

**ORIGINAL RESEARCH**

# Comparison of Vapocoolant and Eutectic mixture of local anaesthetic(EMLA) Cream for Epidural Injection: A Prospective Trial

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Received: 26 February, 2025

Accepted: 20 March, 2025

Published: 03 April, 2025

## ABSTRACT

**Introduction:** Effective pain management during epidural procedures is crucial to ensure patient comfort and prevent anxiety-related movement. Traditional subcutaneous local anaesthetic infiltration, though effective, may itself cause discomfort or provoke movement. EMLA cream, a non-invasive alternative, has shown efficacy in needle-related procedures but requires prolonged application time. Vapocoolant spray offers immediate analgesia with minimal preparation but lacks sufficient evidence in deeper procedures like epidural injections. This study aimed to compare the analgesic effectiveness of EMLA cream and vapocoolant spray during epidural needle insertion. **Methods:** A prospective, randomized controlled trial was conducted with 140 adult patients (aged 18–65), ASA 1&2 scheduled for elective epidural injections. Participants were randomized into two groups: Group E received 2.5 g EMLA cream applied under occlusion for 60 minutes; Group V received vapocoolant spray (ethyl chloride) applied 10 cm from the skin for 60 seconds immediately before the procedure. Pain intensity during needle insertion was assessed using the Numeric Rating Scale (NRS), along with secondary outcomes including patient movement, duration of analgesia, satisfaction (Likert scale), and adverse events. **Results:** Both groups were comparable in age, sex, and baseline characteristics. The mean NRS pain score was significantly lower in Group E ( $1.86 \pm 1.27$ ) compared to Group V ( $2.51 \pm 1.42$ ) with  $p = 0.005$ . Patient movement was significantly less frequent in the EMLA group (10%) compared to the vapocoolant group (22.9%),  $p = 0.040$ . Satisfaction scores favored the EMLA group, though not statistically significant. Mild adverse events like skin irritation were more common in the EMLA group but did not reach statistical significance. **Discussion:** This study demonstrates that EMLA cream provides superior analgesia during epidural needle insertion compared to vapocoolant spray. Although vapocoolant is less effective in reducing pain, it offers advantages such as immediate onset, cost-effectiveness, and ease of application, making it useful in time-sensitive settings. The findings support EMLA as a preferred option when sufficient application time is available, while vapocoolant may serve as a practical alternative in emergencies. Further large-scale, multicenter studies are recommended to explore combined or sequential strategies for optimizing patient comfort during neuraxial procedures.

**Keywords:** Topical analgesia, neuraxial procedures, injection anxiety, acute pain management, procedural sedation, pain perception

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## INTRODUCTION

Pain management during neuraxial procedures is a critical aspect of patient care, the anticipation of needle puncture pain, uncontrolled pain during medical interventions, including epidural injections, can provoke significant anxiety and adversely affects patient comfort and overall procedural experience.<sup>1</sup>

Clinicians often employ subcutaneous local anaesthetic infiltration at the skin to blunt the pain of epidural needle insertion, but this approach is not universally standard and may itself cause discomfort or patient movement during the procedure.<sup>2</sup>

Additionally, local anaesthetic infiltration carries a risk of allergic reactions to the anaesthetic, although

true hypersensitivity to amide local anaesthetic agents (e.g., lidocaine) is uncommon.<sup>3</sup>

EMLA cream, a eutectic mixture of lidocaine and prilocaine, has long been used to provide dermal anaesthesia for needle-related procedures. EMLA has proven effective in reducing pain during spinal anaesthesia. However, Early studies examining EMLA for epidural placement yielded mixed results.<sup>4</sup> Ralston et al. reported that topical EMLA applied before a 16-gauge epidural needle insertion did not significantly decrease pain compared to standard local anesthetic infiltration, suggesting that EMLA alone may not provide sufficient deep tissue analgesia for thick epidural needles.<sup>5</sup>

