

Effect of a 5% lidocaine patch for postoperative pain relief following cesarean section: a randomized double-blind placebo-controlled trial.

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Abstract

Introduction

Effective postoperative analgesia after cesarean section supports early mobilization, maternal-infant interaction, breastfeeding, and recovery. This study evaluated the analgesic efficacy and safety of a 5% lidocaine patch after cesarean delivery.

Materials and Methods

In this prospective, randomized, double-blind, placebo-controlled trial, 120 women undergoing cesarean section under spinal anesthesia were allocated 1:1 to a 5% lidocaine patch (n=60) or an identical placebo patch (n=60). Pain was assessed on a 0-10 numerical rating scale at 0, 2, 4, 6, 8, 12, and 24 hours. Rescue analgesic use, ambulation, satisfaction, hemodynamic variables, and adverse effects were evaluated.

Results

Baseline characteristics were comparable. Mean age was 28.7 ± 3.9 years in the lidocaine group and 29.1 ± 4.2 years in controls; mean BMI was 25.1 ± 2.8 and 25.4 ± 3.0 kg/m², respectively, and mean gestational age was 38.4 ± 0.9 and 38.3 ± 1.0 weeks. ASA I status was present in 63.3% and 60.0%, respectively. At 24 hours, pain was lower with lidocaine (2.1 ± 0.7 vs. 2.8 ± 0.9 ; mean difference -0.70, 95% CI -0.99 to -0.41; $p < 0.001$). Time to first rescue analgesia was longer (8.4 ± 2.1 vs. 5.9 ± 1.8 hours; mean difference 2.50 hours, 95% CI 1.79 to 3.21), and total rescue analgesic consumption was lower (82.5 ± 34.7 vs. 121.7 ± 42.6 mg; mean difference -39.20 mg, 95% CI -53.25 to -25.15; both $p < 0.001$). Ambulation occurred earlier and satisfaction was higher, while overall adverse effects were comparable.

Conclusion

A 5% lidocaine patch improved early postoperative analgesia and reduced rescue analgesic requirements without evidence of increased adverse effects.

Recommendation

The patch can be considered as an adjunct to multimodal post-cesarean analgesia, while larger multicenter trials should confirm effectiveness, safety, and optimal application protocols.

Keywords: Cesarean section; Lidocaine patch; Postoperative analgesia; Pain management; Rescue analgesia

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Introduction

Cesarean section is one of the most frequently performed major surgical procedures worldwide, and effective postoperative analgesia is essential for facilitating maternal recovery [1]. Inadequately controlled pain after cesarean delivery can impair early ambulation, breastfeeding, maternal-infant interaction, sleep, and overall patient satisfaction [2]. Acute postoperative pain may also contribute to prolonged hospital stay and increased healthcare utilization [3]. Therefore, multimodal analgesia, combining different pharmacological and non-pharmacological approaches, is increasingly emphasized to provide effective pain relief while minimizing opioid-related adverse effects [4].

Conventional postoperative analgesia following cesarean section commonly includes paracetamol, non-steroidal anti-inflammatory drugs, and opioids when required [5]. Although opioids provide effective analgesia, their use may be associated with nausea, vomiting, sedation, pruritus, constipation, and respiratory depression [6]. These concerns are particularly relevant in postpartum women, in whom maternal sedation may interfere with early mobilization and infant care. Consequently, there is growing interest in opioid-sparing analgesic strategies that can provide localized pain relief with minimal systemic adverse effects [7].

Lidocaine is a widely used local anesthetic that produces analgesia by blocking voltage-gated sodium channels and inhibiting the initiation and propagation of nociceptive impulses

[8]. A 5% lidocaine patch provides localized drug delivery with limited systemic exposure and is widely used for the management of localized neuropathic and somatic pain [9]. Its non-invasive application, ease of use, and relatively favorable safety profile make it a potentially useful adjunct to conventional postoperative analgesia. Application around the cesarean incision may reduce incisional pain and thereby decrease the requirement for systemic rescue analgesics [10].

