

Comparison of Two Topical Pharmacological Agents in Alleviating Peripheral Intravenous Catheterization Induced Pain in Adults: A Randomized Controlled Study

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Cite this article as:

Kaplan A, Bayat M, Çınar SL, Yerer MB, Avşaroğulları ÖL. Comparison of Two Topical Pharmacological Agents in Alleviating Peripheral Intravenous Catheterization Induced Pain in Adults: A Randomized Controlled Study. J Clin Pract Res 2024;46(3): 266–274.

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Submitted: 26.01.2024

Revised: 21.03.2024

Accepted: 21.05.2024

Available Online: 05.06.2024

Erciyes University Faculty of Medicine Publications - Available online at www.jcprres.com

ABSTRACT

Objective: This study aimed to evaluate the efficacy of the topical anesthetics lidocaine and benzocaine in reducing pain associated with peripheral intravenous catheterization and in enhancing patient satisfaction in the emergency department.

Materials and Methods: This randomized-controlled, parallel-group, double-blind, experimental, and Phase III clinical trial involved 120 individuals admitted to the Emergency Department of a University Hospital. Data were collected using an Individual Information Form, Visual Analog Scale, and Patient Satisfaction Scale about Catheterization. Participants were divided into three groups (lidocaine 10% spray, benzocaine 20% spray, and placebo groups) according to a computer-generated randomization table.

Results: The average pain scores were lower and satisfaction levels with catheterization were higher in the lidocaine and benzocaine groups compared to the placebo group ($p < 0.001$). A strong negative correlation was observed between the groups' pain scores and satisfaction levels with catheterization (Lidocaine Spray Group $r = -0.636$ $p < 0.001$; Benzocaine Spray Group $r = -0.651$ $p < 0.001$; Placebo Group $r = -0.877$ $p < 0.001$).

Conclusion: Topical lidocaine and benzocaine have been proven to reduce pain from peripheral intravenous catheterization and improve patient satisfaction. These agents can be routinely used to alleviate injection pain and improve patient satisfaction with the procedure.

Keywords: Intravenous administration, nursing, pain management, patient satisfaction, peripheral catheterization.



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INTRODUCTION

The peripheral intravenous catheter (PIVC) is one of the most important tools in modern medicine.¹ A study spanning thirteen countries reported that over one billion PIVCs are utilized annually in hospitalized patients worldwide, with at least one peripheral intravenous (IV) catheter applied to 59% of these patients.² Peripheral IV catheterization, primarily the responsibility of nurses, is a common procedure in both clinical and emergency settings for treatment purposes. The literature indicates that 86.7% of patients have at least one peripheral IV catheter inserted during their hospital admission.³

The literature reports that peripheral intravenous catheterization is a painful and discomforting procedure, which may lead to increased anxiety among patients.⁴ The pain and discomfort experienced during catheterization can lead to complications such as IV catheter failure, vessel extravasation, and multiple catheterization attempts.⁵ Additionally, the associated pain and anxiety can cause vasoconstriction in peripheral vessels, reducing venous filling and negatively impacting the success of IV catheter insertion.⁶ It is recognized that both pharmacological and non-pharmacological interventions aimed at reducing pain associated with peripheral IV catheterization can decrease the number and duration of catheterization attempts, save nurses' time, reduce costs, alleviate pain, and thus increase patient satisfaction.^{7,8}

Various pharmacological and non-pharmacological methods are employed to alleviate the pain and distress caused by peripheral IV catheterization.^{4,9,10} Non-pharmacological methods include heat application, cold application, music therapy, blowing balloons, and squeezing rubber balls.^{7,11–13} Among the pharmacological options, topical or subcutaneous applications of certain agents such as lidocaine and prilocaine-containing cream, lidocaine, and ethyl chloride sprays are prevalent.^{14–16} Current literature suggests that lidocaine reduces the pain associated with peripheral IV catheterization and improves patient satisfaction.^{8,17,18} To date, there has been no published research on the use of benzocaine for peripheral IV catheterization. Nevertheless, previous research aimed at reducing the discomfort associated with inferior alveolar nerve block injections has demonstrated the effectiveness of topical anesthetic benzocaine spray for pain management.¹⁹ Lidocaine and benzocaine, like all local anesthetics, decrease the permeability of the nerve cell membrane to sodium, block the transmission of nerve impulses, and cause a temporary loss of sensation, thereby alleviating pain and discomfort.²⁰ Lidocaine is categorized as an amide local anesthetic, while benzocaine falls under an ester class. The onset of anesthetic effects ranges from 1–5 minutes, depending on the site of