In contrast, Elson et al. demonstrated that applying EMLA cream for at least 90 minutes, combined with 1% lidocaine infiltration, optimized patient comfort during epidural needle insertion.<sup>6</sup>

Vapocoolant spray (100 % w/v ethyl alcohol) have emerged as a rapid and convenient alternative for mitigating injection pain. These sprays act by instantly cooling the skin; the rapid evaporation induces a sudden drop in cutaneous temperature that transiently numbs the area by disrupting nociceptive signal conduction. Vapocoolants offer several advantages, notably an almost immediate onset of analgesia without the need for advance preparation, as well as low cost and wide availability in clinical practice.<sup>1</sup>

Their efficacy in pain reduction has been demonstrated across various settings. For example, in school-aged children receiving immunizations, a topical vapocoolant was found to be as effective as EMLA cream in reducing injection pain. Similarly, in adults undergoing repeated arteriovenous fistula cannulations for hemodialysis, vapocoolant spray prevented moderate needle puncture pain to a degree comparable with EMLA, with no patients experiencing severe pain with either method.<sup>7</sup>

While EMLA cream has been traditionally used to reduce needle insertion pain, its results in epidural application in epidural application have been variable. Vapocoolant spray offers a rapid, non-invasive alternative but has not been adequately studied for deeper procedures such as deeper procedures such as epidural injections. Therefore, the present study was designed to compare the analgesic efficacy of EMLA cream versus vapocoolant spray in reducing pain during epidural injections, with the aim of identifying an optimal strategy for improving patient comfort during this common invasive procedure.

## METHODOLOGY

### Study Design and Setting

A prospective, randomized, controlled trial was conducted, following approval from the Institutional Ethics Committee . The study adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines and was registered with the Clinical Trials Registry (CTRI/2024/07/070084).

## Participants

### • Inclusion Criteria:

- Adults aged 18–65 years, ASA 1 &2 scheduled for elective epidural injections.

### • Exclusion Criteria:

- Contraindications to epidural anaesthesia.
- Known allergies to local anaesthetics or components of vapocoolant spray.
- Pregnancy or breastfeeding.
- Significant neurological or psychiatric disorders affecting pain perception.

## Sample Size Calculation

Based on the study by Nazer et al. (2023), a sample size of 70 patients per group (total N = 140) was determined to detect a significant difference in pain scores, with a power of 80% and a significance level of 0.05.<sup>8</sup>

## Randomization and Blinding

Participants were randomly assigned to one of two groups using a computer-generated randomization sequence:

- **EMLA Cream Group (Group E):** Application of EMLA cream at the epidural needle insertion site.
- **Vapocoolant Spray Group (Group V):** Application of vapocoolant spray at the epidural needle insertion site.

Due to the nature of the interventions, blinding of patients and clinicians was not feasible; however, outcome assessors remained blinded to group allocation.

## Interventions

- **EMLA Cream Group (Group E):** A 2.5 g dose of EMLA cream (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%) was applied to the skin at the epidural needle insertion site and covered with an occlusive dressing for 60 minutes prior to the procedure.
- **Vapocoolant Spray Group (Group V):** A vapocoolant spray containing ethyl chloride was applied to the skin at the epidural needle insertion site from a distance of 10 cm for 60 seconds immediately before the procedure.

## Outcome Measures

### • Primary Outcome:

- Pain intensity during needle insertion, assessed using the Numeric Rating Scale (NRS), where 0 indicates no pain and 10 indicates the worst imaginable pain.

### • Secondary Outcomes:

- Patient movement during needle insertion, categorized as present or absent.
- Duration of pain relief, measured from the time of needle insertion to the first report of pain at the insertion site.

- Patient satisfaction with pain management, assessed using a 5-point Likert scale (1 = very dissatisfied, 2- Dissatisfied, 3- Enough Satisfied, 4- Satisfied, 5 = Very satisfied).
- Incidence of adverse events, such as skin irritation or allergic reactions, monitored throughout the procedure and recovery period.

