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COMPARATIVE STUDY OF ANIMATED DISTRACTION, TOPICAL ANESTHESIA, AND THEIR COMBINATION IN REDUCING PAIN AND PROCEDURAL DISTRESS DURING IV CANNULATION IN CHILDREN AGED 1 TO 5 YEARS

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Abstract

Background: Intravenous (IV) cannulation is a common but distressing procedure in pediatric care, particularly in young children. While topical anesthetics such as EMLA cream reduce sensory pain, they often fail to address behavioral distress. Animated distraction has emerged as a promising non-pharmacological alternative. However, limited data exist on their combined use in preschool-aged children.

Objective: To compare the effectiveness of animated distraction, topical anesthesia (EMLA), and their combination in reducing pain and procedural distress during IV cannulation in children aged 1 to 5 years.

Methods: In this randomized controlled trial, 180 children aged 1–5 years requiring IV cannulation were randomly assigned into three groups: animated distraction only, topical anesthesia only, and a combination of both. Pain was assessed using the FLACC (Face, Legs, Activity, Cry, Consolability) scale. Secondary outcomes included crying duration, cooperation, cannulation time, success rates, adverse events, and parental satisfaction. Multivariate regression identified predictors of lower pain scores.

Results: The combination group had the lowest mean FLACC score (2.6 ± 1.4) compared to animated distraction (3.2 ± 1.6) and topical anesthesia (5.8 ± 2.1) ($p < 0.001$). Mild pain (FLACC < 4) was most frequent in the combination group (71.7%). The combination also resulted in significantly shorter crying duration (28.9 ± 12.7 seconds), faster cannulation (70.8 ± 18.9 seconds), higher first-attempt success rate (93.3%), better cooperation (9.1 ± 0.9), and highest parental satisfaction (9.3 ± 0.7). Multivariate analysis confirmed that both animated distraction (aOR = 3.9) and the combined approach (aOR = 7.8) were independent predictors of lower pain scores. No serious adverse events were reported.

Conclusion: Combining animated distraction with topical anesthesia significantly improves pain control, behavioral cooperation, and parental satisfaction in young children undergoing IV cannulation. This multimodal strategy is safe, effective, and practical for routine pediatric use.

Keywords: IV cannulation, children, pain, EMLA, animated distraction, FLACC scale, procedural distress, randomized controlled trial

INTRODUCTION

Intravenous (IV) cannulation is among the most common invasive procedures in pediatric settings, frequently eliciting considerable pain and procedural distress in young children and their caregivers (1). The acute discomfort and anxiety triggered by IV cannulation can lead to both immediate and long-term psychological effects, including the development of needle phobia, heightened distress during subsequent medical encounters, and decreased compliance with healthcare interventions (1,2). While the fear of needles in children often stems from the anticipation of pain, this fear can distort their understanding of the procedure's purpose, further amplifying anxiety and apprehension about hospitalization (3). Therefore, the effective management of procedural pain and distress is essential to delivering high-quality, child-centered pediatric care.

Pharmacological methods such as topical anesthetics—including eutectic mixtures like EMLA or lignocaine gel—are traditionally used to reduce the sensory pain associated with cannulation by numbing the skin (1,4). While these agents are effective in lowering nociceptive pain, they often fail to address the emotional and behavioral distress experienced by children during the procedure (2,4). Additionally, their relatively long onset time can pose a logistical limitation in fast-paced clinical environments.

To address these limitations, nonpharmacological approaches—particularly distraction-based interventions—have gained increasing attention. Animated distraction, involving the use of audiovisual content such as cartoons, has demonstrated utility in diverting a child's attention away from the painful stimulus, thereby decreasing pain perception and improving procedural cooperation (1,5).

Several randomized controlled trials have demonstrated that animated distraction can be at least as effective, and sometimes superior, to topical anesthetics in alleviating pain and distress during intravenous (IV) cannulation in children. One study found that children who watched a cartoon during IV insertion experienced significantly lower levels of pain and fear compared to those who watched an informational video, underscoring the value of audiovisual distraction for procedural comfort. Another trial evaluating cartoon distraction during IV injection also reported markedly reduced pain scores and distress levels compared to control groups (6,7).

