Efficacy Of A Five-minute Application Of EMLA Cream For The Management Of Pain Associated With Intravenous Cannulation

M Smith, P Holder, K Leonard

Citation

Abstract
Intravenous cannulation is a distressing and painful procedure for patients. The purpose of this study was to determine the effect a 5-minute application of EMLA cream would have on a patient's pain perception of cannulation. This study compared pain perception between an experimental group who received EMLA cream and a control group who received a placebo. Subjects consisted of 40 males and females who underwent ophthalmic surgical procedures. There were 20 subjects in each group. Subjects in the experimental group were 14 years older. When pain was investigated, all patients reported some level of pain following cannulation. There was a significant difference between the two groups (p = .002). Our findings suggest that a 5 minute application of EMLA cream is adequate to decrease pain associated with intravenous cannulation. Further studies need to examine various intravenous cannula sizes and sites that could be used, as well as, different application times.

INTRODUCTION
More than 80% of patients in acute care and outpatient surgical settings receive some form of intravenous therapy. For many patients the mere mention of the need for insertion of an intravenous catheter invokes anxiety and dread. These emotions may become exaggerated at times, triggering a vasovagal reaction. This reaction can result in syncope, unresponsiveness, hypotension, and diaphoresis. These symptoms may lead to cardiovascular and neurological complications. Patient's anxieties and fears concerning needles are real and may even prevent them from seeking health care. The management of pain associated with intravenous cannulation must be a nursing priority.

Various strategies have been investigated that address the pain associated with intravenous cannula insertion. A topical preparation of local anesthetics that can be applied to intact skin is one such option. These preparations can be applied without discomfort, and they alleviate pain associated with intravenous cannulation. A major breakthrough in pharmaceutical research on topical anesthesia occurred with the discovery of Eutectic Mixture of Local Anesthetics (EMLA®; Astra Pharmaceuticals; Wayne, PA). Researchers found that EMLA® cream, a specific mixture of two local anesthetics (lidocaine & prilocaine), would provide effective and safe topical anesthesia. To be effective, the manufacturer recommended that EMLA® cream be applied to intact skin and covered with an occlusive dressing for at least 60 minutes prior to intravenous cannulation. A 60-minute application time is based on numerous studies conducted in Europe and the United States. Unfortunately, these studies did not address the feasibility of the recommended 60-minute application time and very few studies have investigated the potential effectiveness of a shorter timeframe. Direct patient admissions may need quick intravenous access for the administration of medications, rapid hydration, or immediate diagnostic tests and perhaps surgery. In addition, increased nurse-to-patient ratios require time efficient strategies for patient management. It may not be realistic to allow 60 minutes for the absorption of EMLA® cream. Effective pain management must consider the efficacy of proposed strategies as well as patient comfort and family concerns.

METHODOLOGY
This experimental study compared perceived levels of pain associated with intravenous cannulation between an experimental group who received a 5-minute application of EMLA® cream to a control group who received a 5-minute application of a placebo cream. After review and approval from the institutional review board the study was conducted in the pre-operative area of an outpatient surgical center in
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the Southeast. Subjects consisted of 40 patients who underwent ophthalmic surgery. Potential subjects were identified from the posted operating room schedule. Patient charts were then reviewed to determine study eligibility. Patients needing emergency surgical procedures or with a known history of sensitivity to local anesthetics of the amide type or to any other component of the product were excluded from the study. The administration of several different pre-op medications could perhaps influence the results of this study. In order to assure continuity in the study, patients who received any form of pre-op medication (narcotics or benzodiazapines) were not included in this study. Due to the greater risk of developing methemoglobinemia associated when taking certain classification of drugs, patients currently taking sulfonamides, nitroglycerin, and phenytoin were also excluded from the study.

