Single-Centre, Prospective, Non-Randomised Comparative Study of Topical Lidocaine/Prilocaine (EMLA) versus No Anaesthetic During Paediatric Venipuncture

Sara Belandžić[1,2], Ivan Šklebar[2,3,4]

[1] Children's Hospital Srebrnjak Zagreb, Croatia

[2]Faculty of Health Studies Catholic University of Croatia Zagreb, Croatia

[3]Clinical Hospital Centre Zagreb Zagreb, Croatia

[4]Bjelovar University of Applied Sciences, Bjelovar, Croatia

Sara Belandžić
sara22grgic@gmail.com

Ivan Šklebar
ivan.sklebar@unicath.hr
ORCID:0000-0002-4557-7626

Corresponding author:
Ivan Šklebar
Faculty of Health Studies
Catholic University of Croatia
Ilica 244, Zagreb, Croatia
ivan.sklebar@unicath.hr

DOI: https://www.doi.org/10.64332/ujbb.2.2.4

Abstract

Background: Venipuncture is a common paediatric procedure often associated with pain and fear. Inadequate pain management can cause distress, poor cooperation, and avoidance of future medical procedures. Topical anaesthetics such as EMLA cream offer a simple, non-invasive method of pain relief.

Aim: To evaluate the effect of topical EMLA cream on children's pain and fear during venipuncture.

Methods: This single-centre, prospective, non-randomised comparative study was conducted at the Children's Hospital Srebrnjak, Zagreb, Croatia, from October to December 2024. A total of 104 children aged 7–10 years requiring venipuncture were included. Participants were assigned to either the intervention group (n = 52) or the control group (n = 52) based on parental consent for topical anaesthetic use. Pain intensity after venipuncture was assessed using the Visual Analogue Scale (VAS, 0–10), and fear was self-rated before the procedure on a numerical scale from 0 to 10. Data were analysed using the Mann–Whitney U test and Spearman's correlation, with significance set at $P < 0.05$.

Results: Children who received EMLA reported significantly lower pain scores (mean VAS 2.1 ± 1.2) compared with controls (4.8 ± 1.5, $P < 0.001$). Pre-procedural fear showed a moderate positive correlation with pain intensity ($\rho = 0.45$, $P < 0.01$). No significant sex differences were found.

Conclusion: Topical EMLA cream effectively reduces procedural pain in children during venipuncture. Addressing both pain and fear is essential for a comprehensive and compassionate approach to paediatric care.

Keywords: venipuncture, children, pain, EMLA, local anaesthetic, non-randomised comparative study

Introduction

Pain is defined by the International Association for the Study of Pain (IASP) as an unpleasant sensory and emotional experience associated with actual or potential tissue damage (1). It is not only a physiological signal but also a subjective experience influenced by emotional, psychological, and social factors (2). In modern healthcare, pain is recognised as the fifth vital sign, which underscores the need for systematic assessment in every patient encounter (3).

In paediatrics, pain management is particularly complex. Children undergoing diagnostic and therapeutic procedures often report procedural pain as more distressing than the underlying illness itself (2, 3). Venipuncture, one of the most frequently performed invasive procedures, represents a major source of acute pain and anxiety (4, 5). Poorly managed pain during venipuncture can lead to long-term consequences, including needle phobia, heightened anxiety, and avoidance of medical care (6).

Accurate pain assessment in children requires age-appropriate tools. Younger children often rely on behavioural scales such as FLACC (Face, Legs, Activity, Cry, Consolability) or NIPS (Neonatal Infant Pain Scale), while older children can use self-report scales such as Wong-Baker FACES or the Visual Analogue Scale (VAS) (6-8). For children aged seven and above, the VAS has been shown to be both reliable and valid (6).

Children's cognitive development also influences their understanding of and response to pain. According to Piaget's theory, children aged 7–11 are in the concrete operational stage, which enables them to verbalise their experiences, understand simple medical explanations, and cooperate with healthcare staff (9).