### Procedure

1. **Baseline Assessment:** Participants underwent a baseline evaluation, including demographic data collection.
2. **Intervention Application:**
  - **Group E:**
    - Patients were positioned comfortably.
    - A 2.5 g dose of EMLA cream was applied to the designated skin area at the epidural insertion site.
    - The area was covered with an occlusive dressing and left for 60 minutes prior to needle insertion
  - **Group V:**
    - Patients were positioned comfortably.
    - The vapocoolant spray was applied to the designated skin area at the epidural insertion site from a distance of 10 cm for 30–60 seconds immediately before needle insertion.
3. **Epidural Injection:** Following the respective intervention, the epidural injection was performed using a standard 18G epidural needle under aseptic conditions.

4. **Pain and Movement Assessment:** Immediately after needle insertion, pain intensity was assessed using the NRS, and any patient movement during the procedure was documented.
5. Adverse events were monitored and recorded during and after the procedure.

### Statistical Analysis

**Descriptive Statistics:** Data were described in terms of range; mean  $\pm$  standard deviation ( $\pm$  SD), frequencies (number of cases) and relative frequencies (percentages) as appropriate. To determine whether the data were normally distributed, a Kolmogorov-Smirnov test was used. Comparison of quantitative variables between the study groups was done using Mann Whitney *U* test for independent samples for non-parametric data. For comparing categorical data, Chi square ( $\chi^2$ ) test was performed and Fisher exact test was used when the expected frequency is less than 5. A probability value (*p* value) less than 0.05 was considered statistically significant. All statistical calculations were done using (Statistical Package for the Social Science) SPSS 21.0 version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

### Ethical Considerations

Informed consent was obtained from all participants. The study complied with the Declaration of Helsinki principles, ensuring participant confidentiality and the right to withdraw at any time without consequence.

## RESULTS

It was observed that the groups were similar in terms of sex, age and ASA physical status (Table 1 & 2).

**Table 1- Gender Distribution**

		Group E		Group V		Total	Chi-square value	p-value
		No. of Cases	%age	No. of Cases	%age			
SEX	F	31	44.3%	28	40.0%	59	0.264	0.608
	M	39	55.7%	42	60.0%	81		
Total		70	100%	70	100%			

**Table 2: Comparison of Age in Years**

	GROUP	N	Mean	Std. Deviation	Std. Error Mean	Z	p-value
AGE (YRS)	E	70	44.59	12.112	1.448	1.372	0.172
	V	70	41.93	10.765	1.287		

The mean NRS score for pain was 1.86 (1.266) in Group E and 2.51 (1.422) in the Group V, as seen in Table 4

**Table 3: Comparison of pain intensity during epidural injection between the EMLA cream group and the vapocoolant spray group.**

		Group E		Group V		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
NRS	0	13	18.6%	5	7.1%	18	11.554	0.073
	1	15	21.4%	12	17.1%	27		
	2	18	25.7%	20	28.6%	38		
	3	17	24.3%	16	22.9%	33		
	4	7	10.0%	10	14.3%	17		
	5	0	0.0%	6	8.6%	6		

	6	0	0.0%	1	1.4%	1		
Total		70	100.0%	70	100.0%	140		

**Table 4: The Difference in NRS (Mean) Scores**

	GROUP	N	Mean	Std. Deviation	Std. Error Mean	p-value
NRS	E	70	1.86	1.266	.151	0.005
	V	70	2.51	1.422	.170	

Patient movement during the procedure was significantly less in Group E(p=0.004) suggesting more effective motor control(Table 5)

**Table 5: Comparison of patient movement during epidural injection between the EMLA cream group and the vapocoolant spray group.**

		Group E		Group V		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age		4.214	0.040
MOVEMENT	Absent	63	90.0%	54	77.1%	117		
	Present	7	10.0%	16	22.9%	23		
Total		70	100.0%	70	100.0%	140		

Patient satisfaction scores on the Linkert scale were higher in Group E ,though the difference was not statistically significant, as seen in Table 6.