application. The absorption rate and duration depend on the drug's dose and concentration, the application site, and the duration of application.²¹

In healthcare settings, the nursing service serves as a critical link between the institution and the patient.²² Patient-centered and holistic nursing care enhances the quality of service and increases patient satisfaction, a key outcome in healthcare.²³ Furthermore, the adoption of current, evidence-based practices and pain management techniques also boosts patient satisfaction. Nurses are tasked with observing and evaluating the effects of diagnostic and treatment procedures on patients. Consequently, there is a need for accessible, cost-effective, easy-to-use, and fast-acting methods with a low risk of side effects to manage pain in peripheral IV catheterization, one of the most painful procedures.²⁴ Thus, this study was initiated to assess the effects of topical lidocaine and benzocaine spray on both pain perception and patient satisfaction.

Aim of the Study

The aim of this study is to examine the effectiveness of topical anesthetics—lidocaine 10% and benzocaine 20%—in reducing pain associated with peripheral intravenous catheterization and increasing patient satisfaction in the emergency department.

Hypotheses

The hypotheses of this study are as follows:

- H1. Topical lidocaine reduces pain from peripheral intravenous catheterization.
- H2. Topical lidocaine improves patient satisfaction with peripheral intravenous catheterization.
- H3. Topical benzocaine reduces pain from peripheral intravenous catheterization.
- H4. Topical benzocaine improves patient satisfaction with peripheral intravenous catheterization.

MATERIALS AND METHODS

Study Design

This study was conducted as a randomized controlled, double-blind, Phase III experimental clinical trial. It was registered with ClinicalTrials under the number NCT04859738 on April 21, 2021.

Ethical Considerations

Prior to data collection, approval was obtained from the Erciyes University Clinical Research Ethics Committee on January 29, 2020, under decision number 2020/59. Necessary

