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EFFICACY OF EMLA 5% CREAM VERSUS PLACEBO IN REDUCING PAIN DURING PERIPHERAL INTRAVENOUS CANNULATION: A PROSPECTIVE COMPARATIVE STUDY

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ABSTRACT

Introduction: Peripheral intravenous (IV) cannulation is a common invasive procedure often associated with pain and anxiety, impacting patient comfort and cooperation. Topical anesthetics like EMLA 5% cream have shown potential in reducing pain during such procedures, but its efficacy compared to placebo requires further evaluation, particularly regarding analgesic effect and hemodynamic stress response. **Methodology:** A prospective, randomized, comparative study was conducted involving 80 adult patients (ASA I–III) scheduled for elective surgeries. Participants were randomized into two groups: Group I received EMLA 5% cream applied under occlusion for 45–60 minutes prior to cannulation, and Group II received a placebo cream under identical conditions. Pain was assessed using the Visual Analogue Scale (VAS) immediately after cannulation and at 15 minutes post-procedure. Hemodynamic parameters—pulse rate (PR) and mean arterial pressure (MAP)—were recorded at baseline, immediately after, and 15 minutes post-cannulation. Data were analyzed using Student's t-test and Chi-square test, with significance set at $p < 0.05$.**Results:** Baseline demographics were comparable across groups. The EMLA group demonstrated significantly lower VAS pain scores immediately after cannulation (2.48 ± 1.12) and at 15 minutes (1.63 ± 0.88) compared to the placebo group (6.72 ± 1.01 and 6.18 ± 1.12, respectively; $p < 0.001$). Hemodynamic responses were attenuated in the EMLA group, with stable pulse rates and MAP values post-cannulation, whereas the placebo group showed significant increases in both parameters ($p < 0.05$). Conclusion: EMLA 5% cream applied under occlusion for 45–60 minutes prior to peripheral IV cannulation significantly reduces pain and blunts hemodynamic stress responses compared to placebo. These findings support its use as an effective topical anesthetic to improve patient comfort and physiological stability during elective intravenous cannulation.

KEYWORDS : Peripheral Venous Catheters; Local Anesthetics; Pain Measurement; Randomized Controlled Trial; Hemodynamics

INTRODUCTION

Peripheral intravenous (IV) cannulation is one of the most frequently performed invasive procedures in clinical practice, providing essential vascular access for administration of fluids, medications, and blood products.[1] Despite its routine nature, IV cannulation is often associated with significant pain and discomfort, which can provoke anxiety, reduce patient cooperation, and adversely affect the overall patient experience.[2] Effective pain management during IV cannulation is therefore a critical component of patient-centered care, aimed at minimizing both physical and psychological distress.

Pain during IV cannulation primarily results from needle insertion through the skin and vein wall, stimulating peripheral nociceptors and triggering a nociceptive response.[3] This pain can be influenced by various factors including vein condition, cannula size, patient anxiety, and operator skill.[4] The physiological stress response to pain also manifests as sympathetic nervous system activation, leading to transient hemodynamic changes such as increased heart rate and blood pressure, which may be particularly detrimental in patients with cardiovascular comorbidities.[5]

Topical anesthetics have emerged as effective pharmacological interventions to reduce pain during superficial procedures like IV cannulation.[6] Among these, EMLA 5% cream—a eutectic mixture of lidocaine and prilocaine—has demonstrated significant analgesic efficacy by blocking sodium channels in peripheral nerves, thereby inhibiting pain signal transmission.[7] However, its requirement for application under occlusion for 45 to 60 minutes prior to the procedure limits its utility in urgent clinical settings.

Placebo-controlled studies are essential to establish the true analgesic benefit of topical agents by accounting for psychological and sensory factors influencing pain perception. Comparing EMLA cream with placebo allows for rigorous evaluation of its efficacy in reducing pain and attenuating hemodynamic stress responses during IV cannulation.

This study aimed to compare the efficacy of EMLA 5% cream versus placebo in reducing pain during peripheral intravenous cannulation. By assessing pain scores and hemodynamic parameters, this investigation seeks to provide evidence-based guidance on the role of EMLA cream in enhancing patient comfort and procedural success in elective clinical settings.

METHODOLOGY

A prospective, randomized, comparative study was conducted over a period of 2 months at S.S. Institute of Medical Sciences and Research Centre, Davangere. The study included 80 adult patients aged between 18 and 65 years, scheduled for elective surgeries and classified as ASA physical status I to III. Patients were randomly allocated into two groups of 40 participants each using computer-generated random numbers.

Adult patients aged 18–65 years of either gender who were undergoing elective surgeries and classified as ASA physical status I, II, or III were included. Patients scheduled for emergency surgeries, those with known hypersensitivity to EMLA cream or local anesthetics, a history of methemoglobinemia or use of drugs causing methemoglobinemia, mental illness, or open wounds or skin infections on the dorsum of the hand were excluded.

In Group I (EMLA group), a thick layer of 1 g (equivalent to 1 mL) of EMLA 5% cream was applied over a prominent vein on the dorsum of the hand and covered with an occlusive dressing for 45 to 60 minutes prior to intravenous cannulation. In Group II (Placebo group), a placebo cream identical in appearance to EMLA was applied in the same manner and under occlusion for the same duration before cannulation to maintain blinding.

Peripheral intravenous cannulation was performed using an 18-gauge intravenous cannula in both groups. Only patients with successful cannulation on the first attempt were included in the final analysis.

Pain was assessed using the Visual Analogue Scale (VAS) at

two time points: immediately after cannulation (0 minutes) and 15 minutes post-cannulation. Hemodynamic parameters, including pulse rate (PR) and mean arterial pressure (MAP), were recorded at baseline, immediately after cannulation, and at 15 minutes post-procedure.

