An Evidence-Based Practice Review of EMLA Compared with ELA-Max for Pain Reduction in Pediatric IV Insertion

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Abstract

The Evidence Based Practice (EBP) team created the following PICO: "In pediatric patients getting an IV inserted, how does EMLA-cream compared to ELA-max affect pain reduction?" and selected the best research evidence to review. The team synthesized the evidence finding numerous similarities indicating no statistical significance in the suppression of pain between ELA-Max and EMLA-cream. While the team found no statistical significance, several noteworthy clinical differences were determined such as cost, time, clinical expertise, and patient preferences. These results are utilized to recommend organizational policies that promote the use of ELA-Max over EMLA-cream in intravenous insertion in pediatric populations.

Intravenous (IV) insertion in pediatrics is a common procedure completed in both inpatient and outpatient settings. The perceived sensation of pain is often associated with IV cannulation among the pediatric population. The current standard for treatment of pain in multiple procedures, including IV cannulation, is the topical anesthetic, EMLA cream (eutectic mixture of local anesthetics) (Kleiber, Sorenson, Whiteside, Gronstal, & Tannous, 2002). However, with the introduction of ELA-Max (a 4% lidocaine topical anesthetic), questions are raised as to which anesthetic is more effective in suppressing pain. With this question in mind, the evidence-based practice (EBP) team developed a PICO or EBP question. A PICO addresses the key aspects of clinical questions, with P standing for patient population, I for intervention, C for comparison intervention, and O for outcome desired. The PICO for this project is as follows: "In pediatric patients getting an IV inserted, how does EMLA cream compared to ELA-max affect pain reduction?"

Nursing Patient Care Problem

One of the most distressing and painful procedures for children is needle insertion as evidenced by the following data: out of 17 categories of sources of pain in a sample of 297 pediatric subjects, intravenous procedures were rated the second highest for the worst pain (Cummings, Reid, Finley, & McGrath, & Ritchie, 1996). One prevalent painful event for the pediatric population is IV insertion, which is experienced by the majority of inpatients within the pediatric population (Blount, Piira, Cohen, & Cheng, 2006). Children perceive pain as a multidimensional experience, which if not addressed can have longstanding biopsychosocial effects. Nurses are crucial in managing patient pain, therefore they must be able to assess a child's pain and employ applicable strategies to alleviate it in the clinical setting (O'Regan,Wills, & O'Leary, 2010). Also, nurses ensure the initiation of adequate pain relief measures and follow-up with an evaluation of their effectiveness. The nursing patient care problem is within the pediatric population and the pain they experience during IV insertion. The current standard for dealing with IV insertion pain in the pediatric population is the administration of a topical anesthetic, such as EMLA cream. More recently, ELA-Max has been used as a substitute for EMLA cream during common epithelial procedures. The EBP team's goal was to determine which topical anesthetic was more effective in suppressing pain in pediatric patients during IV cannulation.

Selection of Evidence

The research analysis team corresponded with Susan Thomas, an IUSB librarian, to locate the best evidence-based research articles on the PICO. Selected databases were Ebscohost, CINAHL, Cochrane Library, and PubMed. Search terms used were EMLA, ELA-Max, IV insertion, IV cannulation, venipuncture, peripheral catheterization, pediatrics, pain, discomfort, Lidocaine, Prilocaine, and anesthetic. Five pieces of evidence that address the PICO were chosen to be analyzed: Eichenfield, Funk, Fallon-Friedlander, & Cunningham, 2002; Friedman et al., 1999; Kleiber et al., 2002; Koh et al., 2004; and Tang, Goon, & Goh, 2004.

According to the Critical Appraisal of Evidence, which describes the seven levels within the hierarchy of evidence, level I evidence would be the best evidence for an intervention PICO because it is a systematic review of randomized controlled trials (Fineout-Overholt, Mazurek, Melnyk, Stillwell, & Williamson, 2010). Due to the lack of level I evidence addressing the team's PICO, three level II articles (individual randomized controlled trials) were chosen, which directly focused on the team's clinical issue. The team also used two level IV research articles (case-control and cohort studies) due to the fact that at that time, no prior studies had been conducted. Friedman et al. (1999) and Tang et al. (2004) are both level IV evidence having no studies done prior to these, while Eichenfield et al. (2002), Kleiber et al. (2002), and Koh et al. (2004) are Level II evidence.