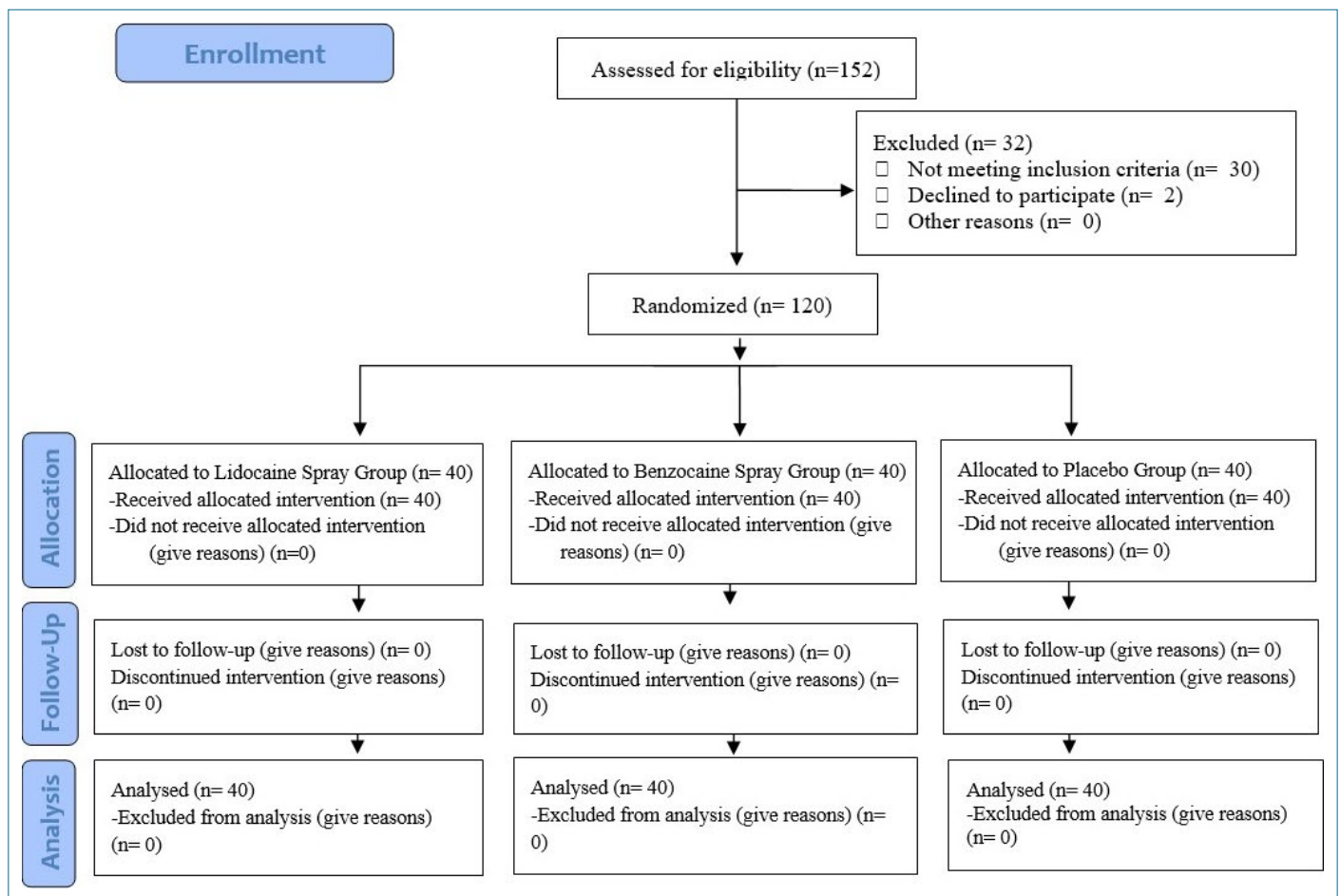


Figure 1. Diagram of the consolidated standards for reporting trials.

permissions were also secured from the Ministry of Health, the Turkish Medicines and Medical Devices Agency, and the institution where the study was conducted. A comprehensive explanation of the study's objectives ensured that participants were well-informed. Written informed consent was obtained from all willing participants, with strict adherence to the principles of the Declaration of Helsinki throughout every phase of the study.

Sample

The study was conducted in the emergency department of a university hospital in the Central Anatolia Region of Türkiye between February and November 2020. The sample consisted of 120 individuals who met the inclusion criteria and agreed to participate. Power analysis, using the Minitab program, calculated the sample size based on a similar study's results, which noted a 39.5% difference in pain levels, a 5% type 1 error rate, and 90% power.¹⁴ Consequently, the minimum required sample size was determined to be 120

(n=40 for each group). Figure 1 illustrates the consolidated standards for reporting trials diagram.

Patients eligible for the study were required to 1) speak and understand Turkish, 2) be aged between 18–65, 3) have orientation to time and place, 4) and have an average pressure pain threshold of 8–16 lb. The exclusion criteria included: 1) experiencing bodily pain, 2) having undergone IV catheter insertion in the last month, 3) using analgesics in the last 24 hours, 4) suffering from psychiatric illnesses, 5) using central nervous system drugs, 6) having a chronic disease, 7) presenting with phlebitis, scar tissue, dermatitis, incisions, or signs of infection at the catheter insertion site.

Data Collection Tools

Data were collected using an Individual Information Form, a Visual Analog Scale, and a Patient Satisfaction Form regarding catheterization. A dolorimeter apparatus with a pressure capacity of 66 pounds (30 kilograms) was used to assess the pressure pain threshold of the participants.