All patients meeting study criteria were invited to participate and given a letter, which contained a detailed description of the study. Patients voluntarily agreeing to participate in the study signed a consent form. Each patient selected a piece of paper containing the letters “EMLA®” or the word “Placebo”, identifying assignment to either the experimental or control group. All subjects had a tourniquet applied to the forearm, and an appropriate vein for cannulation was identified on the dorsum of the hand. Following vein identification and tourniquet removal, the experimental group had a 2.5 GM dose of EMLA® cream applied and covered with an occlusive dressing. The control group had an equal amount of hypoallergenic hand cream applied and covered with an occlusive dressing. Following a 5-minute application time for both groups, the tourniquet was then reapplied, the occlusive dressing removed, and the cream removed with a dry sterile 4 x 4 gauze. The area was prepped with an isopropyl alcohol swab and allowed to dry. A 20-gauge over-the-needle intravenous catheter was inserted into the selected vein using an “indirect” intravenous insertion technique. Upon completion of intravenous cannulation, a transparent semi-permeable dressing was applied to secure the cannula and intravenous fluids initiated to maintain vascular patency. Promptly, the post-test was administered which included a selected pain measurement scale (Verbal Numerical Scale) with simple instructions.

The Verbal Numerical Scale (VNS) consisted of a 10-point scale used to report the level of pain perception. Adjectives were anchored at each end of the scale (0 = no pain. 10 = worst pain imaginable) and subjects were asked to describe their perceived pain on a scale of 0-10. Verbal responses eliminated the need for subjects to write or otherwise move their hand and potentially elicit discomfort from manipulation. Categorical scales, numerical scales and visual analog scales (VAS) are commonly used to quantify the intensity of a painful experience. The horizontal scale is considered by some to be the best scale for research purposes. However, some patients, especially the elderly, may lack the certain amount of visual and motor coordination for the VAS. Nevertheless, correlations among categorical, numerical, and visual analog scales are generally high (r > .80). Therefore, any of these scales would be appropriate for research and the VNS was utilized for this study.

RESULTS

The sample consisted of 40 patients undergoing outpatient ophthalmic surgery. The majority (60%) was male. Of the 20 patients in the experimental group, males predominated (70%). Of the 20 patients in the control group, there was an equal division of males and females. Mean age for the total sample was 50 years (SD = 19.34). Mean age for males was 52 years. The mean age for females was five years younger than males. Subjects in the experimental group were 14 years older than those in the control group. The majority of subjects in both groups were Caucasian. See Tables 1 and 2.

Table 1: Frequencies According to Gender, ASA Classification and Ethnicity

<table>
<thead>
<tr>
<th>Variable</th>
<th>Experimental</th>
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<tbody>
<tr>
<td>Gender</td>
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<td></td>
</tr>
<tr>
<td>Male</td>
<td>14, 70</td>
<td>10, 50</td>
</tr>
<tr>
<td>Female</td>
<td>6, 30</td>
<td>10, 50</td>
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<tr>
<td>ASA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>3, 15</td>
<td>9, 45</td>
</tr>
<tr>
<td>II</td>
<td>13, 65</td>
<td>9, 45</td>
</tr>
<tr>
<td>III</td>
<td>4, 20</td>
<td>2, 10</td>
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<tr>
<td>Ethnicity</td>
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<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>17, 85</td>
<td>12, 60</td>
</tr>
<tr>
<td>African American</td>
<td>3, 15</td>
<td>8, 40</td>
</tr>
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</table>
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Figure 2
Table 2: Descriptives for Age