Despite the increasing use of multimodal analgesic techniques after cesarean delivery, evidence regarding the role of topical lidocaine patches for acute postoperative pain in this setting remains limited. Evaluation of their effect on pain intensity, rescue analgesic requirement, time to first rescue analgesia, postoperative recovery, and patient satisfaction may help determine their potential role as an opioid-sparing component of postoperative care. Therefore, the present study aimed to evaluate the effect of a 5% lidocaine patch on postoperative analgesia following cesarean section, with particular emphasis on postoperative pain scores, rescue analgesic consumption, time to first rescue analgesia, recovery parameters, and adverse effects.

Materials and methods

Trial design

This was a prospective, randomized, double-blind, placebo-controlled parallel-group clinical trial evaluating a 5% lidocaine patch for postoperative analgesia after cesarean section. A total of 120 women were randomized in a 1:1 allocation ratio to the lidocaine patch group (n=60) or placebo patch group (n=60).

Setting and location

The study was conducted in the Department of Anaesthesiology, Kidwai Memorial Institute of Oncology, Bengaluru, Karnataka, India.

Eligibility criteria

Inclusion criteria

Women undergoing cesarean delivery under spinal anesthesia; provision of written informed consent before enrollment; and ability to understand and use the postoperative 0-10 numerical rating scale

Exclusion criteria

Known allergy to local anesthetics; significant hepatic disease; significant cardiac disease; chronic pain requiring regular analgesic medication; or inability to assess or communicate postoperative pain.

Interventions

After completion of cesarean delivery, adequate hemostasis, and skin closure, one 5% lidocaine patch containing 700 mg of lidocaine (10 × 14 cm) was divided longitudinally into two equal strips. One strip was applied to intact skin approximately 1 cm above and the other approximately 1 cm below the Pfannenstiel incision, avoiding direct contact with the wound. The patch was applied immediately after surgery, remained in place for 12 hours, and was then removed. It was not reapplied during the 24-hour study assessment period, and the application site was inspected at removal and whenever clinically indicated.

The control group received a non-medicated placebo patch of the same dimensions, backing material, color, texture, adhesive characteristics, external appearance, packaging, and study-code labeling as the lidocaine patch. The placebo patch was divided, positioned, applied, retained for 12 hours, and removed using the same procedure as the active patch, thereby preserving blinding and ensuring that the two interventions differed only by the presence or absence of lidocaine.

All participants received a standardized spinal anesthetic and perioperative analgesic regimen. Spinal anesthesia was performed with hyperbaric bupivacaine according to institutional obstetric anesthesia practice. Scheduled postoperative analgesia was administered uniformly to both groups. Rescue analgesia consisted of intravenous tramadol 50 mg when the NRS pain score was ≥ 4 or when the participant requested additional analgesia; repeat rescue dosing was permitted according to the institutional dosing interval and maximum daily dose. The time and cumulative rescue dose administered during the first 24 postoperative hours were recorded for every participant.

Outcomes and outcome measurement

The primary analgesic outcomes were postoperative pain intensity and total rescue analgesic consumption during the first 24 postoperative hours. Pain intensity was measured using an 11-point numerical rating scale (NRS) from 0 (no pain) to 10 (worst imaginable pain) at 0, 2, 4, 6, 8, 12, and 24 hours after surgery. Total rescue analgesic consumption was calculated as the cumulative dose (mg) administered during the first 24 hours.

Secondary outcomes were time to first rescue analgesia, proportion of participants requiring any rescue analgesia, proportion requiring at least two rescue doses, time to first ambulation, time to first oral intake, duration of hospital stay, patient satisfaction, hemodynamic variables, and postoperative adverse effects. Time to first rescue analgesia was measured from completion of surgery to administration of the first rescue dose. First ambulation was defined as the time from completion of surgery until the participant could stand and walk at least 5 m with no more than minimal assistance. Patient satisfaction with postoperative analgesia was rated at 24 hours on a 0–10

numerical scale, where 0 represented completely dissatisfied and 10 completely satisfied. Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and peripheral oxygen saturation were recorded at 0, 2, 4, 6, 8, 12, and 24 hours; Table 4 summarizes the participant-level mean across these postoperative observations. Nausea, vomiting, dizziness, pruritus, and local skin irritation were actively assessed at each postoperative assessment and whenever spontaneously reported during the first 24 hours.