At the same time, fear plays a crucial role in pain perception. Fear of needles is widespread and may amplify the intensity of pain (10-13). Distracting techniques, parental presence, and empathetic communication have been identified as effective non-pharmacological interventions (14).

Pharmacological methods, such as the application of topical anaesthetics, further enhance pain relief. Topical anaesthetics like EMLA cream, which contains lidocaine and prilocaine, provide localised analgesia by blocking sodium channels in peripheral nerves (15-18). They are widely recommended for minor procedures such as venipuncture and have demonstrated efficacy in reducing both pain and distress in children (15-21). However, despite evidence supporting their use, these measures are not consistently implemented in routine paediatric practice (18, 19, 21).

The present study aimed to evaluate the effect of EMLA cream on children's perception of pain and fear during venipuncture and to explore possible associations with sex.

Materials and methods

Study design

This was a single-centre, prospective, non-randomised comparative study.

Ethics

The study was approved by the Ethics Committee of the Children's Hospital Srebrnjak (approval no. 04-891/1-24). Written informed consent was obtained from parents or legal guardians prior to participation.

Participants

Participants were children aged 7–10 years who required venipuncture for diagnostic purposes at the Children's Hospital Srebrnjak, Zagreb. The study was conducted from October to December 2024. Inclusion in the study was based on parental consent for the use of a topical anaesthetic: children whose parents consented formed the EMLA group, while those whose parents declined constituted the control group. Exclusion criteria included known allergy to lidocaine/prilocaine, dermatological conditions at the puncture site, or developmental disorders interfering with communication.

Group allocation

Participants were assigned to either the intervention (n = 52) or control group (n = 52) based on parental consent for EMLA application (self-selection). Consequently, group allocation was non-randomised, and potential self-selection bias is acknowledged.

Intervention

In the intervention group, 1 g of EMLA cream was applied to the venipuncture site (approximately 2–3 cm^2 area) and covered with an occlusive dressing for 60 minutes before the procedure. The control group underwent standard venipuncture without anaesthetic. Both groups received supportive non-pharmacological measures, including parental presence and verbal reassurance.

Data collection and instruments

Pain intensity was self-rated immediately after venipuncture using the Visual Analogue Scale (VAS, 0 = no pain, 10 = worst imaginable pain). Fear was self-rated immediately before the procedure using a numerical scale from 0 (no fear) to 10 (extreme fear). Each child verbally indicated a number representing their fear level, which was recorded by the research nurse.

Statistical analysis

Data were analysed using IBM SPSS Statistics 29.0 (IBM Corp., Armonk, NY). Descriptive statistics summarised demographic characteristics. Between-group comparisons were conducted using the Mann–Whitney U test, and correlations were assessed with Spearman's rank correlation coefficient. Statistical significance was set at $P < 0.05$, with exact p-values reported where applicable.

Results

A total of 104 children participated in the study, evenly distributed between the intervention group (n = 52) and the control group (n = 52). The mean age of participants was 8.5 ± 1.0 years in the intervention group and 8.6 ± 0.9 years in the control group, with no statistically significant difference between groups ($P > 0.05$). Both groups showed an almost equal sex distribution (26 boys and 26 girls in the intervention group; 27 boys and 25 girls in the control group), minimising the risk of gender-related confounding (Table 1).

Table 1. *Demographic characteristics of participants*

Characteristic	Intervention (n = 52)	Control (n = 52)
Age (mean ± SD)	8.5 ± 1.0	8.6 ± 0.9
Sex (boys/girls)	26/26	27/25

Pain intensity

Pain assessment using the Visual Analogue Scale (VAS) revealed that children in the intervention group reported significantly lower pain intensity compared to the control group. The mean VAS score in the intervention group was 2.1 ± 1.2, while in the control group it was 4.8 ± 1.5 ($P < 0.05$). Nearly half of the children in the control group (48%) reported pain levels of 5 or higher, whereas in the intervention group, only 12% reported scores at or above this threshold. Importantly, none of the children in the intervention group rated their pain as "severe" (≥ 7 on the VAS), while this was reported by 15% of the children in the control group. These findings clearly highlight the analgesic efficacy of topical anaesthetic application.