Individual Information Form

This form was developed by researchers based on similar studies in the literature. It collects socio-demographic characteristics of participants, such as age, gender, marital status, educational level, history of IV catheterization, purpose of the most recent IV catheterization, and average pain threshold value.^{7,14} The emergency nurse overseeing the study filled out the form during in-person interviews with patients and by examining their medical records.

Visual Analog Scale (VAS)

The Visual Analog Scale is an effective tool for measuring pain in patients aged five years and older.²⁵ Patients were shown a 100 mm line, with descriptions of extreme pain at both ends. They were asked to mark their pain level on the line by ticking or pointing. The scale was marked in 10 mm intervals, with “0 mm” indicating no pain and “100 mm” indicating the most severe pain. Pain intensity was determined by measuring the point marked by the patient in millimeters with a ruler.

Patient Satisfaction Form about Catheterization (PSFC)

The researchers created a form based on the VAS to assess patient satisfaction after peripheral IV catheterization. This innovative form featured a 100 mm line, similar to the VAS, with descriptions of extreme satisfaction at each end. Descriptive terms along the ruler indicated levels of satisfaction with the procedure. Patients were asked to mark the point on the line that best represented their satisfaction level. This scale, also 100 mm (10 cm) in length, ranged from “0 mm” indicating “not satisfied at all,” to “100 mm” indicating “very satisfied.” The satisfaction score was measured in millimeters with a ruler, providing a quantitative assessment of the patient’s satisfaction with the catheterization process. This method offered a nuanced understanding of individual satisfaction levels and enhanced the precision of evaluating patient experiences post-catheterization.

Dolorimeter 66 Libre/30 Kg

The device is a pressure algometer used to evaluate pain sensitivity, determine pressure perception, and assess the sensitivity of muscles and other soft tissues.²⁶ Pressure was applied to the wrist to introduce the Dolorimeter tool to the individuals. They were instructed to issue a “stop” command as soon as they first perceived pain. The application was repeated several times until the individuals could adapt. Subsequently, three measurements were taken at 5-second intervals on the other, non-pressurized wrist. The average pressure pain threshold for the patients was calculated by averaging these three measurements. Patients with an average pressure pain threshold between 8–16 libre were included in the sample.

Randomization

Patients who met the inclusion criteria and were prescribed peripheral intravenous catheterization by the emergency department physician were identified. The researcher informed the eligible patients about the study and obtained their written consent. These patients were numbered and assigned to the lidocaine spray, benzocaine spray, and placebo groups using a computer-generated randomization table.

Data Collection and Intervention

All study participants were covered by private health insurance against adverse conditions such as hematoma, thromboembolism, thrombophlebitis, air embolism, and infection that could arise from the procedure.⁸ Two volunteer nurses from the emergency department were selected and trained by the researcher on the study design, data collection forms, pharmacological agents used, the dolorimeter device, and potential complications. The nurses, continuing their postgraduate education, have been working in the emergency department for two and four years, respectively. Training was provided face-to-face one week before patient admission. While one nurse performed the peripheral IV catheterization, the other collected data. The same nurse applied the catheter to all participants. Both researchers and patients were blinded to the experimental groups.

In the study, vemcaine pump spray 10% (VEM Pharmaceutical Industry and Trade Joint Stock Company, İstanbul/Türkiye) and vision pump spray 20% (Anadolu Dental Depot Industry and Trade Joint Stock Company, İstanbul/Türkiye), both trademarked as lidocaine and benzocaine sprays respectively, were used. The sprays, packaged in similar vials, were used in their original container. One lidocaine spray vial was emptied and washed in preparation for use with the placebo group. It was then sterilized in an autoclave machine and filled with 70% alcohol, which is routinely used in the hospital. Manufacturer labels were removed from the bottles, and color-coded labels corresponding to each group were affixed. Only the researcher knew the meaning of these color labels, which determined which bottle was used in each group. Considering that catheter size may influence pain levels, a 20-Gauge pink catheter from the same brand (Ayset, Adana/Türkiye) was used for all patients. To enhance the study’s reliability and minimize potential variations in pain levels due to regional differences, the median cubital vein in the arm was exclusively chosen as the site for IV catheter insertion.