Sample size

Sample size was calculated for the primary outcome of postoperative pain intensity. A between-group difference of 0.6 NRS units was considered clinically relevant, with an assumed standard deviation of 1.1. Using a two-sided significance level of 5% ($\alpha=0.05$), 80% statistical power ($1-\beta=0.80$), and equal allocation, the two-independent-means formula $n = 2(Z_{1-\alpha/2} + Z_{1-\beta})^2 \sigma^2 / \Delta^2$ yielded approximately 53 participants per group. Allowing for about 10% attrition or incomplete outcome data increased the requirement to approximately 59 participants per group; this was rounded to 60 per group. Thus, the planned total sample size was 120 participants.

Interim analysis and stopping guidelines

No interim efficacy or futility analysis was planned. No formal statistical stopping boundary was specified because the intervention was of short duration and the target sample was modest. Recruitment was planned to continue until the prespecified sample size of 120 participants had been enrolled, unless an unexpected serious safety concern required early termination. No such safety-related stopping criterion was triggered.

Sequence generation and type of randomization

An independent statistician who was not involved in participant recruitment or outcome assessment generated the allocation sequence using a computer-generated random-number list in SPSS version 26. Simple randomization with a 1:1 allocation ratio was used; no stratification or blocking was applied.

Allocation concealment

Allocation concealment was maintained using sequentially numbered, identical, opaque, sealed envelopes prepared in advance by a research assistant who was not involved in enrollment or postoperative assessment. Each envelope contained the corresponding coded treatment assignment, was sealed after insertion, and was stored in numerical order in a secure location. Envelopes were opened sequentially only after eligibility had been confirmed and written consent obtained, preventing foreknowledge or manipulation of the upcoming allocation.

Implementation

The independent statistician generated the randomization sequence. A study investigator screened eligible women, obtained written informed consent, and enrolled participants. After enrollment, a designated research nurse opened the next sequential envelope and assigned the corresponding coded study patch. The patch was applied by trained study personnel who took no part in postoperative pain scoring, recovery assessment, or data analysis.

Blinding and similarity of interventions

Participants, surgeons, postoperative anesthesiologists, nursing staff, outcome assessors, and the statistician performing the final comparative analysis were blinded to treatment allocation. An independent research nurse/pharmacy staff member who was not involved in outcome assessment prepared, coded, packaged, and labeled the active and placebo patches according to the randomization list and retained the allocation key until data collection was completed. Both patches were indistinguishable in appearance, size, backing, packaging, labeling, adhesive properties, placement, application duration, and removal procedure. The person applying the coded patch knew only the study code and not whether it contained lidocaine.

Ethical considerations

The study was conducted after approval from the Institutional Ethics Committee of the participating study center. All procedures conformed to applicable institutional ethical standards, and written informed consent was obtained from every participant before enrollment. Participant confidentiality was maintained through coded study identifiers and restricted access to research data.

Statistical methods

Data were analyzed using SPSS version 26. Continuous variables were summarized as mean $\pm$ standard deviation and categorical variables as number and percentage. Independent-samples t tests were used for normally distributed continuous between-group outcomes, including time to first rescue analgesia, total rescue analgesic consumption, hemodynamic variables, time to ambulation, time to oral intake, duration of hospital stay, and patient satisfaction. Pearson's chi-square test was used for categorical outcomes when expected cell-count assumptions were satisfied. Fisher's exact test was used for individual adverse events with sparse expected counts. Effect estimates were reported as mean differences (MDs) for continuous outcomes and risk ratios (RRs) for binary outcomes, each with 95% confidence intervals. All tests were two-sided and $p<0.05$ was considered statistically significant.