Fear and pain correlation

Fear levels, assessed through a child-friendly questionnaire, showed a moderate positive correlation with pain intensity (Spearman's $\rho = 0.45$, $P < 0.01$). Children who expressed higher pre-procedural fear were more likely to report elevated VAS scores, regardless of anaesthetic application. This emphasises the close interplay between emotional state and pain perception in paediatric patients.

Sex differences

Although no statistically significant differences were found between boys and girls in either group, a trend toward greater variability in girls' reports was observed. Girls were more likely to report both very

low and very high pain scores compared to boys, whose responses tended to cluster more narrowly around the mean. This variability suggests potential differences in coping strategies or emotional expression between genders, which warrants further investigation in larger samples.

Subgroup analysis

When stratified by age, children in the younger subgroup (7–8 years) generally reported slightly higher pain scores compared to those aged 9–10 years, although this difference did not reach statistical significance ($P > 0.05$). This trend may reflect developmental differences in coping skills and understanding of the procedure.

Distribution analysis

Examination of the distribution of pain scores revealed that while the majority of children in the intervention group clustered around low VAS scores (1–3), the control group exhibited a broader spread, with a considerable number of participants reporting scores in the moderate-to-severe range (5–7). This divergence emphasises not only the analgesic benefit of EMLA cream but also its consistency in reducing variability in children's responses.

Fear and variability

Descriptive analysis showed that children who rated themselves as "very afraid" before the procedure almost always reported higher pain scores, even if they had received EMLA. This highlights the profound impact of psychological factors and suggests that addressing fear in parallel with pharmacological management could yield the most favourable outcomes.

Children in the intervention group reported significantly lower VAS scores than the control group (mean 2.1 ± 1.2 vs. 4.8 ± 1.5, $P < 0.05$) (Table 2).

Table 2. *Pain intensity (VAS scores)*

Group	Mean VAS ± SD	*P*-value
EMLA group	2.1 ± 1.2	< 0.05
Standard venipuncture	4.8 ± 1.5	

Fear levels were positively correlated with pain intensity ($\rho = 0.45$, $P < 0.01$) (Figure 1). No significant sex differences were found, though greater variability was noted among girls.

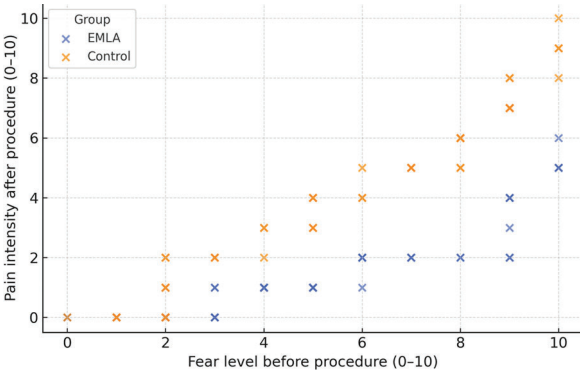

Figure 1. *Correlation between pre-procedural fear and pain intensity in children with (blue) and without (orange) topical anaesthetic.*

Discussion

The results of this study confirm that topical local anaesthetic application significantly reduces children's pain during venipuncture, aligning with a growing body of evidence advocating for the routine use of EMLA cream and similar agents in paediatric practice (18,22). The nearly 50% reduction in mean VAS scores between the intervention and control groups underscores the clinical relevance of this intervention. By minimising pain associated with venipuncture, healthcare providers can improve immediate patient comfort and help prevent long-term psychological consequences often linked to repeated painful procedures in childhood, such as needle phobia and avoidance of medical care (23–25).

One of the most significant findings of this study was the positive correlation between fear and pain perception. This supports the biopsychosocial model of pain, which recognises that physical sensations are closely linked with psychological and emotional states (25). In paediatric populations, anticipatory fear of needles is a well-documented phenomenon that can amplify the subjective experience of pain (6,12). Even when pharmacological analgesia was provided, children with higher levels

of fear still tended to report more pain. This suggests that addressing emotional and psychological factors is equally important as pharmacological management. Therefore, techniques such as distraction, parental presence, and therapeutic communication should be integrated alongside anaesthetic use to achieve comprehensive pain relief (14,19).

