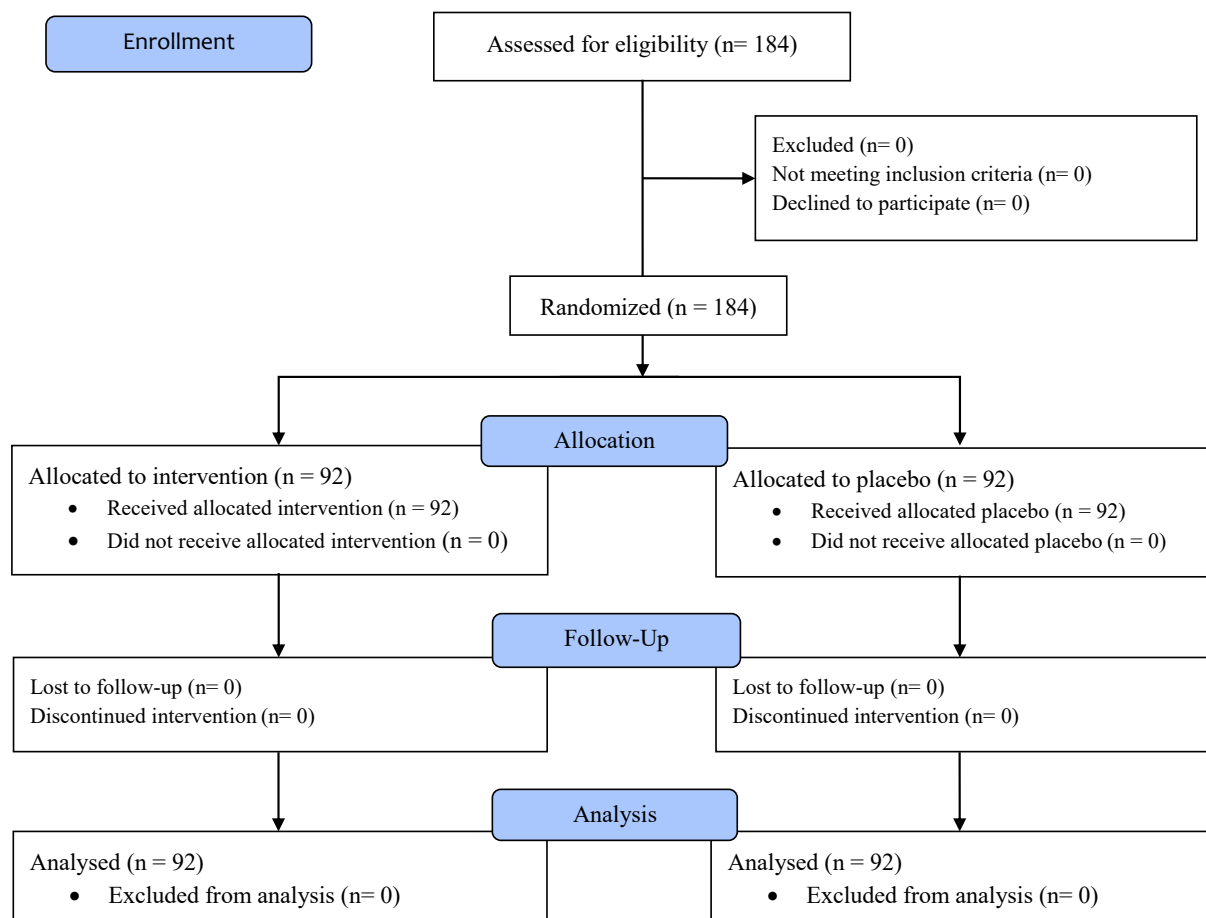
Sample size was calculated using the N4Studies application (18-20) for a two-sided comparison of independent means in a randomized controlled trial with 1:1 allocation. Estimates were taken from Abedzadeh et al(13): mean  $\pm$ SD NRS 12 hours postpartum of  $2.63 \pm 2.01$  in the intervention group and  $3.60 \pm 2.40$  in the control group. With  $\alpha = 0.05$ , 80% power, and an anticipated 10% dropout rate, the required sample size was 92 participants per group (total  $n = 184$ ).

Statistical analyses were performed using Stata version 13 (StataCorp, College Station, TX). Continuous data were reported as mean  $\pm$  SD, and categorical data as frequencies (percentages). Independent samples t-test was used to compare continuous variables; results were presented as mean differences with 95% confidence intervals (CI). For categorical variables, chi-square or Fisher's exact tests were applied, and relative risks (RR) with 95% CI were estimated using a generalized linear model. All tests were two-sided, with  $p < 0.05$  considered statistically significant. All analyses followed the intention-to-treat principle.