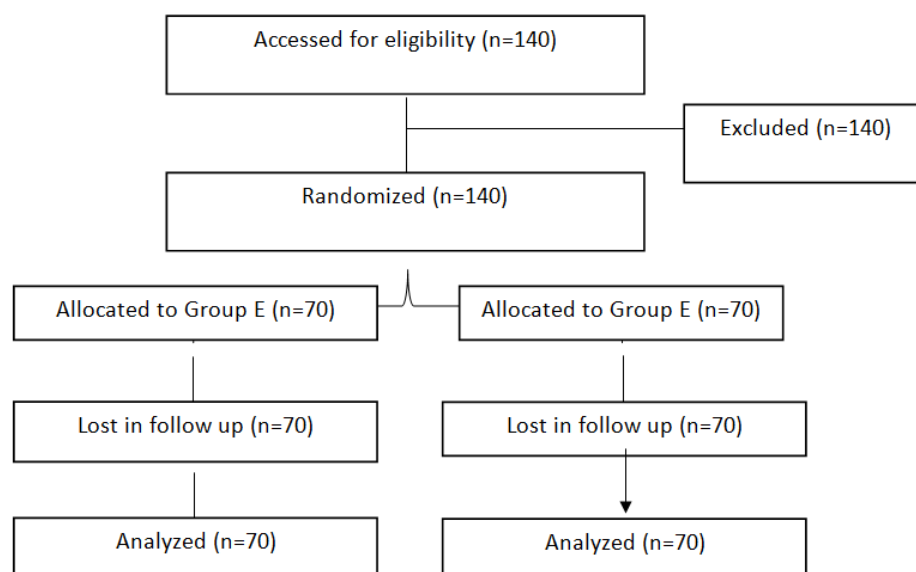
**Table 6: Comparison of patient satisfaction score(Linkert scale) between two groups**

		Group E		Group V		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age		6.388	0.094
Linkert scale	1	4	5.7%	9	12.9%	13		
	2	28	40.0%	37	52.9%	65		
	3	10	14.3%	7	10.0%	17		
	4	28	40.0%	17	24.3%	45		
	5	70	100.0%	70	100.0%	140		

Notably, adverse events such as skin irritation and allergy were more frequently reported in Group E, although the difference was not statistically significant(p=0.118) (Table 7).

**Table 7: Comparison of adverse event between two groups**

		Group E		Group V		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age		5.869	0.118
ADVERSE EVENTS	Itching	2	0.0%	2	2.9%	2		
	nil	64	91.4%	67	95.7%	131		
	skin allergy	2	2.9%	0	0.0%	2		
	skin irritation	4	5.7%	1	1.4%	5		
Total		70	100.0%	70	100.0%	140		



**FIGURE 1: Study flow according to the Consolidated Standards of Reporting Trials (CONSORT) diagram.**

## DISCUSSION

This study was conducted to evaluate and compare the analgesic efficacy of vapocoolant spray and EMLA cream during epidural needle insertion—a topic that has not been extensively investigated in existing literature. To the best of our knowledge, this is one of the first randomized clinical trials to explore the use of vapocoolant spray specifically for epidural procedures. While vapocoolants have been widely used for pain relief in superficial interventions such as intravenous cannulation,<sup>8</sup> immunization,<sup>9</sup> and spinal anesthesia,<sup>1</sup> arteriovenous cannulation<sup>10</sup> their application in deeper neuraxial techniques remains largely uncharted.

Our findings contribute novel insights into this area and highlight the potential of vapocoolant spray as a fast-acting, non-invasive alternative for improving patient comfort during epidural analgesia, especially in time-sensitive or resource-limited settings.