The present findings are consistent with international studies demonstrating the effectiveness of EMLA cream in reducing venipuncture pain (18). By demonstrating significant benefits even in a modest sample, this study contributes to the growing body of evidence supporting the systematic implementation of local anaesthetics in paediatric clinical practice. Although no statistically significant differences were found between boys and girls, the greater variability observed in girls' responses may indicate gender-related differences in emotional expression or coping mechanisms. Previous studies suggest that girls may report pain more openly (26), whereas boys may underreport discomfort due to cultural or social expectations. Although speculative in this context, these findings warrant further investigation in larger samples, as understanding such differences could help tailor paediatric pain management strategies.

From a clinical and ethical perspective, the results of this study have immediate implications. Standardising the use of topical anaesthetics such as EMLA cream could significantly enhance the quality of paediatric care, ensuring that children are not subjected to unnecessary pain during routine procedures. Nurses, who are often at the frontline of venipuncture, play a key role in implementing these measures (27). Moreover, educating parents about the availability and efficacy of topical anaesthetics could increase their acceptance and demand, thereby promoting a culture of pain-sensitive paediatric practice. The findings of Taddio et al. (2013) demonstrated that educating parents about pain management strategies is highly effective in increasing their knowledge, confidence, and intention to apply these interventions. Before reviewing the educational materials, most parents were unaware of evidence-based methods for reducing procedural pain. However, after exposure to pamphlets and videos, their understanding and confidence improved significantly. The authors concluded that under-treatment of pain during routine procedures is not due to parental indifference, but rather to a lack of knowledge—an issue that can be addressed through targeted education (28).

In addition to pharmacological interventions, integrating psychological support and non-pharmacological strategies is crucial to effectively address the multidimensional nature of procedural pain. Studies have shown that distraction techniques, relaxation, guided imagery, and parental presence can significantly reduce both pain intensity and anxiety during venipuncture and other needle-related procedures. For example, a randomised clinical trial demonstrated that combining topical anaesthetic with distraction led to a marked decrease in children's reported pain and fear levels compared to standard care (23). Other studies have further confirmed that non-pharmacological interventions serve as valuable adjuncts to pharmacological analgesia, enhancing comfort and cooperation during procedures (14,29,30).

The ethical dimension of paediatric pain management should also be emphasised. Children have the right to adequate pain control, as recognised by international health organisations (20,31). Undertreating or neglecting procedural pain can therefore be considered a breach of this right. Ensuring access to effective analgesic strategies, such as topical anaesthetics, is not only a matter of best clinical practice but also an ethical responsibility.

This study has several strengths and limitations that should be acknowledged. Its main strength lies in the prospective design and inclusion of both physiological and psychological aspects of pain assessment. Incorporating self-reported fear scores provided valuable insights into the emotional dimension of paediatric pain. However, the single-centre setting may

limit generalisability, and group allocation based on parental consent rather than randomisation introduces potential self-selection bias. Furthermore, long-term effects and responses to repeated procedures were not evaluated. Despite these limitations, the results strongly support integrating topical anaesthetics into routine paediatric practice. Future research should explore multimodal approaches that combine pharmacological, psychological, and environmental interventions to further improve children's experiences during medical procedures.

Conclusion

The study confirmed that the use of topical local anaesthetic significantly reduces pain intensity in children during venipuncture. A strong positive correlation between fear and pain perception indicates that emotional factors substantially influence the experience of pain. Although no significant gender differences were found, greater variability in girls' responses suggests possible differences in emotional expression. These findings highlight the importance of addressing both physical and psychological components of pain to improve the quality of paediatric care.

Declarations

Acknowledgements: This study was part of Sara Belandžić's Master of Nursing thesis, originally written and presented in the Croatian language. The thesis is available in the online repository: https://urn.nsk.hr/urn:nbn:hr:224:875376

Authors' contributions: Sara Belandžić designed and conducted the study, analysed the data, and drafted the manuscript under the supervision of Assoc. Prof. Ivan Šklebar. Both authors approved the final version.

