

A Comparison of Buffered Lidocaine Versus ELA-Max Before Peripheral Intravenous Catheter Insertions in Children

Janet Luhmann, MD*; Sarah Hurt, CCLS‡; Mario Shootman, PhD§; and Robert Kennedy, MD*

ABSTRACT. *Background.* Peripheral intravenous catheter (PIV) insertion is a common, painful experience for many children in the pediatric emergency department. Although local anesthetics such as injected buffered lidocaine have been shown to be effective at reducing pain and anxiety associated with PIV insertion, they are not routinely used. ELA-Max, a topical local anesthetic, has the advantage of needle-free administration but has not been compared with buffered lidocaine for PIV insertion.

Objective. To compare the reduction of pain and anxiety during PIV insertion provided by subcutaneous buffered 1% lidocaine or topical ELA-Max in children.

Methods. A randomized trial in children 4 to 17 years old undergoing PIV insertion with 22-gauge catheters was conducted. Children received either buffered lidocaine or ELA-Max. Buffered lidocaine was administered by using 30-gauge needles to inject 0.1 to 0.2 mL subcutaneously just before PIV insertion. ELA-Max was applied to the skin and occluded with Tegaderm 30 minutes before PIV insertion. Self-reported Visual Analog Scale (VAS) questionnaires (rating on a scale of 1–10; 1 = no pain, anxiety) were completed by patients and their parents before PIV insertion to assess baseline perceptions about pain and anxiety associated with PIV insertion and immediately after PIV insertion to assess pain and anxiety associated with the experience. After PIV insertion, the nurse who inserted the PIV also completed a VAS questionnaire assessing technical difficulty and satisfaction with the local anesthesia. A blinded observer also completed a VAS questionnaire to assess pain and anxiety associated with the PIV insertion. Data were analyzed by using χ^2 and *t* tests.

Results. Sixty-nine subjects were enrolled, and questionnaires were completed by all (mean age: 12.1 \pm 4.5 years; 61% female). There were no differences for buffered lidocaine and ELA-Max groups in age, gender, race, prior IV experience, or baseline pain and anxiety. There were no significant differences between buffered lidocaine and ELA-Max in mean pain and anxiety after PIV insertion by patient, parent, and blinded observer ratings. Nurse ratings of technical difficulty, number of PIV-insertion attempts, and satisfaction with local anesthesia also were not significantly different for buffered lidocaine and ELA-Max groups.

Conclusions. ELA-Max provided similar pain and anxiety reduction during PIV insertion in children compared with injected buffered lidocaine. Technical difficulty and satisfaction by nurses inserting the PIV also were similar. *Pediatrics* 2004;113:e217–e220. URL: <http://www.pediatrics.org/cgi/content/full/113/3/e217>; *ELA-Max, buffered lidocaine, IV insertion.*

ABBREVIATIONS. PIV, peripheral intravenous catheter; IV, intravenous catheter; VAS, Visual Analog Scales.

Peripheral intravenous catheter (PIV) insertion is commonplace and an unpleasant experience in hospitalized children. Furthermore, it has been reported that needle insertion is the most frightening medical procedure in hospitalized children.¹ However, advances in analgesic regimens such as the use of topical and buffered injected anesthetics can make IV insertions almost painless.

Buffered lidocaine is a local anesthetic that is comprised of 1 part sodium bicarbonate with 10 parts of 1% lidocaine. The pain associated with anesthetic infiltration is reduced by buffering the pH to 7.0 to 7.4.^{2–4} We have reported previously that buffered lidocaine significantly reduces distress associated with PIV insertion in children.⁵

ELA-Max is a 4% lidocaine cream that features a liposomal delivery system and is administered topically. It has been shown to effectively reduce pain associated with venipuncture in children.^{6,7}

Although buffered lidocaine and ELA-Max have been demonstrated to reduce distress associated with needle insertions, we have found no study comparing the use of these 2 agents. The purpose of this study was to compare reduction of pain and anxiety during PIV insertion provided by subcutaneous buffered lidocaine or topical ELA-Max. Our secondary goal was to compare the effect of these regimens on technical difficulty associated with inserting PIVs.