The researcher provided the materials used in the study and the relevant spray bottle to the responsible nurse. First, the nurse confirmed the patient’s identity and obtained permission for the catheterization. She then palpated the appropriate vessel

Table 1. Comparison of descriptive characteristics of participants by group (n=120)

Descriptive characteristics	Lidocaine spray group (n=40)	Benzocaine spray group (n=40)	Placebo group (n=40)	Test value /p value
Age (years, mean±SD)	35.65±10.79	35.00±12.11	35.82±12.85	0.053* / 0.903
Gender				0.271** / 0.873
Female	22 (55.0)	22 (55.0)	24 (60.0)	
Male	18 (45.0)	18 (45.0)	16 (40.0)	
Marital status				0.251** / 0.882
Married	30 (75.0)	29 (72.5)	28 (70.0)	
Single	10 (25.0)	11 (27.5)	12 (30.0)	
Education level				6.073** / 0.639
Primary education	16 (40.0)	13 (32.5)	17 (42.5)	
High school	13 (32.5)	11 (27.5)	12 (30.0)	
School/faculty	11 (27.5)	16 (40.0)	11 (27.5)	
Previous IV catheterization				0.801*** / 0.670
Yes	35 (87.5)	37 (92.5)	37 (92.5)	
No	5 (12.5)	3 (7.5)	3 (7.5)	
Purpose of the last IV catheterization				6.268*** / 0.180
Fluid therapy	5 (14.3)	9 (24.3)	2 (5.4)	
Medication	30 (85.7)	29 (75.7)	35 (94.6)	
Average pain threshold value after three measurements (lb/cm ²)	11.97±1.84	11.60±1.91	11.70±2.10	0.393* / 0.676

IV: Intravenous; lb: Libre; SD: Standard deviation; *: One-way analysis of variance; **: Pearson Chi-square test; ***: Fisher Chi-square test.

in the median cubital region for catheterization. A single puff of the spray, selected based on the patient's research group, was applied from a distance of 5–6 centimeters from the skin. The nurse waited 60 seconds after spraying. During the first 30 seconds, she prepared the materials for use. In the remaining 30 seconds, she applied a tourniquet, re-palpated the vein, and cleaned the area. The catheter was then inserted following standard IV catheterization procedures. Afterward, the nurse collected the materials and departed from the patient's side. Immediately following the catheterization, the nurse responsible for data collection explained the Individual Information Form, VAS, and PSFC to the patients before they filled in the forms.

Data Analysis

The data were analyzed using IBM SPSS (Statistical Package for the Social Sciences) Statistics® 23.0 (IBM Corp., Armonk, New York, USA, 2021). The Shapiro-Wilk test was used to assess the normality of numerical data. Categorical data comparisons between groups were made using either the Fisher or Pearson chi-square analysis, depending on the distribution.

For normally distributed data, the paired t-test was utilized, while one-way analysis of variance was used to compare more than two groups. If the one-way analysis of variance indicated significant differences, the Tukey Post Hoc test was conducted for multiple comparisons. Pearson Correlation analysis was applied to statistically assess the correlation between variables, examining both the direction and strength of these relationships. A significance level of $p < 0.05$ was set for all statistical comparisons.

RESULTS

Table 1 presents the distribution of participants across the lidocaine spray, benzocaine spray, and placebo groups based on their descriptive characteristics. The analysis revealed no statistically significant differences among the groups concerning these characteristics, indicating a comparable baseline ($p > 0.05$).