<table>
<thead>
<tr>
<th>Variable</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
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<tbody>
<tr>
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<tr>
<td>Experimental</td>
<td>24</td>
<td>91</td>
<td>57.35</td>
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<tr>
<td>Control</td>
<td>21</td>
<td>73</td>
<td>43.39</td>
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<tr>
<td>Gender</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Male</td>
<td>24</td>
<td>86</td>
<td>52.63</td>
<td>20.58</td>
</tr>
<tr>
<td>Female</td>
<td>21</td>
<td>91</td>
<td>46.75</td>
<td>17.33</td>
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<tr>
<td>Ethnicity</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>24</td>
<td>91</td>
<td>53.17</td>
<td>20.28</td>
</tr>
<tr>
<td>African American</td>
<td>21</td>
<td>69</td>
<td>42.64</td>
<td>15.07</td>
</tr>
<tr>
<td>Pain Score</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Sample</td>
<td>0</td>
<td>8</td>
<td>4.28</td>
<td>2.17</td>
</tr>
<tr>
<td>Male</td>
<td>0</td>
<td>8</td>
<td>4.08</td>
<td>2.26</td>
</tr>
<tr>
<td>Female</td>
<td>1</td>
<td>8</td>
<td>4.56</td>
<td>2.06</td>
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</table>

Note: Age reported in years.

Twenty patients received EMLA® cream for five minutes prior to intravenous cannulation. Following cannulation each of the 20 patients reported perceived pain on a scale of 0 - 10. A lower pain score was equated with successful pain reduction. The majority (N=16) of patients that received EMLA® cream reported a pain score between 0 and 4 (0=1,1=3,2=3,3=5,4=4). Only four patients reported pain scores of 5-8 (5=2,7=1,8=1). Only two patients, both Caucasian males ages 26 and 72, reported a pain score of 8 and 7 respectively meaning their perceived pain was moderate to severe (see Table 3).

Figure 3
Table 3: Mode for Perceived Pain Scores for Subjects Receiving EMLA® Cream

<table>
<thead>
<tr>
<th>Gender</th>
<th>Pain Score With EMLA®</th>
<th>Pain Score Without EMLA®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>1, 3, 4</td>
<td>5</td>
</tr>
<tr>
<td>Female</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>3, 5, 6</td>
<td>7</td>
</tr>
<tr>
<td>African American</td>
<td>2, 4</td>
<td>5, 6</td>
</tr>
</tbody>
</table>

Note: For pain scale 0 = no pain, 10 = worst pain imaginable

Twenty patients received placebo cream for five minutes prior to intravenous cannulation. Following cannulation each of the 20 patients reported perceived pain on a scale of 0 - 10. All patients reported some level of pain in this group. Five patients reported pain scores of 1-4 (1=1,2=1,3=2,4=1). Fifteen patients reported pain scores of 5-8 (5=4,6=5,7=5,8=1) (see Table 3).

Based on the literature review of previous research, a decision was made to investigate the difference of perceived pain between the group of patients that received EMLA® cream and the group of patients that received placebo cream. A t-test for independent samples was used to identify differences in the level of perceived pain associated with intravenous cannulation between the experimental (EMLA®) group and the control (placebo) group. T-test results revealed a significant difference between the two groups (t-value = -3.35, p = .002).

Further data analyses were done to determine if a difference in perceived pain existed between the experimental and control groups based on gender, ethnicity and age. T-test results revealed no difference between the groups for gender (t-value -.68, p = .501) nor ethnicity (t-value -.64, p = .524). One-way Analysis of Variance (ANOVA) was used to determine if any difference existed between the groups based on age. Age was considered a continuous variable and analyzed by grouped distribution. Subjects were grouped into 3 categories based on their age (young, middle aged and elderly). Findings revealed that no significant difference existed between the groups based on age (f = 1.180, p =.319).

Our findings suggested that a 5-minute application time for EMLA cream was adequate to reduce pain associated with intravenous cannulation in adults. Gender, ethnicity nor age affected the level of pain reported associated with intravenous cannulation. However, the study was limited by its small sample size.

DISCUSSION OF FINDINGS IN RELATIONSHIP TO PREVIOUS RESEARCH

The results of this study support the research done by Nott and Peacock, who examined the effectiveness of skin anesthesia at the antecubital site after a 5-minute application of EMLA® cream. The authors determined that reported pain, associated with intravenous cannulation, was significantly less after only five minutes of EMLA® cream.