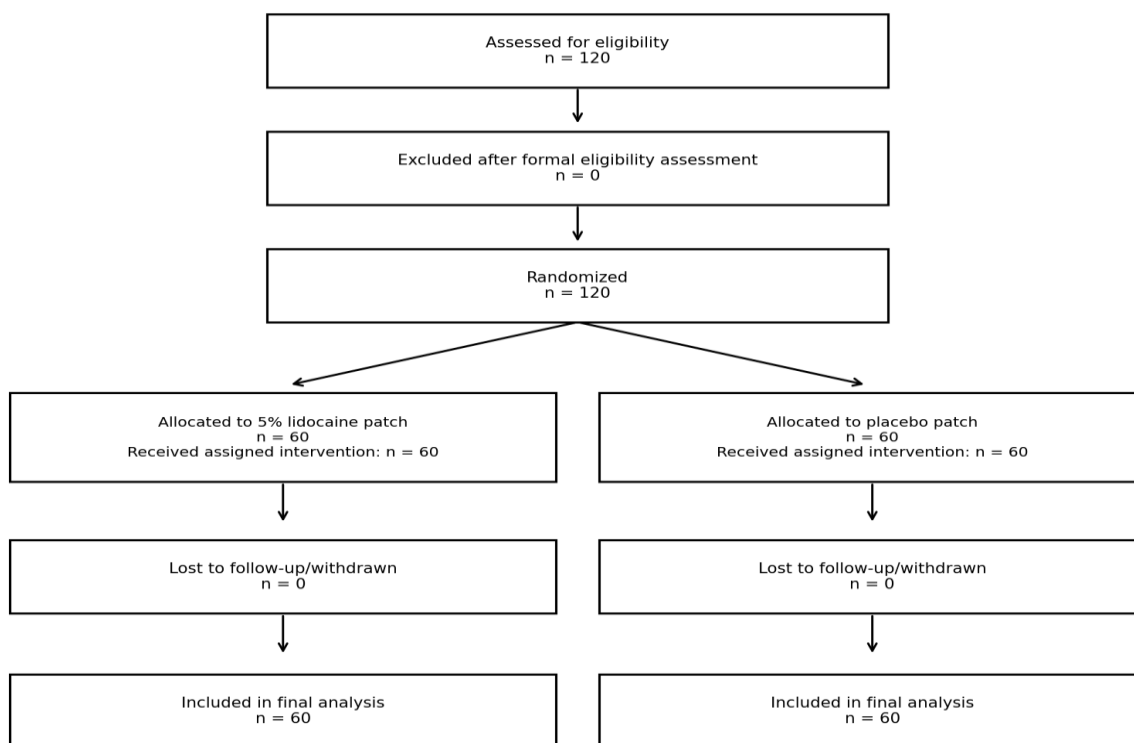
Postoperative NRS pain scores measured repeatedly at 0, 2, 4, 6, 8, 12, and 24 hours were evaluated using a two-way repeated-measures analysis with treatment group as the between-participant factor, time as the within-participant factor, and a group×time interaction to assess whether pain trajectories differed between groups. When the sphericity assumption was not satisfied, the Greenhouse–Geisser correction was applied. Prespecified between-group comparisons at each assessment time were performed using independent-samples t tests, with corresponding mean differences and 95% confidence intervals reported. The repeated-measures analysis was used for the overall longitudinal inference, while pointwise comparisons described the timing and magnitude of treatment differences.

Results

Participant flow and recruitment

A total of 120 women who met the initial screening criteria underwent formal eligibility assessment. No woman was excluded after formal eligibility assessment; therefore, all 120 participants were randomized. Sixty were allocated to the 5% lidocaine patch group and 60 to the placebo group. All participants received the assigned intervention, completed the 24-hour postoperative assessment, and were included in the final analysis. There were no post-randomization withdrawals or losses to follow-up during the primary 24-hour study period (Figure 1)

Figure 1. Participant flow through the randomized trial



Participants were recruited from 01/06/2025 to 31/12/2025. The intervention and primary follow-up covered the first 24 postoperative hours, and hospital-stay outcomes were followed until discharge. Recruitment was stopped after the prespecified

target of 120 randomized participants was reached; there was no early termination for efficacy, futility, safety, or administrative reasons.