Analysis and Critique of Evidence

Theoretical/Conceptual Framework

The theoretical/conceptual framework across all studies is medical/physiologically based with an emphasis on patient comfort. It is known that the transmission of pain from the periphery to the Central Nervous System (CNS) can be blocked using lidocaine anesthetics, which include EMLA and ELA-Max. Transmission is the movement of the action potential from the site of injury towards the CNS for processing. Local anesthetics work as membrane-stabilizers to block the projection along nociceptor fibers to the CNS (Lewis, Dirksen, Heitkemper, & Bucher, 2014).

The variables or concepts used in the Tang et al. (2004) study were ELA-Max and EMLA creams and their ability to raise the pain threshold induced by warmth and heat. In the Friedman et al. (1999) study, the researchers used four anesthetics for the suppression of pain stimuli resulting from the use of a dermatologic laser. Koh et al. (2004) and Kleiber et al. (2002) tested the efficacy of EMLA cream and ELA-Max during IV cannulation, while Eichenfield et al. (2002) tested their efficacy using venipuncture.

Design

All five evidence-based research articles are quantitative in design. Tang et al. (2004) and Friedman et al. (1999) are both comparative studies and quasi-experimental; Eichenfield et al. (2002) is a double-randomized blinded crossover trial; Kleiber et al. (2002) and Koh et al. (2004) are both Randomized Controlled Trials (RCTs).

Sample

Two of the studies analyzed had significantly small sample sizes for their research. Tang et al. (2004) had a sample size of 11 and Friedman et al. (1999) had a sample size of 12. In the Tang et al. study, there were 11 subjects total: five women and six men, with a mean age of 41 years. There were exclusions from this study that included pregnant and nursing females, subjects under the age of 21 years old, and known allergies to any form of topical anesthetics. There was also no mention of how the researchers obtained the subjects for this

study. In the Friedman et al. (1999) study, there were 12 subjects total: five women and seven men, with a mean age of 35 years old. These 12 individuals were noted as volunteers and had given informed consent, but there was no mention of how the subjects were chosen. There were exclusions from this study that included history of allergies to anesthetics, respiratory or cardiac disease, seizure disorders or neuropathy, pregnancy, and subjects being under the age of 18 years old. Of the 12 subjects, only nine returned for the two additional sessions that were two weeks apart from one another.

In the Kleiber et al. (2002) study there was a total of 30 subjects with ages 7-12 years old. All 30 subjects in this study were Caucasian, English speaking, and in the appropriate grade for their age. In the Koh et al. (2004) study there were a total of 60 subjects, 33 males and 27 females, aged 8-17 years old. All subjects were in need of surgery, which was the determining factor that selected them for this study.

The Eichenfield et al. (2002) study used convenience sampling for the selection of their subjects. All subjects were doubly randomized to the treatment regimen and to the order that the topical anesthetics were applied before venipuncture. The subjects were scheduled for repeat venipuncture (for non-study-related reasons) at two sites. This study consisted of 120 children ranging from 3-15 years of age with a mean age of 7.9 years. Twenty children were in San Diego, CA and 100 children were in West Palm Beach, FL. All subjects were scheduled for at least two venipunctures for non-study-related reasons at two sites. Three patients were excluded from analysis because of incomplete data or serious protocol violation. There were exclusion criteria for this study, which included known allergies to ELA-Max or EMLA, the use of any analgesic or anxiolytic medications at the time of the study, and patients with concurrent severe skin disease. Parents or guardians had to be available to observe both venipunctures and had to be willing to complete the Observed Behavioral Distress scoring tool.