Despite the growing evidence supporting both topical anesthesia and animated distraction, there remains limited research directly comparing their individual and combined effects, particularly in very young children aged 1 to 5 years—a group that is especially vulnerable to procedural distress and may have unique developmental and behavioral responses to pain management strategies (4). A recent randomized clinical trial involving children aged 3–16 years indicated that both EMLA and distraction, as well as their combination, can reduce pain during IV cannulation, with no significant differences in self-reported pain among the groups (4) . However, data specific to the 1–5-year age group remain sparse.

Given the importance of minimizing pain and distress during pediatric IV cannulation, a comparative study examining the efficacy of animated distraction, topical anesthesia, and their combination in children aged 1 to 5 years is warranted. Such research could inform best practices for procedural pain management in this vulnerable population, guiding clinicians in selecting interventions that are both effective and feasible in real-world pediatric settings.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, parallel-group, three-arm randomized controlled trial conducted in the pediatric emergency and outpatient departments of a tertiary care teaching hospital. The trial aimed to compare the effectiveness of animated distraction, topical anesthesia (EMLA cream), and their combination in reducing pain and procedural distress during intravenous (IV) cannulation in children aged 1 to 5 years. The study followed CONSORT guidelines for trial reporting. The allocation ratio was 1:1:1.

Participants

Children aged 1 to 5 years requiring IV access for clinical indications were screened for eligibility. Inclusion criteria included:

- Age between 12 and 60 months
- Indication for IV cannulation
- Written informed consent obtained from a parent or legal guardian

Exclusion criteria included:

- Children with developmental delay or neurocognitive impairment
- History of traumatic or repeated prior IV cannulations
- Allergies to lidocaine/prilocaine
- Uncontrolled behavioral disorders or active sedation

Randomization and Allocation Concealment

Participants were randomized using a computer-generated block randomization sequence (block size of 6), stratified by age groups (12–35 months and 36–60 months). Allocation was concealed using sequentially numbered, opaque, sealed envelopes prepared by an independent statistician not involved in recruitment or assessment.

Interventions

Children were randomly assigned to one of the following three groups:

- **Group A: Animated Distraction Only** Age-appropriate cartoon videos were played on tablets beginning two minutes before and continuing throughout the IV cannulation procedure.
- **Group B: Topical Anesthesia Only** A eutectic mixture of lidocaine 2.5% and prilocaine 2.5% (EMLA cream) was applied under occlusive dressing 45 minutes before IV cannulation at the planned site.
- **Group C: Combination of Animated Distraction and Topical Anesthesia** EMLA cream was applied 45 minutes prior, as in Group B, and animated distraction was also administered as in Group A during the procedure.

All IV cannulations were performed by experienced pediatric nurses following standard aseptic protocols. No sedation was used in any group.

Outcome Measures

- **Primary Outcome**:
    - Pain during IV cannulation, assessed using the FLACC (Face, Legs, Activity, Cry, Consolability) scale immediately after the procedure by a blinded observer.
- **Secondary Outcomes**:
    - Duration of procedure (in seconds, from tourniquet application to successful cannulation)
    - Number of attempts required for successful cannulation
    - Nurse-reported child cooperation (10-point Likert scale)
    - Crying duration (in seconds)
    - Parental satisfaction (10-point Visual Analog Scale)
    - Adverse events (e.g., skin irritation or allergic reactions)

Sample Size Calculation

Assuming a minimum clinically significant difference of 2 points in FLACC score between any two groups, with a standard deviation of 2.5, power of 80%, and $\alpha = 0.05$, a sample size of 51 children per group was calculated. Accounting for potential 15% attrition, a total of 60 children per group were recruited (N = 180).