Data were tabulated and analyzed using SPSS version 26.0. Quantitative variables were expressed as mean ± standard deviation (SD), and qualitative variables as frequencies and percentages. Comparisons between groups were performed using Student's t-test for continuous variables and Chi-square test for categorical variables. A p-value < 0.05 was considered statistically significant.

RESULTS

The baseline demographic characteristics were comparable between the EMLA and placebo groups, indicating successful randomization and minimizing the possibility of confounding factors influencing the study outcomes (Table 1).

Table 1: Baseline Characteristics of the Study Population

Variable	EMLA Group (n=40)	Placebo Group (n=40)	p value
Age (years), Mean ± SD	42.8 ± 11.6	44.1 ± 12.3	0.632
Male, n (%)	24 (60.0)	23 (57.5)	0.821
Female, n (%)	16 (40.0)	17 (42.5)	
ASA I, n (%)	28 (70.0)	27 (67.5)	0.917
ASA II, n (%)	10 (25.0)	11 (27.5)	
ASA III, n (%)	2 (5.0)	2 (5.0)	

p value <0.05; Hence statistically significant

Pain scores assessed using the Visual Analogue Scale (VAS) were significantly lower in the EMLA group immediately after cannulation and at 15 minutes compared to the placebo group. Participants receiving placebo reported severe pain with mean VAS scores remaining between 6 and 7, whereas EMLA provided substantial analgesia (Table 2).

Table 2: Comparison of VAS Scores between EMLA and Placebo Groups

Time Point	EMLA Group (Mean ± SD)	Placebo Group (Mean ± SD)	t value	p value
Immediately after cannulation(0min)	2.48 ± 1.12	6.72 ± 1.01	17.74	<0.001*
15min after cannulation	1.63 ± 0.88	6.18 ± 1.12	20.15	<0.001*

*p value <0.05; Hence statistically significant

Hemodynamic parameters demonstrated a significantly lower stress response in the EMLA group. Pulse rate and mean arterial pressure increased markedly following cannulation in the placebo group, whereas values remained relatively stable in patients who received EMLA cream (Table 3).

Table-3: Comparison of Hemodynamic Parameters between EMLA and Placebo Groups

Parameter	EMLA Group (Mean ± SD)	Placebo Group (Mean ± SD)	p value
Pulse Rate – Baseline (beats/min)	78.6 ± 8.7	79.1 ± 9.2	0.804
Pulse Rate – 0 min	80.2 ± 8.5	89.4 ± 9.8	<0.001*
Pulse Rate – 15 min	78.8 ± 8.1	86.2 ± 9.1	<0.001*
MAP – Baseline (mmHg)	88.3 ± 7.6	87.9 ± 8.0	0.812
MAP – 0 min	89.6 ± 7.8	96.8 ± 8.4	<0.001*
MAP – 15 min	88.7 ± 7.5	93.1 ± 8.2	0.014*

*p value <0.05; Hence statistically significant

DISCUSSION

Pain during peripheral intravenous (IV) cannulation is a common problem that leads to more discomfort and anxiety for patients. Effective pain relief strategies are important to enhance the patient experience and ensure the procedure goes smoothly. EMLA cream, which contains lidocaine and prilocaine, offers skin numbing but needs enough application time for the best results. This study found that EMLA 5% cream significantly reduced pain during IV cannulation when compared to a placebo. This was shown by lower Visual Analogue Scale (VAS) scores immediately after the procedure and again 15 minutes later. Heart rate and mean arterial pressure were also lower, suggesting less physiological stress.

These findings agree with Shrinivas et al., who observed significantly lower pain scores in a larger randomized trial involving 200 patients using a 60-minute application period. Both studies confirm the effectiveness and safety of EMLA when applied long enough with occlusion.[8]

In contrast, Yamamoto et al. reported no significant pain relief when EMLA was applied for only 20 minutes, underscoring the need for adequate application time. Their results support the idea that shorter application is not enough for effective pain relief.[9]

Smith et al. looked at a much shorter, 5-minute application with patients undergoing ophthalmic surgery. They also found reduced pain compared to the placebo. This suggests that even a brief application could provide meaningful pain relief in situations that require quick vascular access. Differences in cannula sizes—18-gauge in this study and 20-gauge in Smith et al.—might also affect how pain is perceived. [10]

McCluskey et al. demonstrated that while EMLA helps reduce pain from cannula insertion, it does not significantly ease the pain of propofol injection. This shows that its effectiveness can vary depending on the procedure. They proposed that higher concentrations or longer application times may be necessary for deeper pain relief. [11]

The present study's results are similar with the broader literature supporting EMLA cream's role in reducing pain from peripheral intravenous cannulation when applied for sufficient duration under occlusion. Differences in outcomes across studies primarily relate to variations in application time and the specific pain stimulus assessed. The current findings reinforce the clinical recommendation for at least 45 minutes of EMLA application to achieve effective analgesia during venous cannulation, while shorter application periods, as shown by Yamamoto et al., may not confer significant benefit.

CONCLUSION

The study concludes that EMLA 5% cream, when applied under occlusion for 45 to 60 minutes prior to peripheral intravenous cannulation, significantly reduces pain as measured by Visual Analogue Scale scores compared to placebo. Additionally, EMLA cream effectively attenuates the hemodynamic stress response, demonstrated by more stable pulse rate and mean arterial pressure values post-cannulation. These findings support the use of EMLA cream as a safe and effective topical anesthetic to enhance patient comfort and reduce physiological distress during elective intravenous cannulation procedures. The results align with existing literature emphasizing the importance of adequate application duration for optimal analgesic efficacy.

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