Method

The methods in all five articles reviewed were the same, in that they all applied topical anesthetics to the site before the painful stimuli was added in order to measure how well the anesthetics blocked the pain of the chosen stimuli. Variables such as which topical anesthetics were applied, how much anesthetic was applied, where the anesthetics were applied, and what created the painful stimuli differed across the studies. EMLA cream and ELA-Max were the two primary topical anesthetics applied across all studies, while in the Friedman et al. (1999) study, tetracaine and betacaine-LA were tested as well. Since the team's PICO was focused on differences between EMLA and ELA-Max all of these studies fit the criteria. The amount applied in most studies was 2.5 g of EMLA and ELA-Max, except in Tang et al. (2003) where an unstated, but equal amount of both were applied, and Friedman et al. (1999), where 0.3 mL of each anesthetic was applied. Where the anesthetics and painful stimuli were applied varied among the studies with Tang et al. (2003) and Friedman et al. (1999) using the subjects' volar forearms: Koh et al. (2004) and Klieber et al. (2002) using the subjects' posterior hands, and Eichenfield et al. (2002) not specifically stating the area used. Again this corresponds well with the team's PICO because the hands, antecubital fossae, or lower forearms are common areas used for intravenous insertion in the pediatric population. In Tang et al. (2004) they used a blunt-tipped thermosensory analyzer to apply the painful stimuli. Friedman et al. (1999) used a Q-switched Nd:YAG laser to achieve their painful stimuli and Eichenfield et al. (2002) used venipuncture. Klieber et al. (2002) and Koh et al. (2004) both used intravenous insertion to create their painful stimuli, with the last two coinciding perfectly with the team's PICO statement.

Findings

The findings across all studies indicated no statistically significant difference between EMLA and ELA-Max in the suppression of pain. However, there are a few differences that the researchers stated in their findings that may relate to clinical significance. Tang et al. (2004) found that there was no statistically significant difference between the two anesthetics, but EMLA cream was the superior anesthetic in raising the pain threshold of the subjects at 30 and 60 minutes after removal. Friedman et al. (1999) compared four anesthetics, including EMLA and ELA-Max, and found no statistically significant difference between them, but EMLA and ELA-Max were the superior anesthetics in the suppression of pain at both time intervals compared to the tetracaine gel and betacaine-LA ointment. Kleiber et al. (2002) concluded that neither anesthetic was completely effective for all children in relieving pain. The findings of Eichenfield et al. (2002) were that both ELA-Max and EMLA alleviated the pain from the venipuncture procedures. However, there was no clinically or statistically significant difference in the patients' VAS scores at the following times: 30 minute or 60 minute treatment group, 30 minute ELA-Max treatment without occlusion and 60 minute EMLA treatment with occlusion. There was also no clinical or statistical significant difference between ELA-Max and EMLA treatment in parental or blinded researcher Observed Behavioral Distress scores.

Limitations/Design Flaws

Limitations and design flaws within the Tang et al. (2004) study include: small sample size, uncertainty of how the sample was chosen, uncertainty of who collected the data for the study, subjectivity of pain, and heat application to the first arm caused the patient to anticipate pain on the second arm and thus terminate the treatment before the pain threshold was actually met. Within the Tang et al. (2004) study, there was no mention of reliability or validity of the research tools used, including no mention of the accuracy or precision of the analyzer for administering pain. Time was used in order to measure each subject's reaction time to thermal sensory pain induced by warmth and heat. They used the computerized thermal sensory analyzer to induce warmth and heat pain; subjects then pushed a button to stop the timer when they felt pain. The researchers then based the mean time on an average of four measurements (to make a mean of each individual separately): baseline (before application of cream), after removal of the cream, 30 minutes after the removal of the cream, and 60 minutes after the cream was removed.

Some limitations and design flaws within the Friedman et al. (1999) study are similar to those of Tang et al. (2004), which include the small sample size, uncertainty of how the researchers chose the sample or how the volunteers were chosen, uncertainty of who collected the data for the study, and that the pain sensations were all subjective. Another limitation was the confusing use of terms "placebo" and "control" throughout the article. The EBP team could not decipher whether there was a difference between these terms or if they were being used interchangeably throughout the article. There was no mention of reliability or validity of the research tools used. A major limitation to the study was that the researchers used an interval pain scale of 0 (no pain) to 4 (maximal pain), which is not a well-known or standard scale to use while assessing pain. It was not stated why they chose to use this scale within the article. The pain rating was assessed verbally before the procedure and then again 30 minutes after the 60 minute application period.

Design flaws and limitations within Eichenfield et al. (2002) include the researcher's statement of not comparing the product's efficacy at prolonged application times, the uncertainty of how time was measured in the study, and blinded staff rated difficulty of the venipuncture procedure as "easy," "difficult," or "very difficult" without defining the terms.