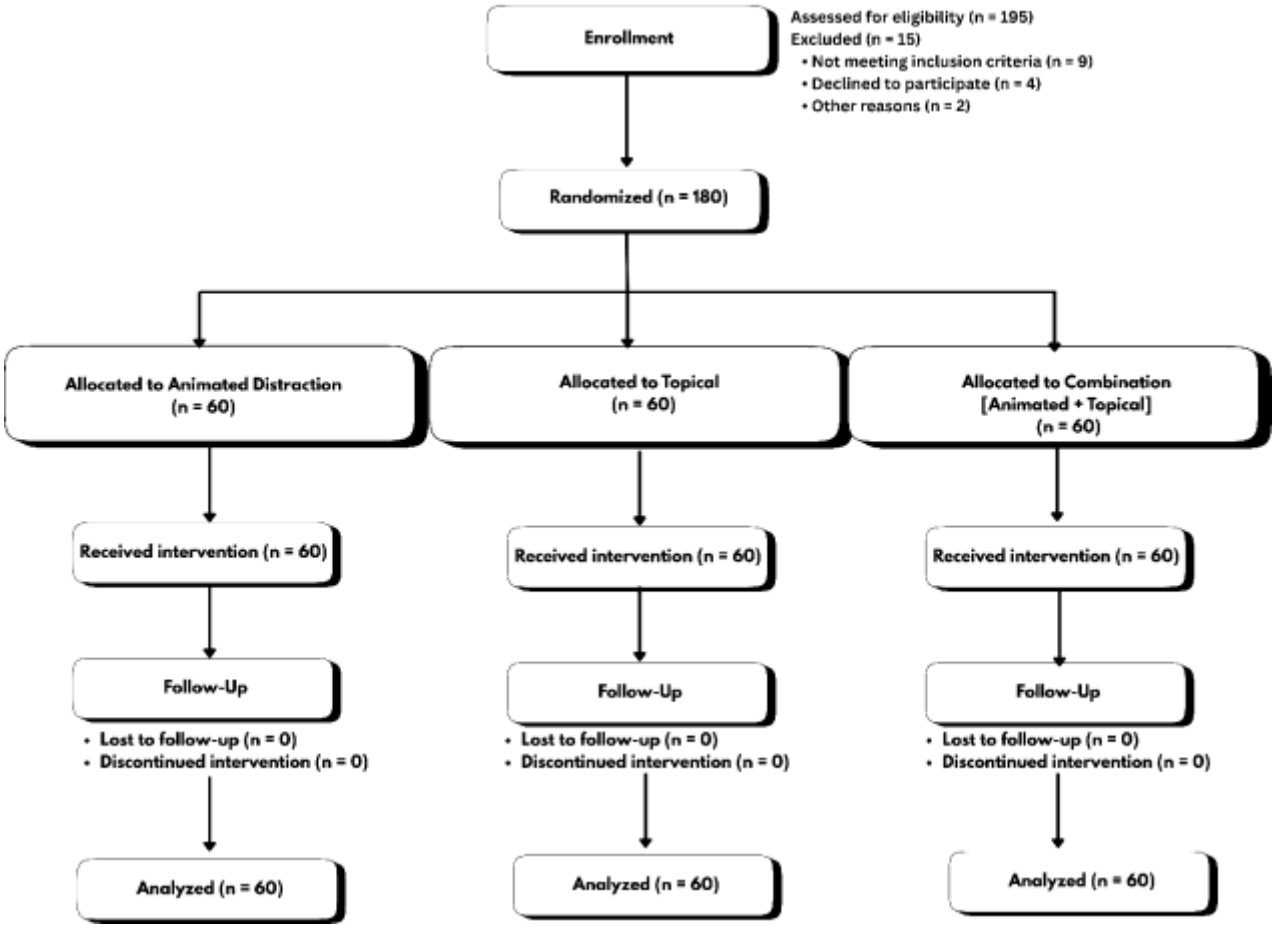
Blinding

Due to the visible nature of the interventions, blinding of participants and caregivers was not feasible. However, the outcome assessor recording pain scores and secondary outcomes remained blinded to group allocation.