## Results

The trial enrolled a total of 184 women, with 92 participants allocated to receive 2% lidocaine gel and 92 allocated to the placebo group. As demonstrated in the CONSORT flow diagram in Fig. 1, all 184 randomized participants completed the study protocols and were included in the final intention-to-treat analysis. Baseline maternal and neonatal characteristics were comparable between the two study arms as demonstrated in Table 1. All participants underwent a mediolateral episiotomy and sustained a second-degree perineal tear. The mean maternal age was  $26.8 \pm 5.64$  years in the lidocaine group and  $27.22 \pm 4.91$  years in the

placebo group<sup>(4)</sup>. The distribution of primigravid women (50.0% vs 41.3%,  $p = 0.236$ ) and the mean gestational age at delivery ( $38.65 \pm 1.08$  vs  $38.65 \pm 1.03$  weeks) showed no statistically significant differences<sup>(5)</sup>. Neonatal outcomes, including the distribution of male infants (51.1% vs 46.7%) and birth weight ( $3,055.76 \pm 319.71$  vs  $3,131.58 \pm 313.35$  grams), were also balanced between the groups. Additionally, the estimated blood loss was similar between the intervention and placebo groups ( $135 \pm 66.01$  mL vs  $147.28 \pm 71.38$  mL)<sup>(7)</sup>. Furthermore, no cases of multiple gestations or fetal growth restriction were enrolled in the study population<sup>(8)</sup>.



**Fig. 1.** CONSORT flow diagram of the randomized, double-blind, placebo-controlled trial assessing topical 2% lidocaine gel for post-episiotomy analgesia in 184 postpartum women, demonstrating the progression from enrollment to final analysis.

**Table 1.** Comparison of baseline maternal and neonatal characteristics between the topical 2% lidocaine gel and placebo groups.

| Variable                                           | Intervention (n = 92) | Placebo (n = 92)  | p value* |
|----------------------------------------------------|-----------------------|-------------------|----------|
| Age (years)                                        | 26.8 ± 5.64           | 27.22 ± 4.91      | 0.636    |
| Primigravida                                       | 46 (50.00%)           | 38 (41.30%)       | 0.236    |
| Previous abortion                                  | 12 (13.04%)           | 13 (14.13%)       | 0.830    |
| Gestational age (weeks)                            | 38.65 ± 1.08          | 38.65 ± 1.03      | 1.000    |
| Underlying disease                                 |                       |                   |          |
| Diabetes mellitus                                  | 8 (8.70%)             | 6 (6.52%)         | 0.578    |
| Others                                             | 4 (4.3%)              | 5 (5.43%)         | 1.000    |
| Smoking                                            | 2 (2.17%)             | 1 (1.09%)         | 1.000    |
| Alcohol use                                        | 2 (2.17%)             | 0 (0%)            | 0.497    |
| History of methamphetamine use                     | 5 (5.43%)             | 4 (4.35%)         | 1.000    |
| Pre-pregnancy body mass index (kg/m <sup>2</sup> ) | 24.49 ± 5.59          | 24.48 ± 5.31      | 0.982    |
| Estimated blood loss (mL)                          | 135 ± 66.01           | 147.28 ± 71.38    | 0.253    |
| Male baby                                          | 47 (51.09%)           | 43 (46.74%)       | 0.555    |
| Birth weight (grams)                               | 3,055.76 ± 319.71     | 3,131.58 ± 313.35 | 0.106    |

Data are presented as mean ± standard deviation or n (%).

\* p values from Pearson's chi-square or Fisher's exact tests for categorical variables and independent samples t-test for continuous variables.

The primary outcome is summarized in Table 2. Pain scores and analgesic requirements regarding the primary outcome, the mean NRS pain scores were numerically lower in the lidocaine group at all assessment points; however, these differences were not statistically significant. Specifically, at 6, 12, and 24 hours postpartum, the mean differences were -0.11

(95% CI -0.50, 0.28), -0.21 (-0.56, 0.15), and -0.21 (-0.51, 0.10), respectively (Table 2). In alignment with these findings, the requirement for rescue analgesia within the first 24 hours was comparable between groups, with 46.7% of women in the lidocaine group and 56.5% in the placebo group requiring additional pain medication (RR 0.83, 95% CI 0.62, 1.10).