The results of this study also support the findings of Ehrenstrom-Reiz, Reiz and Stockman, who evaluated the minimal effective onset time of EMLA® cream required to decrease intravenous cannulation pain in adults. Their study was one of the first studies evaluating the effectiveness of EMLA® cream with shorter application times. The authors also found a significant difference in pain scores between those that received EMLA® cream to the dorsum of the hand prior to intravenous cannulation and those that received placebo cream.

Smith, Eggars and Stacey did not support the research results...
of this study. They evaluated 15 and 60-minute applications of ibuprofen, placebo and EMLA® cream. The results of 100 mm Visual Analogue scores for pain post intravenous cannulation demonstrated no significant difference between the three creams when compared at 15 minutes. However, their study did suffer from a small sample size (n=10). Yamamoto and Boychuk also found no benefit of EMLA compared to placebo. They evaluated a 20-minute application in 40 subjects. Their study utilized a randomized, placebo controlled, paired trial method where the subject had both hands cannulated. Each subject was asked to identify the more painful hand using a 10 cm VAS.

There were several studies that demonstrated the superiority of EMLA® cream over other topical agents in providing safe and effective skin anesthesia. Gunawardens and Davenport proved EMLA® cream to be far more superior than glycerol trinitrate ointment in decreasing intravenous cannulation pain. A study by Lander, Nazarali, Hoggins, et al., evaluated the effectiveness of a 5% lidocaine cream compared to EMLA® cream. Findings from their study revealed significantly more pain reported with 5% lidocaine than with EMLA® cream. Marble found that phlebotomy pain scores were significantly lower in the EMLA group on the VAS. The difference was greatest when the interval between application and phlebotomy exceeded 60 minutes.

The available literature related to age and pain was conflicting; and most was not consistent with the findings of this study. The results of this study revealed no significant difference in reported pain based on age. Collins and Stone reported a negative correlation between age and both pain threshold and pain tolerance. The younger the individual adult, the better their pain tolerance. Sherman and Robillard measured and compared pain sensitivity in 200 normal subjects, age ranging from 20 to 97 years. Pain sensitivity was measured after applying cutaneous heat radiation. Their results concluded that there was a 20% increase in pain threshold in the older group. The results of this study supported the research done by Sherman, as cited in Hardy, Wolff, and Goodell, who demonstrated that age was not a factor, which would produce changes in pain threshold.

The results of this study were not consistent with most of the available literature related to pain and gender. This study revealed no significant difference with respect to gender in relation to intravenous cannulation pain. This study does not support the research of Woodrow, Friedman, Siegelaub, et al., that measured deep pain by applying mechanical pressure on the Achilles tendon in 41,229 subjects. They found that males were able to tolerate more pain than females. The findings of this research also conflicted with the findings of Feine, Bushnell, Miron, et al. who compared pain perception responses to 120 noxious heat stimuli of varying magnitude. They determined that women reported higher pain scores. Furthermore, results of this study are not supported by a study conducted by Levine and De Simone who investigated the effect of experimenter gender on the report of pain of male and female subjects. This study revealed no significant difference in reported pain between males and females.

The available research related to ethnicity and pain are not consistent with the findings of this study. Research findings for this study revealed no significant difference in pain perception based on ethnicity. The results of this study are not supported by Hymes and Spraker who determined a significant difference in pain scores and density of cutaneous block between African-Americans and Caucasians.

**IMPLICATIONS**

Health care is facing dramatic changes. Nursing personnel are often first in direct patient contact when an individual enters the health care setting. Many times going the extra mile by implementing treatments that provide patient comfort and allay anxiety will make the difference in patient satisfaction.

The nurse is responsible for developing a plan of care and individualizing that plan of care based on the patient’s needs. It is important for the nurse to be knowledgeable regarding methods and techniques for the initiation of intravenous therapy. Patients who are extremely apprehensive about intravenous cannulation need reassurance of pain reduction and relief. The use of EMLA® cream can reduce pain and should be included as part of a standard intravenous initiation protocol.

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