Statistical Analysis

Data were analyzed using SPSS software version 25.0. Continuous variables were expressed as mean ± standard deviation or median (IQR), and categorical variables as frequencies and percentages. Between-group comparisons were performed using ANOVA or Kruskal–Wallis tests for continuous variables, and Chi-square tests for categorical variables. Post-hoc Bonferroni or Dunn's test was used for pairwise comparisons. A p-value < 0.05 was considered statistically significant.

Figure 1 CONSORT Flow Diagram



RESULTS

Table 1 presents the baseline characteristics of the study participants. Baseline characteristics were comparable across all three groups. There were no statistically significant differences in age, gender distribution, weight, prior IV cannulation history, or parental anxiety scores ($p > 0.05$), confirming that randomization effectively balanced participant characteristics.

Table 1: Baseline Characteristics of Study Participants (N = 180)

Characteristic	Animated Distraction (n = 60)	Topical Anesthesia (n = 60)	Combination (n = 60)	p-value
Mean age (months)	36.4 ± 13.2	35.7 ± 12.8	36.1 ± 13.0	0.93
Gender (Male:Female)	34:26	33:27	32:28	0.89
Mean weight (kg)	12.3 ± 2.1	12.1 ± 2.4	12.2 ± 2.2	0.88

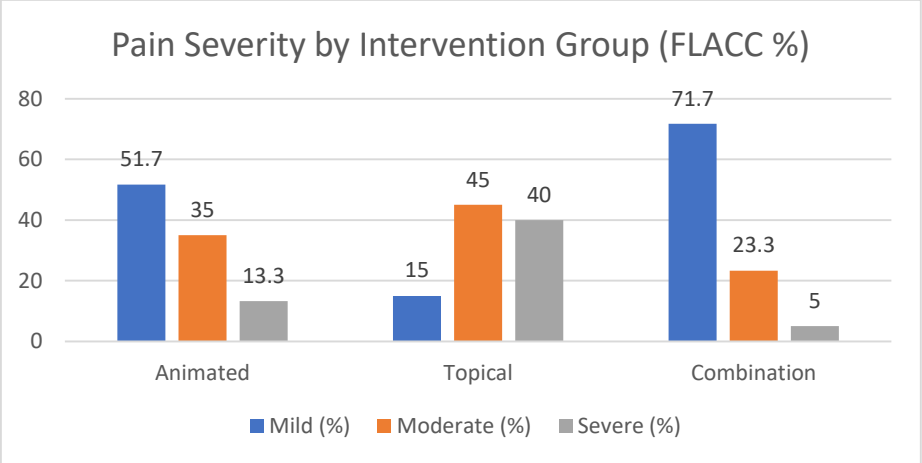
Prior IV cannulation (%)	28 (46.7%)	30 (50.0%)	29 (48.3%)	0.93
Parental anxiety score (VAS)*	4.1 ± 1.3	4.0 ± 1.5	4.2 ± 1.4	0.77

Table 2 and Figure 2 summarize the pain scores based on the FLACC scale during IV cannulation. Children in the combination group experienced the least pain during IV cannulation, with a significantly lower mean FLACC score (2.6 ± 1.4) compared to both the animated distraction group (3.2 ± 1.6) and the topical anesthesia group (5.8 ± 2.1) ($p < 0.001$). The proportion of children experiencing mild pain (FLACC < 4) was highest in the combination group (71.7%), followed by animated distraction (51.7%) and lowest in the topical anesthesia group (15.0%). Conversely, the topical group had the highest rate of severe pain (40%), which was significantly greater than both other groups. These results indicate that combining animated distraction with topical anesthesia provides the most effective pain relief during IV cannulation.