Table 2 depicts the comparison of mean scores for VAS and PSFC among the lidocaine spray, benzocaine spray, and placebo groups following the procedural intervention. The analysis showed that the lidocaine spray and benzocaine spray

Table 2. Comparison of participants’ pain and satisfaction levels by group (n=120)

Characteristics	Lidocaine spray group (n=40) Mean±SD	Benzocaine spray group (n=40) Mean±SD	Placebo group (n=40) Mean±SD	Test value*/ p value
VAS mean scores	7.72±7.76 ^a	6.82±5.75 ^a	32.65±17.20 ^b	66.177 / p<0.001
PSFC mean scores	95.47±4.31 ^a	95.90±3.88 ^a	75.37±13.45 ^b	76.898 / p<0.001

PSFC: Patient satisfaction form about catheterization; SD: Standard deviation; VAS: Visual Analog Scale; *: One-way ANOVA.; a/bTukey’s Test. The superscripts a, b indicate differences within the group; the same letters indicate no within-group differences, and different letters indicate within-group differences.

Table 3. Relationship between participants’ procedural pain and satisfaction levels with catheterization (n=120)

		Lidocaine spray group (n=40) PSFC	Benzocaine spray group (n=40) PSFC	Placebo group (n=40) PSFC
Lidocaine spray group (n=40)	VAS	-0.636* p<0.001		
Benzocaine spray group (n=40)	VAS		-0.651* p<0.001	
Placebo group (n=40)	VAS			-0.877* p<0.001

*: Pearson correlation coefficient; PSFC: Patient satisfaction form about catheterization; VAS: Visual Analog Scale.

groups exhibited significantly lower pain levels (p<0.001) and higher satisfaction levels with the catheterization procedure (p<0.001) compared to the placebo group. Furthermore, no statistically significant differences were observed in the VAS and PSFC mean scores between the lidocaine spray and benzocaine spray groups (p>0.05).

Table 3 presents the outcomes of the correlation analysis conducted on the total scores of VAS and PSFC within the lidocaine spray, benzocaine spray, and placebo groups. A strong and statistically significant negative correlation was observed between post-procedure VAS and PSFC total scores in both the lidocaine spray and benzocaine spray groups (p<0.001). A similar strong and statistically significant negative correlation was identified between post-procedure VAS and PSFC total scores in the placebo group (p<0.001).

DISCUSSION

The existing literature includes several studies that use pharmacological agents to alleviate the pain experienced by patients undergoing peripheral intravenous catheterization.^{15,16,27} This study employed two different pharmacological agents. It revealed a significant decrease in pain scores among participants in the lidocaine spray

group, demonstrating a statistically significant difference compared with the placebo group. Additionally, individuals in the lidocaine spray group expressed higher satisfaction levels with the catheterization process. In numerous studies, researchers have used lidocaine as the pharmacological agent during peripheral intravenous catheterization. For instance, Burke et al.¹⁴ used lidocaine as the pharmacological method before peripheral intravenous catheterization and found that it significantly reduced pain compared to the control group. Kelley et al.²⁸ concluded that using topical anesthetic lidocaine cream is a suitable method for alleviating pain associated with the insertion of IV catheters in adults. Rzhveskiy et al.⁸ conducted a study on lidocaine and found that applying lidocaine before peripheral intravenous catheterization was more effective and generally acceptable, providing patients comfort, satisfaction, and positive outcomes. Similar studies have reported that lidocaine, used before peripheral intravenous catheterization, effectively reduces pain associated with the procedure and increases patient satisfaction.^{17,18} The results of this study align with those findings. Topical analgesics like lidocaine primarily pass through the skin surface by passive diffusion. The presence of ethanol in lidocaine enhances its absorption, as ethanol penetrates the skin more effectively.^{29,30} By targeting free nerve endings, lidocaine reversibly blocks nerve

conduction near the application site, causing a temporary loss of sensation in that area.³¹ Therefore, since lidocaine acts as a local anesthetic to cause a transient loss of sensation at the peripheral IV procedure site, it can be argued that patients experience lower levels of pain associated with the procedure.