The age and sex distribution between the EMLA and vapocoolant groups were similar, with no significant differences ( $p > 0.05$ ). Conventional subcutaneous infiltration with local anesthetics such as 2% lidocaine is commonly used to reduce pain during epidural needle insertion. While effective, this method involves an additional needle prick, which can itself cause discomfort and provoke anxiety or movement during the procedure in woman undergoing LSCS. In contrast, EMLA cream—a eutectic mixture of lidocaine and prilocaine—offers a non-invasive alternative with proven efficacy in various needle-related procedures. Hameed and Khan (2024) found that EMLA cream was comparable to lidocaine infiltration in reducing pain during spinal needle insertion, with higher maternal satisfaction.<sup>2</sup>

However, a limitation of EMLA is its delayed onset, requiring at least 45–60 minutes of occlusive application, which may not be practical in emergency

settings. Additionally, some early studies, such as Ralston et al., noted that EMLA alone may be insufficient for deeper procedures involving larger gauge needles, like those used for epidurals.<sup>5</sup> Nonetheless, findings by Elson and Paech (1995) support its use when applied with sufficient time or combined with lidocaine infiltration. Overall, while local anaesthetic injections provide deeper and faster analgesia, EMLA cream remains a viable, patient-friendly option in planned procedures where preparation time is available.<sup>6</sup>

In our study, patients who received EMLA cream reported significantly lower pain scores compared to those who received vapocoolant spray, indicating superior analgesic efficacy. The mean pain score during epidural needle insertion in the EMLA group (Group A) ( $1.86 \pm 1.27$ ) compared to vapocoolant group ( $2.51 \pm 1.42$ ), with  $p$  value of 0.005. This indicates that EMLA cream provided more effective pain relief than vapocoolant spray in patients undergoing procedures. This aligns with findings from Firdaus et al., who demonstrated that EMLA cream reduced pain more effectively than vapocoolant during spinal injections. The deeper dermal penetration of EMLA likely contribute to its enhanced effect.<sup>1</sup> However, it is important to note that vapocoolant still provided and may serve as a practical alternative when immediate onset is needed or when preparation time is limited.

The secondary outcomes of this study are supported by earlier research showing similar trends. In our findings, fewer patients in the EMLA group showed movement during the epidural procedure compared to the vapocoolant group, suggesting better comfort and tolerance. A similar outcome was noted by Firdaus et al.<sup>1</sup> (2018) during spinal injections, where EMLA reduced discomfort-related reactions. Patient satisfaction was also slightly higher in the EMLA

group, aligning with the results of Hameed and Khan (2024),<sup>2</sup> who found greater satisfaction among women given EMLA before spinal anesthesia. Adverse effects in both groups were mild and infrequent, with only a few cases of skin irritation or itching—comparable to the findings of Gupta et al. (2017), where both EMLA and vapocoolant were well tolerated during immunization procedures.<sup>11</sup> These similarities suggest that our results are consistent with past evidence and strengthen the role of EMLA cream in improving patient cooperation and comfort during epidural injections.

Overall, this study adds useful information about the role of EMLA cream and vapocoolant spray in making epidural procedures more comfortable for patients. EMLA cream clearly showed better results in reducing pain and minimizing patient movement, which can help make the procedure smoother and safe. On the other hand, vapocoolant spray, though slightly less effective, offered practical advantages like quick action, low cost, and ease of use, which may be helpful in busy or emergency settings.

Despite these strengths, the study has several limitations. The study was done at a single centre with a limited number of patients, all undergoing planned procedures. This means the findings might not apply to other groups, like children, elderly patients, or urgent procedures. The lack of double blinding may have introduced assessment bias. Additionally, patient pain perception is subjective and may be influenced by anxiety, cultural factors, and prior experiences; which were not accounted for.

Future researches with larger, multicenter trials and diverse patient population is needed to confirm these findings and explore the role of combined or sequential analgesic strategies to further enhance patient comfort and procedural success. The authors declares no conflict of interest related to this study.

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