The Kleiber et al. (2002) study had several limitations as well. This study was performed in a non-clinical setting because these children were receiving needle insertion, which was not necessary for medical purposes. The children involved "volunteered" for this study and were paid $40 for their participation. The EBP team believes this raises a potential ethical issue if parents pushed their child to participate for the $40 being offered. Additionally, all subjects were Caucasian, which is not representative of the entire population of children.

Koh et al.'s (2004) limitations include inconsistent documentation of IV needle size and not controlling for IV sites. Also, the pre-operative environment is highly controlled, which may lack clinical application beyond the scope of the research. These limitations could have influenced the children's pain and anxiety ratings.

Synthesis of Evidence

The synthesis of evidence among the studies indicates that there is no statistically significant difference between EMLA and ELA-Max in the suppression of pain. The EBP team's PICO "In pediatric patients getting an IV inserted, how does EMLA cream compared to ELA-max affect pain reduction?" was addressed. It is important to note that two of the articles, Tang et al. (2004) and Friedman et al. (1999), were dermatological in nature using thermosensory procedures instead of needle insertion. Eichenfield et al. (2002) used venipuncture instead of IV insertion, unlike Koh et al. (2004) and Kleiber et al. (2002). Despite these differences in pain procedures the EBP team believes the research to be pertinent to the PICO.

All five studies analyzed have common findings that address the research analysis team's PICO. EMLA is not more effective compared to ELA-Max in regards to IV insertion in the pediatric population. Having reviewed the studies, the EBP team concludes that there were no major differences from one study to the next.

Application of Findings

There is no practice change recommended by the reviewed evidence in reference to relief of pain with IV insertion performed on children. However, the EBP team believes it would be beneficial to incorporate the use of ELA Max more so than EMLA cream in a clinical setting due to the difference of application time. ELA-Max significantly reduces the time for application from the recommended and tested 60 minutes for EMLA cream down to 30 minutes. Also, ELA-Max does not need an occlusive dressing, which could be a cost-saving measure. ELA-Max is also non-prescription, while EMLA cream requires a prescription. The setting for practice change would be in any non-emergent setting where a child would be getting an IV inserted, whether inpatient or outpatient.

A possible policy change would be for parents to apply over-the counter ELA-Max 30 minutes prior to appointment time in order to shorten waiting time for patients and families. Along with home-application of this medication, the policy would also include providing education about possible adverse reactions due to the application of ELA-Max. A possible procedure change could be utilizing less expensive materials with this procedure, such as a cotton ball and tape instead of using a more expensive occlusion dressing such as a Tegaderm. Policy-holders could also do an in-service for staff on differences between EMLA and ELA-Max and why they are changing procedures to ELA-Max within their establishment.

Under current practices, nurses exercising clinical judgment may find it more efficient to forego the use of topical anesthetics due to lengthy application times and time constraints. The nurse's clinical judgment and evaluation might affect the implementation of the practice change by being more likely to use ELA-Max due to its 30 minute application time compared with the 60 minute application time of EMLA cream. Due to the shorter application time,

this practice change could increase the overall use of topical anesthetics before IV insertion in children.

Some patient preferences or concerns that may impact implementation of this practice change may include the parent's not wanting any anesthetic applied to their child's skin before a procedure such as IV insertion, the parents not wanting to apply the cream themselves before their appointment, or parents who do want to cut back on their waiting time so they will apply the anesthetic before their appointment time.

Conclusion

Beginning their search with an intervention PICO of "In pediatric patients getting an IV inserted, how does EMLA cream compared to ELA-max affect pain reduction?" the EBP team conducted a thorough critique and review of five evidence-based research articles that were directly applicable. While there were numerous differences among the studies, there were enough similarities confirming no statistical significance between the two topical anesthetics. The research analysis team concluded that while all five studies revealed there was no statistical significance between the pain reduction efficacies of EMLA cream and ELA-Max topical anesthetics, there was enough evidence to warrant the creation of new clinical practice policies to promote the use of ELA-Max over EMLA cream when IV insertion is necessary in non-emergent, inpatient and outpatient settings among pediatric patients.

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