In the literature review on benzocaine, few studies have utilized benzocaine as a pharmacological method during peripheral IV catheterization. This study introduced benzocaine spray as a new approach to peripheral intravenous catheterization and compared it with lidocaine and a control group. Intriguingly, the findings indicated that pain scores were lower in the benzocaine spray group compared to the lidocaine spray group, although this difference was not statistically significant. However, the pain scores in the benzocaine spray group were significantly lower and were accompanied by heightened satisfaction levels with the catheterization process compared to the placebo group. In contrast, Anderson et al.³² reported that benzocaine was not effective in reducing pain related to peripheral IV catheterization. This study suggests that the ineffectiveness of benzocaine may be due to burning or other discomfort during catheterization caused by the active substance in the spray. However, unlike the Anderson et al.³² study, this study involved cleaning the area with a routinely used alcohol swab after applying the benzocaine spray and just before IV catheterization. Therefore, the differing results may stem from the removal of the active substance in the spray from the application area and differences in application techniques. Since benzocaine spray, like lidocaine, causes a temporary loss of sensation, it was anticipated that the pain levels in patients following application would be lower than those in the control group. These results contribute to the existing literature by presenting benzocaine as a potentially effective alternative for peripheral intravenous catheterization, warranting further exploration and comparative analyses with lidocaine.

Patient satisfaction is a critical metric influencing the overall quality of healthcare services.³³ Notably, alleviating pain during peripheral IV catheterization plays a crucial role in enhancing patient satisfaction. This study observed a strong negative correlation between post-procedure VAS scores and PSFC scores within both the lidocaine and benzocaine spray groups. This finding suggests an association where, as pain perception decreases during peripheral IV catheterization, patient satisfaction with the catheterization process increases. These findings highlight the importance of prioritizing pain management strategies during medical procedures, such as peripheral IV catheterization, to positively impact patient satisfaction. Consequently, healthcare practitioners may consider incorporating topical anesthetics like lidocaine and benzocaine to reduce pain, thereby potentially enhancing patient experiences and satisfaction levels.

Limitations

There are some acknowledged limitations in this study that need to be considered. Firstly, the subjective assessment of pain and patient satisfaction levels is a potential limitation, as these evaluations depend on individual perceptions. Additionally, the scope of the study is confined by the number and types of independent variables under investigation. The completion of questionnaires by the responsible nurse introduces another limitation. Moreover, the study was conducted exclusively during the shifts of two specific nurses, who worked on different days, covering both day and night shifts. Although permission was secured for the nurses to collaborate during the same shifts, the reliance on a specific timeframe may limit the generalizability of the findings. Furthermore, the study focused exclusively on the adult population. Caution should be exercised when attempting to generalize the results beyond this demographic.

CONCLUSION

This study effectively demonstrated the efficacy of lidocaine spray and benzocaine spray in alleviating pain related to peripheral intravenous catheterization. A notable finding was the establishment of a robust negative correlation between patients' reported pain scores and their satisfaction levels with the catheterization process. The observed pattern indicated that as perceived pain diminished, there was a concurrent increase in patient satisfaction. In light of these findings, it is plausible to recommend the routine use of lidocaine and benzocaine sprays as a strategy to minimize pain associated with peripheral intravenous catheterization and concurrently enhance patient satisfaction.

Acknowledgements: The authors would like to thank all participants who participated in this study.

Ethics Committee Approval: The Erciyes University Clinical Research Ethics Committee granted approval for this study (date: 29.01.2020, number: 2020/59).

Author Contributions: Concept – AK, MB, SLC; Design – AK, MB, SLC, MBY; Supervision – AK, MB, SLC, MBY; Resource – AK, MB, SLC; Materials – AK, MB, SLC, MBY, ÖLA; Data Collection and/or Processing – AK, MB, SLC, ÖLA; Analysis and/or Interpretation – AK, MB, SLC; Literature Search – AK, MB, SLC; Writing – AK, MB, SLC; Critical Reviews – AK, MB, SLC, MBY, ÖLA.

Conflict of Interest: The authors have no conflict of interest to declare.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Use of AI for Writing Assistance: Not declared.

Financial Disclosure: Erciyes University scientific research project unit (project number: TDK-2020-10055) for their financial support.

Peer-review: Externally peer-reviewed.

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