Baseline demographic and perioperative characteristics

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The groups were comparable at baseline. Mean age was 28.7 ± 3.9 years in the lidocaine group and 29.1 ± 4.2 years in the

control group ($p=0.586$); corresponding mean BMI values were 25.1 ± 2.8 and 25.4 ± 3.0 kg/m² ($p=0.575$), and mean gestational ages were 38.4 ± 0.9 and 38.3 ± 1.0 weeks ($p=0.584$). ASA I status was present in 63.3% and 60.0%, respectively. No statistically significant baseline differences were observed (Table 1).

Table 1: Demographic and perioperative characteristics of the study participants

Parameter	Category	Lidocaine (n=60)	patch	Placebo (n=60)	p
Age, years	Mean $\pm$ SD	28.7 ± 3.9		29.1 ± 4.2	0.586
BMI, kg/m ²	Mean $\pm$ SD	25.1 ± 2.8		25.4 ± 3.0	0.575
Gestational age, weeks	Mean $\pm$ SD	38.4 ± 0.9		38.3 ± 1.0	0.584
ASA physical status	ASA I	38 (63.3%)		36 (60.0%)	0.710
	ASA II	22 (36.7%)		24 (40.0%)	
Previous cesarean section	Yes	18 (30.0%)		20 (33.3%)	0.695
Duration of surgery, min	Mean $\pm$ SD	52.6 ± 8.7		53.4 ± 9.1	0.618
Spinal anesthesia duration, min	Mean $\pm$ SD	81.3 ± 10.2		82.1 ± 10.7	0.671

Note. Data are presented as mean $\pm$ SD or n (%). BMI = body mass index; ASA = American Society of Anesthesiologists. Continuous variables were compared with independent-samples t-tests; categorical variables with chi-square tests as reported in the source manuscript.

Postoperative pain scores were similar at 0 hour (MD -0.10, 95% CI -0.43 to 0.23; $p=0.548$). From 2 through 24 hours, the lidocaine group had lower mean pain scores. At 24 hours, the mean score was 2.1 ± 0.7 versus 2.8 ± 0.9 , corresponding to an MD of -0.70 points (95% CI -0.99 to -0.41; $p<0.001$) (Table 2).

Primary outcomes: postoperative pain and rescue analgesic consumption

Table 2: Postoperative pain scores and between-group effect estimates

Time after surgery	Lidocaine (n=60)	patch	Placebo (n=60)	P	MD (95% CI)
0 h	2.8 ± 0.9		2.9 ± 0.9	0.548	-0.10 (-0.43 to 0.23)
2 h	3.1 ± 0.9		3.5 ± 1.0	0.025	-0.40 (-0.74 to -0.06)
4 h	3.2 ± 0.9		4.0 ± 1.0	<0.001	-0.80 (-1.14 to -0.46)
6 h	3.0 ± 0.9		3.9 ± 1.0	<0.001	-0.90 (-1.24 to -0.56)
8 h	2.8 ± 0.8		3.7 ± 1.0	<0.001	-0.90 (-1.23 to -0.57)
12 h	2.5 ± 0.8		3.3 ± 0.9	<0.001	-0.80 (-1.11 to -0.49)
24 h	2.1 ± 0.7		2.8 ± 0.9	<0.001	-0.70 (-0.99 to -0.41)

Note. Pain was measured on a 0-10 NRS. MD = mean difference (lidocaine minus placebo); CI = confidence interval. Negative MD favors lidocaine. Pointwise p-values are those reported in the source manuscript; MD 95% CIs were derived from the reported means, SDs, and group sizes.

by 39.20 mg (95% CI -53.25 to -25.15; $p<0.001$). The risk of requiring any rescue analgesia was lower in the lidocaine group (63.3% vs. 85.0%; RR 0.75, 95% CI 0.60 to 0.93), as was the risk of requiring at least two rescue doses (26.7% vs. 48.3%; RR 0.55, 95% CI 0.34 to 0.91) (Table 3).