Ethics considerations: The study was approved by the Ethics Committee of the Children's Hospital Srebrnjak (document number 04-891/1-24). Written informed consent was obtained from parents or guardians.

Funding: This study did not receive external funding.

Competing interests: All authors declare that they have no conflicts of interest.

Data sharing statement: Data supporting this study is available from the corresponding author upon reasonable request.

References

1. International Association for the Study of Pain. IASP terminology [Internet]. Available from: https://www.iasp-pain.org/resources/terminology/
2. McGrath PA. Pain in children: nature, assessment, and treatment. New York: Guilford Publications; 1990.
3. McCaffery M, Pasero C. Pain: clinical manual. 2nd ed. St. Louis: Mosby; 1999.
4. Taddio A, Katz J, Ilersich AL, Koren G. Effect of neonatal circumcision on pain response during subsequent routine vaccination. Lancet. 1997;349(9052):599–603. doi:10.1016/s0140-6736(96)10316-0
5. Srouji R, Ratnapalan S, Schneeweiss S. Pain in children: assessment and nonpharmacological management. *Int J Pediatr.* 2010;2010:474838. doi: 10.1155/2010/474838
6. Orenius T, LicPsych, Säilä H, Mikola K, Ristolainen L. Fear of Injections and Needle Phobia Among Children and Adolescents: An Overview of Psychological, Behavioral, and Contextual Factors. *SAGE Open Nurs.* 2018;4:2377960818759442. doi: 10.1177/2377960818759442
7. von Baeyer CL. Children's self-report of pain intensity: what we know, where we are headed. *Pain Res Manag.* 2009;14(1):39-45. doi: 10.1155/2009/259759
8. Chambers CT, Johnston C. Developmental differences in children's use of rating scales. *J Pediatr Psychol.* 2002;27(1):27-36. doi: 10.1093/jpepsy/27.1.27
9. Merkel SI, Voepel-Lewis T, Shayevitz JR, Malviya S. The FLACC: a behavioral scale for scoring postoperative pain in young children. *Pediatr Nurs.* 1997;23(3):293-7
10. Wong DL, Baker CM. Pain in children: Comparison of assessment scales. *Pediatr Nurs.* 1988;14(1):9–17
11. McMurtry CM, Noel M, Chambers CT, McGrath PJ. Children's fear during procedural pain: preliminary investigation of the Children's Fear Scale. *Health Psychol.* 2011;30(6):780-8. doi: 10.1037/a0024817
12. McLenon J, Rogers MA. The fear of needles: A systematic review and meta-analysis. *J Adv Nurs.* 2019;75(1):30-42. doi: 10.1111/jan.13818
13. Hedén L, von Essen L, Ljungman G. Children's self-reports of fear and pain levels during needle procedures. *Nurs Open.* 2019 ;7(1):376-382. doi: 10.1002/nop2.399
14. Guillari A, Giordano V, Catone M, Gallucci M, Rea T. Non-pharmacological interventions to reduce

procedural needle pain in children (6-12 years): A systematic review. *J Pediatr Nurs.* 2024;78:e102-e116. doi: 10.1016/j.pedn.2024.06.025