Table 2: Pain Scores (FLACC Scale) During IV Cannulation

FLACC Score	Animated Distraction (n = 60)	Topical Anesthesia (n = 60)	Combination (n = 60)	p-value
Mean total score (0–10)	3.2 ± 1.6	5.8 ± 2.1	2.6 ± 1.4	<0.001
FLACC >6 (severe pain) (%)	8 (13.3%)	24 (40%)	3 (5.0%)	<0.001
FLACC 4–6 (moderate pain) (%)	21 (35.0%)	27 (45.0%)	14 (23.3%)	0.04
FLACC <4 (mild pain) (%)	31 (51.7%)	9 (15.0%)	43 (71.7%)	<0.001

Figure 2: Distribution of FLACC Pain Severity Categories Among Children Undergoing IV Cannulation Across Intervention Groups



As shown in Table 3, children in the combination group had the shortest procedure time (mean 70.8 ± 18.9 seconds), followed closely by the animated distraction group (74.6 ± 22.5 seconds), with the longest time observed in the topical anesthesia group (96.2 ± 27.3 seconds) ($p < 0.001$). The highest first-attempt success rate was also noted in the combination group (93.3%), compared to animated distraction (90.0%) and topical anesthesia (75.0%) ($p = 0.01$). Additionally, the nurse-reported cooperation score was significantly higher in the combination group

(9.1 ± 0.9) than in either the animated (8.5 ± 1.1) or topical groups (6.7 ± 1.6), suggesting that combining visual distraction with topical analgesia enhances procedural cooperation and efficiency.

Table 3: Procedure-Related Outcomes

Outcome Measure	Animated Distraction (n = 60)	Topical Anesthesia (n = 60)	Combination (n = 60)	p-value
Mean procedure time (seconds)	74.6 ± 22.5	96.2 ± 27.3	70.8 ± 18.9	<0.001
Successful first attempt (%)	54 (90.0%)	45 (75.0%)	56 (93.3%)	0.01
Number of attempts (median, IQR)	1 (1–1)	1 (1–2)	1 (1–1)	0.01
Nurse-reported cooperation score*	8.5 ± 1.1	6.7 ± 1.6	9.1 ± 0.9	<0.001

***Measured on a 10-point Likert scale**

Table 4 presents data on adverse events and behavioral responses. Children in the combination group exhibited the shortest crying durations (28.9 ± 12.7 seconds), followed by the animated distraction group (39.2 ± 14.6 seconds), and were significantly calmer compared to the topical anesthesia group (59.7 ± 18.3 seconds) ($p < 0.001$). Delays in cannulation due to distress were also least common in the combination group (1.7%), compared to 3.3% in the animated group and 16.7% in the topical group ($p = 0.01$). Mild skin reactions were reported in 5 children from the topical-only group and in 3 children from the combination group. Parental satisfaction was highest in the combination group (mean VAS score 9.3 ± 0.7), followed by animated distraction (8.8 ± 1.0), and lowest in the topical anesthesia group (6.9 ± 1.5) ($p < 0.001$).

Table 4: Adverse Events and Behavioral Responses

Parameter	Animated Distraction (n = 60)	Topical Anesthesia (n = 60)	Combination (n = 60)	p-value
Crying duration (seconds)	39.2 ± 14.6	59.7 ± 18.3	28.9 ± 12.7	<0.001
Delayed cannulation due to distress (%)	2 (3.3%)	10 (16.7%)	1 (1.7%)	0.01
Skin reaction (EMLA-related only)	–	5 (8.3%)	3 (5.0%)	–
Post-procedure parental satisfaction (VAS 1–10)	8.8 ± 1.0	6.9 ± 1.5	9.3 ± 0.7	<0.001