Analgesic requirements also favored lidocaine. Time to first rescue analgesia was 2.50 hours longer (95% CI 1.79 to 3.21; $p<0.001$). Total rescue analgesic consumption was lower

Table 3: Rescue analgesia and postoperative analgesic consumption

Outcome	Lidocaine (n=60)	patch	Placebo (n=60)	P	Effect estimate (95% CI)
Time to first rescue analgesia, h	8.4 ± 2.1		5.9 ± 1.8	<0.001	MD 2.50 (1.79 to 3.21)
Any rescue analgesia, n (%)	38 (63.3%)		51 (85.0%)	0.008	RR 0.75 (0.60 to 0.93)
Total rescue analgesic consumption, mg	82.5 ± 34.7		121.7 ± 42.6	<0.001	MD -39.20 (-53.25 to -25.15)
≥2 rescue doses, n (%)	16 (26.7%)		29 (48.3%)	0.017	RR 0.55 (0.34 to 0.91)

Note. Continuous effects are MDs (lidocaine minus placebo); binary effects are risk ratios (RRs). RR <1 favors lidocaine for rescue-analgesic requirements. CIs were calculated from the reported summary data.

Secondary outcomes

Hemodynamic variables were similar between groups. Mean differences were small and all 95% CIs included zero: heart rate MD -0.70 beats/min (95% CI -3.59 to 2.19), systolic blood pressure MD -1.20 mmHg (95% CI -4.73 to 2.33), diastolic blood pressure MD -0.90 mmHg (95% CI -3.41 to 1.61), mean arterial pressure MD -1.00 mmHg (95% CI -3.57 to 1.57), and SpO₂ MD 0.10% (95% CI -0.21 to 0.41) (Table 4).

Table 4: Postoperative hemodynamic parameters

Parameter	Lidocaine (n=60)	patch	Placebo (n=60)	P	MD (95% CI)
Heart rate, beats/min	82.4 ± 7.8		83.1 ± 8.2	0.626	-0.70 (-3.59 to 2.19)
Systolic BP, mmHg	119.6 ± 9.4		120.8 ± 10.1	0.507	-1.20 (-4.73 to 2.33)
Diastolic BP, mmHg	75.2 ± 6.8		76.1 ± 7.1	0.478	-0.90 (-3.41 to 1.61)
Mean arterial pressure, mmHg	90.0 ± 6.9		91.0 ± 7.3	0.432	-1.00 (-3.57 to 1.57)
SpO ₂ , %	98.1 ± 0.8		98.0 ± 0.9	0.535	0.10 (-0.21 to 0.41)

Note. Values are mean ± SD. MD = mean difference (lidocaine minus placebo); BP = blood pressure; SpO₂ = peripheral oxygen saturation.

Participants receiving lidocaine ambulated 1.40 hours earlier than controls (95% CI -2.07 to -0.73; p<0.001), and patient

satisfaction was 0.90 points higher (95% CI 0.50 to 1.30; p<0.001). Differences in time to first oral intake (MD -0.30 hours, 95% CI -0.72 to 0.12; p=0.154) and hospital stay (MD -0.20 days, 95% CI -0.44 to 0.04; p=0.091) were not statistically significant (Table 5).

Table 5: Postoperative recovery parameters

Outcome	Lidocaine (n=60)	patch	Placebo (n=60)	P	MD (95% CI)
First ambulation, h	10.2 ± 1.7		11.6 ± 2.0	<0.001	-1.40 (-2.07 to -0.73)
First oral intake, h	6.3 ± 1.1		6.6 ± 1.2	0.154	-0.30 (-0.72 to 0.12)
Hospital stay, days	3.1 ± 0.6		3.3 ± 0.7	0.091	-0.20 (-0.44 to 0.04)
Patient satisfaction (0–10)	8.2 ± 1.0		7.3 ± 1.2	<0.001	0.90 (0.50 to 1.30)

Note. Values are mean ± SD. MD = mean difference (lidocaine – placebo); negative MD denotes earlier time outcomes and positive MD denotes higher satisfaction.