15. Taddio A, Soin HK, Schuh S, Koren G, Scolnik D. Liposomal lidocaine to improve procedural success rates and reduce procedural pain among children: a randomized controlled trial. *CMAJ.* 2005;172(13):1691-5. doi: 10.1503/cmaj.045316
16. Baxter AL, Ewing PH, Young GB, Ware A, Evans N, Manworren RC. EMLA application exceeding two hours improves pediatric emergency department venipuncture success. *Adv Emerg Nurs J.* 2013;35(1):67–75. doi: 10.1097/tme.0b013e31827f50cb
17. Batalha LMC, Marques Correia MM. Prevention of venipuncture pain in children: a comparative study of topical anesthetics. *Rev Enf Ref.* 2018;IV(18):93–102.doi: 10.12707/RIV18021
18. Zhao L, Qi P, Wang X, Su X, Liao L. Local analgesia for the relief of pain in children undergoing venipuncture and intravenous cannulation: a systematic review and network meta-analysis. *BMC Anesthesiol.* 2025;25(1):115. doi: 10.1186/s12871-025-02991-6
19. Trottier ED, Ali S, Doré-Bergeron MJ, Chauvin-Kimoff L. Best practices in pain assessment and management for children. *Paediatr Child Health.* 2022;27(7):429–448. doi: 10.1093/pch/pxac048
20. World Health Organization. Guidelines on the management of chronic pain in children. Geneva: World Health Organization; 2020. Available from: https://www.who.int/publications/i/item/9789240017870
21. Trottier ED, Doré-Bergeron MJ, Chauvin-Kimoff L, Baerg K, Ali S. Managing pain and distress in children undergoing brief diagnostic and therapeutic procedures. *Paediatr Child Health.* 2019;24(8):509-535. doi: 10.1093/pch/pxz026
22. Stavleu DC, Mulder RL, Kruimer DM, Mensink MO, Kremer LC, Tissing WJ, et al. Topical analgesia during needle-related procedures in children: a clinical practice guideline. *Arch Dis Child.* 2025;110(8):657-61. doi: 10.1136/archdischild-2024-326917
23. Yu Z, Zhou Y, Xu X, Lin L, Le Q, Gu Y. Pharmacological and non-pharmacological interventions in management of peripheral venipuncture-related pain: a randomized clinical trial. *BMC Pediatr.* 2023;23:58. doi: 10.1186/s12887-023-03855-z
24. Noel M, Chambers CT, McGrath PJ, Klein RM, Stewart SH. The influence of children's pain memories on subsequent pain experience. Pain. 2012;153(8):1563-1572. doi: 10.1016/j.pain.2012.02.020
25. Greenough MJ, Jibb L, Lewis KB, Bucknall T, Lamontagne C, Demery Varin M, et al. A systematic review of the biopsychosocial dimensions affected by chronic pain in children andadolescents: identifying reliable and valid pediatric multidimensional chronic pain assessment tools. *Pain Rep.* 2023;8(6):e1099. doi: 10.1097/pr9.0000000000001099
26. Duff AJA. Incorporating psychological approaches into routine paediatric venepuncture. *Arch Dis Child.* 2003;88(10):931-937. Doi: 10.1136/adc.88.10.931
27. Apaydın Cırık V, Çiftçioğlu Ş, Efe E. Knowledge, Practice and Beliefs of Pediatric Nurses about Pain. *J Pediatr Res.* 2019;6(3):220-227. doi: 10.4274/jpr.galenos.2019.48344
28. Taddio A, Shah V, Leung E, Wang J, Parikh C, Smart S, et al. Knowledge translation of the HELPinKIDS clinical practice guideline for managing childhood vaccination pain: usability and knowledge uptake of educational materials directed to new parents. *BMC Pediatr.* 2013;13:23. doi: 10.1186/1471-2431-13-23
29. Suleman SK, Yahya N, Nilsson S, Enskär K. Comparative efficacy of pharmacological and non-pharmacological interventions for mitigating pain and anxiety associated with venipuncture: a randomised controlled trial. *BMJ Paediatr Open.* 2024 Sep 9;8(1):e002881. doi: 10.1136/bmjpo-2024-00288
30. Lulková M, Brabcová I, Škvor J. Comparison of four non-pharmacological methods of pain relief during venipuncture in children. *J Nurs Soc Stud Public Health Rehabil.* 2025;16(1):4–14. doi: 10.32725/jnss.2025.008
31. Moultrie F, Shriver A, Hartley C, Wilkinson D, Ewer AK, Rogers R, et al. A universal right to pain relief: balancing the risks in a vulnerable patient population. *Lancet Child Adolesc Health.* 2019;3(2):62-4. doi: 10.1016/S2352-4642(18)30269-4