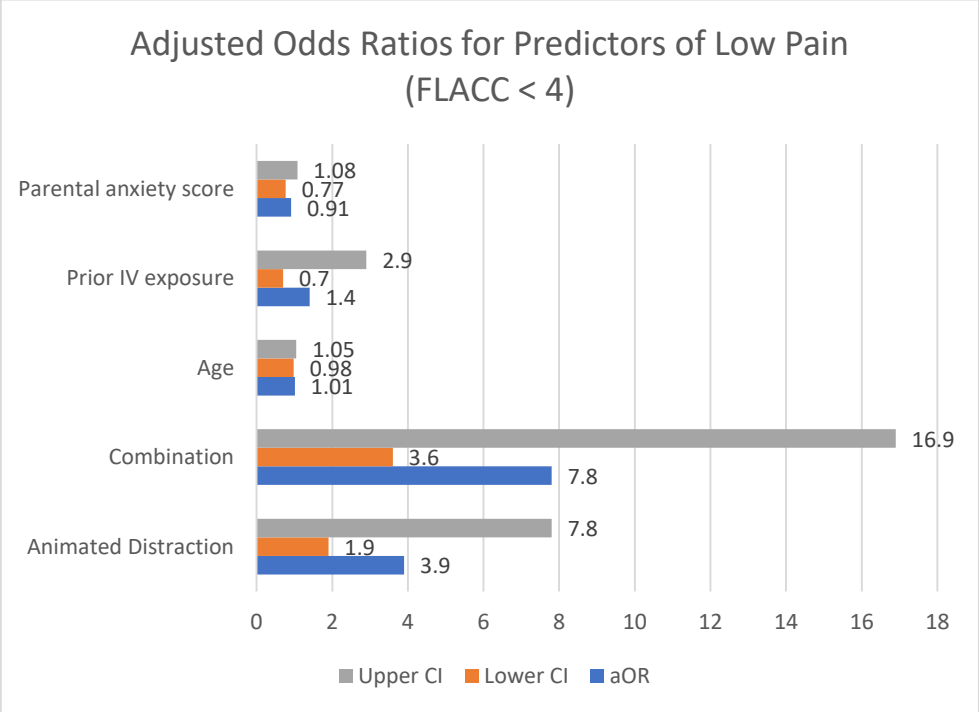
The predictors of lower pain scores (FLACC < 4) are presented in Table 5 and visualized in Figure 3. After adjusting for age, prior IV exposure, and parental anxiety, both animated distraction and combination therapy remained significant independent predictors of lower pain scores. Children in the animated distraction group had 3.9 times higher odds of experiencing low pain scores compared to the topical anesthesia group ($p < 0.001$), while those in the combination group had 7.8 times higher odds ($p < 0.001$). Age, prior IV cannulation history, and parental anxiety were not significant predictors.

Table 5: Multivariate Regression Analysis of Predictors of Lower Pain Score (FLACC < 4)

Predictor Variable	Adjusted Odds Ratio (aOR)	95% CI	p-value
Animated Distraction (vs. Topical)	3.9	1.9–7.8	<0.001
Combination (vs. Topical)	7.8	3.6–16.9	<0.001

Age (per month increase)	1.01	0.98–1.05	0.25
Prior IV exposure (Yes vs. No)	1.4	0.7–2.9	0.35
Parental anxiety score (VAS 1–10)	0.91	0.77–1.08	0.29

Figure 3: Horizontal bar chart illustrating adjusted odds ratios (aOR) with 95% confidence intervals for predictors of low pain score (FLACC < 4).



DISCUSSION

This randomized controlled trial assessed the comparative effectiveness of animated distraction, topical anesthesia using EMLA cream, and their combination in reducing pain and procedural distress during intravenous cannulation in children aged 1 to 5 years. The findings revealed that the combination of animated distraction and topical anesthesia produced the most favorable outcomes across all measured parameters, indicating a significant synergistic benefit.

The mean FLACC pain score was lowest in the combination group (2.6 ± 1.4), compared to the animated distraction group (3.2 ± 1.6) and the topical anesthesia group (5.8 ± 2.1), with a statistically significant difference ($p < 0.001$). Additionally, 71.7% of children in the combination group experienced mild pain (FLACC < 4), a proportion notably higher than that in the animated group (51.7%) and topical group (15%). Severe pain (FLACC > 6) was reported in only 5% of children in the combination group versus 13.3% and 40% in the animated and topical groups, respectively. These results demonstrate that the combined approach not only lowers average pain scores but also reduces the incidence of severe pain episodes.