Overall adverse effects occurred in 25.0% of the lidocaine group and 31.7% of controls (RR 0.79, 95% CI 0.44 to 1.40; p=0.417). The confidence intervals for individual adverse effects were wide and crossed the null, indicating no statistically supported between-group differences in these events (Table 6).

Table 6: Postoperative adverse effects

Adverse effect	Lidocaine (n=60)	patch	Placebo (n=60)	P	RR (95% CI)
Nausea	9 (15.0%)		12 (20.0%)	0.632	0.75 (0.34 to 1.65)
Vomiting	4 (6.7%)		6 (10.0%)	0.743	0.67 (0.20 to 2.24)
Dizziness	3 (5.0%)		5 (8.3%)	0.717	0.60 (0.15 to 2.40)
Pruritus	5 (8.3%)		7 (11.7%)	0.762	0.71 (0.24 to 2.13)
Local skin irritation	2 (3.3%)		1 (1.7%)	1.000	2.00 (0.19 to 21.47)
Any adverse effect	15 (25.0%)		19 (31.7%)	0.418	0.79 (0.44 to 1.40)

Note. Values are n (%). RR = risk ratio (lidocaine/placebo). 95% CIs were derived from the reported counts. Fisher's exact test was used for individual adverse events with sparse cell counts; Pearson's chi-square test was used for the overall adverse-effect comparison.

Ancillary analyses

No prespecified subgroup analysis, adjusted analysis, sensitivity analysis, or other ancillary analysis was performed.

The reported findings therefore represent the prespecified unadjusted comparisons between the randomized treatment groups.

Discussion

The principal finding was that a 5% lidocaine patch improved postoperative pain control after cesarean section. At 24 hours, the pain score was 0.70 points lower with lidocaine than placebo (95% CI -0.99 to -0.41; $p < 0.001$), and statistically significant between-group differences were present from 2 to 24 hours. This pattern is compatible with a local analgesic effect at the incision: lidocaine blocks voltage-gated sodium channels in peripheral nociceptive fibers, reducing initiation and propagation of painful afferent impulses [8]. By acting locally with limited systemic exposure, the patch can complement systemic multimodal analgesics rather than replacing them.

The analgesic benefit was accompanied by lower rescue-analgesic use. Time to the first rescue dose was prolonged by 2.50 hours (95% CI 1.79 to 3.21), total consumption was reduced by 39.20 mg (95% CI -53.25 to -25.15), and the risk of requiring rescue analgesia was reduced (RR 0.75, 95% CI 0.60 to 0.93). These findings support a clinically relevant opioid- or systemic-analgesic-sparing effect, plausibly because attenuation of superficial incisional nociception reduces breakthrough pain during the early postoperative period. Queiroz et al. similarly reported lower pain scores at 6, 12, 24, and 36 hours after cesarean section with a 5% lidocaine patch, including a marked difference at 24 hours [10]. Patel et al. also observed reduced postoperative opioid requests following intraperitoneal lidocaine, while studies of local infiltration have shown variable

reductions in pain and analgesic requirements [11-13]. Differences in route, tissue exposure, dose, timing, and background analgesia probably contribute to variation across studies.

Recovery outcomes also favored the lidocaine patch for ambulation and satisfaction. First ambulation occurred 1.40 hours earlier (95% CI -2.07 to -0.73; $p < 0.001$), and satisfaction was 0.90 points higher (95% CI 0.50 to 1.30; $p < 0.001$). Lower incisional pain can reduce reluctance to move, making standing and walking more comfortable and potentially improving the perception of postoperative care. However, oral intake and hospital stay did not differ significantly, suggesting that these broader recovery endpoints depend on multiple obstetric, institutional, neonatal, and discharge-related factors beyond analgesia alone. The result differs from the trial of topical lidocaine/prilocaine cream by Grosse-Steffen et al., which found no significant improvement in postoperative pain, mobilization, or discharge time [14]. Differences in formulation, local-anesthetic concentration, application technique, and duration of exposure offer plausible explanations.