**Table 2.** Comparison of postpartum episiotomy wound pain scores (NRS) and rescue analgesic requirements between women receiving topical 2% lidocaine gel (n = 92) and placebo (n = 92).

| Variable                        | Intervention (n = 92) | Placebo (n = 92) | Effect estimate (95% CI)                       |
|---------------------------------|-----------------------|------------------|------------------------------------------------|
| Pain score at 6 hours           | 2.69 ± 1.24           | 2.79 ± 1.42      | Mean difference (95% CI) - 0.11 (- 0.50, 0.28) |
| Pain score at 12 hours          | 2.04 ± 1.31           | 2.25 ± 1.14      | Mean difference (95% CI) - 0.21 (- 0.56, 0.15) |
| Pain score at 24 hours          | 1.50 ± 1.08           | 1.71 ± 1.02      | Mean difference (95% CI) -0.21 (-0.51, 0.10)   |
| Additional pain control needed* | 43 (46.74%)           | 52 (56.52%)      | Risk ratio 0.83 (0.62, 1.10)                   |
| Paracetamol                     |                       |                  |                                                |
| 1 tablet (500 mg)               | 41 (44.6%)            | 52 (56.5%)       |                                                |
| 2 tablets (1,000 mg)            | 1 (1.1%)              | 0 (0%)           |                                                |
| Ibuprofen                       |                       |                  |                                                |
| 1 tablet (400 mg)               | 2 (2.2%)              | 3 (3.3%)         |                                                |
| Lochia pad use, pads/day,       | 3.66 ± 0.96           | 3.11 ± 0.86      | Mean difference (95% CI) 0.54 (0.28 to 0.81)   |
| Hospital stays                  |                       |                  | Risk ratio 0.33 (0.15 to 0.75)                 |
| 2 days                          | 85 (92.39%)           | 71 (77.17%)      |                                                |
| > 3 days                        | 7 (7.60%)             | 21 (22.82%)      |                                                |

\*Some patients received more than one medication.

Data are presented as mean ± standard deviation or n (%).

CI: confidence interval

For the secondary outcomes, safety assessments revealed no local application-site adverse events, such as erythema or pruritus, and no systemic lidocaine-related symptoms were reported in either group. Similarly, no systemic lidocaine-related adverse events, such as dizziness, perioral numbness, tinnitus, or palpitations, were reported. At the six-week postpartum follow-up, the incidence of episiotomy-wound complications, specifically dehiscence or infection, was zero in both the intervention and placebo groups.

The mean number of lochia pads used per day was significantly higher in the lidocaine group at  $3.66 \pm 0.96$  pads compared with  $3.11 \pm 0.86$  in the placebo group ( $p < 0.001$ ). Conversely, the length of hospital stay was significantly shorter in the intervention group compared with the placebo group. Specifically, 92.4% of participants in the lidocaine group were discharged within two days, whereas 77.2% of those in the placebo group achieved discharge within the same timeframe. Although a higher proportion of women in the placebo group required hospitalization for three days or longer, these delayed discharges were primarily attributed to neonatal indications, such as neonatal jaundice, rather than maternal factors.

## Discussion

In this randomized, double-blind, placebo-controlled trial, topical 2% lidocaine gel did not reduce post-episiotomy perineal pain compared with placebo. Mean NRS scores at 6, 12, and 24 hours were numerically lower in the lidocaine group but not statistically significant. Rescue-analgesic use (paracetamol, ibuprofen) was similar between groups. No local or systemic lidocaine-related adverse events were recorded, and no episiotomy-wound infection or dehiscence was detected at 6-week follow-up. Collectively, these findings suggested that post-repair application of 2% lidocaine gel did not provide a clinically meaningful analgesic advantage over placebo in the first 24 hours postpartum in this setting. Compared with the Iranian trial by Abedzadeh et al (2011), which showed that 2% lidocaine gel significantly

reduced mean pain scores at 12 hours ( $2.63 \pm 2.01$  vs  $3.60 \pm 2.40$  in the control group) and lowered the need for additional analgesics (8% vs 20%)<sup>(13)</sup>.

Similarly, a Thai randomized trial by Suwannapab et al (2025) reported that 10% lidocaine spray significantly reduced perineal wound pain at 24 and 48 hours after spontaneous vaginal birth with first-second degree perineal tears with mean difference pain score 1.20-1.40<sup>(4)</sup>. Trials using lidocaine-prilocaine combinations, such as Moradi (2019) and Abbas (2020) studies also found greater effectiveness than systemic or injectable comparators<sup>(16, 17)</sup>. The current study did not demonstrate these effects. Such discrepancies may reflect specific methodological variations, including the lower concentration (2%) compared with the 10% formulation used by Suwannapab et al. Additionally, the timing of the first application at four hours post-repair and the high rate of rescue-analgesic use (approximately 50%) in this study may have masked the gel's individual analgesic benefit, especially when compared with trials reporting significantly lower supplemental analgesic requirements.