Behavioral responses further supported the efficacy of the combined approach. The mean crying duration was significantly lower in the combination group (28.9 ± 12.7 seconds) compared to the animated group (39.2 ± 14.6 seconds) and the topical group (59.7 ± 18.3 seconds), again with a p-value < 0.001. Delays in cannulation due to distress were minimal in the combination group (1.7%) and significantly higher in the topical group (16.7%), indicating improved emotional regulation and procedural readiness.

From a procedural standpoint, the combination group had the shortest mean cannulation time (70.8 ± 18.9 seconds), the highest first-attempt success rate (93.3%), and the best nurse-reported cooperation score (9.1 ± 0.9

on a 10-point scale). These improvements in procedural efficiency and cooperation are clinically meaningful, especially in high-turnover pediatric emergency and outpatient units.

The parental satisfaction score was also highest in the combination group (9.3 ± 0.7), compared to 8.8 ± 1.0 in the animated group and 6.9 ± 1.5 in the topical group. This suggests that caregivers not only observed smoother procedures but also felt reassured by the child's comfort, further supporting the acceptability and feasibility of a combined intervention in real-world settings.

Multivariate logistic regression confirmed that both animated distraction (adjusted odds ratio [aOR] = 3.9; 95% CI: 1.9–7.8) and the combination approach (aOR = 7.8; 95% CI: 3.6–16.9) were independent predictors of lower pain scores (FLACC < 4). Age, prior IV exposure, and parental anxiety scores did not significantly impact the pain outcome, reinforcing the robustness of the interventions across different subgroups.

Mild skin reactions were observed in 8.3% of children in the topical-only group and 5.0% in the combination group, with no serious adverse events reported, affirming the safety profile of EMLA cream when used alone or alongside distraction.

These findings are strongly supported by recent literature. A 2023 randomized clinical trial comparing EMLA alone, distraction (toys, cartoons, games, breathing exercises), and their combination concluded that the combination group had the lowest pain scores during venipuncture, along with reduced crying duration and higher procedural success rates (4)**.**This aligns closely with our study outcomes.

There is also substantial evidence supporting the independent effectiveness of animated distraction. Numerous randomized controlled trials and systematic reviews have demonstrated that distraction techniques—such as watching cartoons—can significantly reduce pain intensity, enhance procedural cooperation, and shorten the duration of IV cannulation in children (1,8). Likewise, the analgesic benefit of EMLA cream is well-established; studies consistently report meaningful reductions in pain scores compared to placebo or no treatment, with a low incidence of adverse effects (9,10). However, a commonly recognized limitation of EMLA is its delayed onset, typically requiring approximately one hour to achieve optimal anesthetic effect (11).

Contemporary guidelines emphasize the value of multimodal analgesia as the standard of care, particularly for needle-related procedures. Combining pharmacological agents like EMLA with non-pharmacological strategies such as animated distraction targets both the physiological and psychological components of pain (12).

This approach results in improved pain control, fewer severe pain episodes, better procedural cooperation, and enhanced caregiver satisfaction.Importantly, both EMLA and distraction methods have favorable safety profiles. Mild, transient local skin reactions are occasionally seen with EMLA, and no serious adverse events have been reported with either intervention (4,10). The combined approach is also feasible for routine use in clinical pediatric settings and is associated with improved parental satisfaction and procedural efficiency (4).

LIMITATIONS

This study was limited by its single-center design, which may restrict generalizability to broader pediatric populations. Blinding of participants and caregivers was not feasible due to the visible nature of the interventions, potentially introducing performance bias. Pain was assessed using an observer-based scale (FLACC), which, while validated, may carry subjective variability. Additionally, the study did not evaluate long-term behavioral effects or repeat procedural exposure outcomes.

CONCLUSION

The combination of animated distraction and topical anesthesia significantly reduced pain, distress, and procedural difficulty during IV cannulation in children aged 1 to 5 years. This multimodal approach demonstrated superior effectiveness across all outcome measures—including pain scores, cooperation, and parental satisfaction—compared to either intervention alone. These findings support the integration of combined pharmacological and non-pharmacological strategies as a practical and effective standard for pediatric procedural pain management.

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