Safety outcomes did not show evidence of clinically important hemodynamic disturbance or an increased overall adverse-event burden. Overall adverse effects occurred in 25.0% versus 31.7% (RR 0.79, 95% CI 0.44 to 1.40), while hemodynamic mean differences were small and their confidence intervals crossed zero. Limited systemic absorption from intact-skin topical administration provides a biologically plausible explanation for hemodynamic stability, although the present sample was not large enough to exclude uncommon adverse events. Queiroz et al. likewise reported no meaningful excess of adverse effects [10]. In contrast, Arkfeld et al. found no significant difference in maximum or average postoperative pain between lidocaine and placebo patches after cesarean delivery [15]. Such discordance may reflect differences in patch placement, timing, application duration, baseline multimodal regimens, participant characteristics, pain-assessment schedules, and statistical power.

Generalizability

The findings are most applicable to women undergoing cesarean section under spinal anesthesia who resemble this study population, which had a mean age of approximately 29 years,

mean BMI near 25 kg/m², term gestation, and ASA physical status I-II. Generalization to women receiving general anesthesia, those with substantial medical comorbidity, different perioperative analgesic protocols, or different patch application schedules should be cautious. Replication across multiple obstetric centers, broader risk groups, and standardized application protocols would strengthen external validity.

Limitations

The study has several limitations. It was a single-center trial with 120 participants, which limits precision for uncommon adverse effects and reduces external validity across different obstetric populations and analgesic protocols. Pain and satisfaction were patient-reported outcomes and can vary with individual pain perception despite blinding. Follow-up focused mainly on the first 24 postoperative hours, so persistent post-cesarean pain, breastfeeding-related functional outcomes, and longer-term recovery were not assessed. No subgroup or adjusted analyses were undertaken, and the study was not powered to detect rare lidocaine-related adverse events.

Recommendation

A 5% lidocaine patch can be considered as an adjunct to standard multimodal analgesia after cesarean section when there are no contraindications to topical lidocaine. Clinical use should follow a clearly standardized application, removal, wound-safety, and rescue-analgesia protocol. Future adequately powered multicenter randomized trials should evaluate longer follow-up, uncommon adverse effects, breastfeeding and functional recovery outcomes, and the influence of patch position and duration. Consistent reporting of randomization, blinding, intervention characteristics, and longitudinal pain analyses is also recommended.

Conclusion

In this randomized double-blind placebo-controlled trial, the 5% lidocaine patch was associated with lower postoperative pain, delayed rescue-analgesic requirement, reduced total rescue analgesic consumption, earlier ambulation, and higher patient satisfaction after cesarean section. At 24 hours, pain was lower by 0.70 NRS points, and rescue analgesic consumption was lower by 39.20 mg. Hemodynamic measures and overall adverse effects were comparable between groups. These findings support topical lidocaine as a potentially useful adjunct within multimodal post-cesarean analgesia, while confirmation in larger and more diverse obstetric populations is warranted.

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Conflict of Interest

The authors declare no conflict of interest.

Data Availability

The data supporting the findings of this study are available upon reasonable request from the corresponding author, subject to applicable institutional and ethical requirements.

Author Contributions

Chandrashekar B contributed to conceptualization, study design, methodology, investigation, and supervision. Anup Nisti contributed to participant recruitment, investigation, data collection, data curation, and validation. Praveen Kumar DP contributed to formal analysis, interpretation of findings, literature synthesis, and preparation of the original manuscript draft. All authors contributed to critical revision of the manuscript, approved the final version for submission, and agreed to be accountable for the integrity and accuracy of the work.

List of Abbreviations

ASA, American Society of Anesthesiologists; BMI, body mass index; BP, blood pressure; CI, confidence interval; MD, mean difference; NRS, numerical rating scale; RR, risk ratio; SD, standard deviation; SpO₂, peripheral oxygen saturation; SPSS, Statistical Package for the Social Sciences.

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