Furthermore, the management of postpartum perineal pain in Thailand often involves systemic oral analgesics. Harasai et al (2020) demonstrated that a single dose of 400 mg ibuprofen combined with 1,000 mg acetaminophen provided significantly better pain relief than acetaminophen alone, particularly within the first two hours postpartum<sup>(21)</sup>. In the present study, although participants had access to rescue analgesics like paracetamol and ibuprofen, the addition of topical 2% lidocaine gel did not provide an additive benefit. This suggested that for early postpartum pain, potent systemic oral combinations might be more effective than the low-concentration topical gel used in the present trial.

Regarding the timing and formulation of topical anesthetics, Wongvivattanakarn et al (2025) recently reported that lidocaine-prilocaine cream (EMLA®), when used in conjunction with lidocaine injection, significantly reduced pain during the episiotomy repair process<sup>(22)</sup>. However, they noted that the analgesic

effect diminished by one hour after the repair. This observation aligned with the current findings, where 2% lidocaine gel applied four hours after the repair did not result in a statistically significant reduction in pain scores during the 24-hour postpartum period. These collective findings imply that while topical anesthetics are beneficial for procedural pain during suturing, their role in sustained postpartum pain relief may be limited by their concentration and duration of action.

Our findings are consistent with Delaram et al (2016), who compared 2% lidocaine cream with mefenamic acid after mediolateral episiotomy and reported no significant difference in pain reduction at 6, 12, or 24 hours<sup>(15)</sup>. These data suggested that topical lidocaine may offer analgesia comparable to standard regimens but not superior in the early postpartum period. Importantly, the current study also supported a favorable safety profile of lidocaine gel with no complications such as allergy, infection, or wound problems.

In this study, the number of lochia pads used per day was significantly higher in the lidocaine gel group compared to the placebo group. However, this observation likely represented an incidental finding rather than a true pharmacologic effect of the medication. To our knowledge, no prior study has directly linked topical lidocaine, including gel formulations, to increased postpartum lochia or bleeding. A pharmacokinetic report noted a single instance of slight vaginal bleeding 30–48 hours after vaginal lidocaine gel, but this occurred in a different context and did not establish causation for episiotomy wounds<sup>(23)</sup>. A systematic review of normal lochia patterns highlights the wide variability in both amount and duration of lochia, with methods of assessment ranging from pad weight to subjective self-report, and no standardized definition of what constitutes excessive lochia<sup>(24)</sup>. Given this inherent variability, the current finding may reflect measurement variation. Nevertheless, the observation should be interpreted with caution, and future studies using validated and objective measures of lochia are warranted to clarify

whether this association is real or incidental.

The clinical implication of this study was that topical 2% lidocaine gel did not provide a clinically meaningful reduction in post-episiotomy perineal pain during the first 24 hours compared with placebo. Therefore, it should not be recommended as a first-line analgesic in this setting. Future research should evaluate alternative topical formulations and strengths or multimodal approaches to postpartum perineal pain management, including larger multicenter trials to better define the role of lidocaine gel in postpartum care.

This study had several strengths. The randomized, double-blind, placebo-controlled design reduced the risk of bias, and the sample size was sufficient for between-group comparisons. At the same time, several limitations should be noted. First, this was a single-center study, which may limit generalizability to other settings. Second, while the NRS is a standardized tool, it relies on self-reported data, which is subjective and influenced by individual variability in pain perception. Third, treatment adherence was not quantified (exact amount applied, coverage of internal/external wound edges, contact time) may have technique-related variability. Fourth, rescue-analgesic policies were pragmatic and participant-dependent which could affect the assessment of pain. Fifth, all participants underwent a mediolateral episiotomy and had a second-degree perineal tear. Sixth, lochia was measured by pad counts rather than objective quantification. Seven, the volume of lidocaine administered by injection was adjusted according to the characteristics and size of the episiotomy wound and was not considered part of the study intervention; therefore, the exact amount used in each participant was not recorded.

## Conclusion

This randomized, double-blind, placebo-controlled trial demonstrated that topical 2% lidocaine gel did not provide a clinically meaningful reduction in post-episiotomy perineal pain during the first 24 hours compared with placebo. Throughout the first

24 hours postpartum, both mean NRS pain scores and the requirements for rescue analgesia remained comparable between the intervention and placebo groups. Consequently, topical 2% lidocaine gel should not be recommended as a first-line analgesic for perineal pain relief in this clinical setting.

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## Potential conflicts of interest

The authors declare no conflicts of interest.

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