METHODS

Participants

The pediatric emergency department at St Louis Children's Hospital (St Louis, MO), an urban, university-affiliated hospital, was the setting for the study. A convenience sample of children 4 to 17 years old requiring PIV insertion participated in the study. A convenience sample was used because of the variable hours that a child life specialist was available to provide services. Children were excluded if there was a history of an allergy to local anesthetics or they received analgesics before IV insertion. Informed consent was obtained, and the study was approved by the Human

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TABLE 1. Prior Experience With IV Insertion

	With Prior IV	
	<i>n</i>	%
Buffered lidocaine (<i>n</i> = 33)	15	49
ELA-Max (<i>n</i> = 35)	17	51

P = .80. Note that data are missing from 1 questionnaire.

Studies Committee at Washington University School of Medicine (St Louis, MO).

Design

A randomized, controlled trial was conducted. Children were randomized to receive buffered lidocaine or ELA-Max before IV insertion. The randomization sequence was performed by using a random number generator, assigned in blocks of 10, and maintained in sealed envelopes until consent had been obtained. Children randomized to receive buffered lidocaine had this administered with a 30-gauge needle to subcutaneously inject 0.1 to 0.2 mL 5 minutes before IV insertion. Children randomized to receive ELA-Max had 2.5 g applied to the skin and covered with an occlusive dressing (Tegaderm) overlying the IV site 30 minutes before IV insertion.

All children received similar preparation and distraction techniques by the same child life specialist. The emergency department nurse responsible for inserting the IV selected either the dorsum of the hand or the antecubital fossa for the IV site. All IV attempts were made with a 22-gauge catheter by an emergency department nurse, and all measurements were made after the first IV attempt.

Blinding was accomplished by using a trained, non-health care worker to observe each IV insertion. One of 2 individuals fulfilled this role and was blinded to study purpose and design. The observer was escorted into the treatment room just before IV insertion and after evidence of the type of local anesthesia had been eliminated. Observers were queried about their knowledge of study purpose and design at the completion of the study. Both observers incorrectly responded that the purpose of the study was to evaluate different types of IV catheters, indicating that they were truly blinded to study purpose.

Measures

Our outcome measures were Visual Analog Scales (VAS). Ten-point VAS, ranging from 1 to 10, were used; higher scores indicate greater pain, anxiety, satisfaction, or technical difficulty. Self-reported VAS questionnaires were completed by both the child and parent before the IV insertion to assess baseline perceptions about current level of pain, anxiety, and anticipated pain associated with IV insertion. VAS questionnaires were completed again by both the child and parent immediately after each IV insertion to assess pain and anxiety associated with it. Self-reported pain by the child was the primary outcome measure.

In addition, VAS questionnaires were completed by the nurse inserting the IV to assess technical difficulty and satisfaction. Nurses also reported the number of attempts required to insert the

IV in each child. The blinded observer completed a VAS questionnaire to assess pain and anxiety of the child during IV insertion and perceived technical difficulty of the procedure. *P* values of <0.05 were considered to be statistically significant.

Statistical Methods

To achieve a power of 0.80 and a significance level of .05, a sample size of 34 per group or a total of 68 patients was needed to detect a difference of 1 point on the 10-point VAS. The data were analyzed by using χ^2 tests for categorical data and *t* tests for continuous data.

RESULTS

A convenience sample of 69 subjects with 35 randomized to receive buffered lidocaine and 34 randomized to receive ELA-Max were enrolled from September 2001 to July 2002. The mean age was 12.1 ± 4.5 years (range: 4.3–20.3 years), including 61% females and 51% African Americans. Fifty-three percent of children reported no prior IV-insertion experience (Table 1). Groups were similar in demographic data, prior experience with IV insertion, baseline pain and anxiety, and anticipated pain.

IVs were inserted in the hand in 60% of the children, the antecubital fossa in 39%, and the foot in 1 patient. Nurses successfully inserted the IV on the first attempt in 77% of the patients. There were no statistical differences between buffered lidocaine and ELA-Max groups in number or location of IV attempts.

Although there were no group differences before local anesthesia, most children anticipated pain associated with the upcoming IV insertion, with a mean rating of 6.8 (Fig 1).

There were no statistically significant differences in mean pain ratings between buffered lidocaine and ELA-Max during IV insertion reported by children (buffered lidocaine: 3.4 ± 2.9 ; ELA-Max: 2.6 ± 2.5 ; *P* = .19), parents (buffered lidocaine: 3.3 ± 2.5 ; ELA-Max: 2.5 ± 2.2 ; *P* = .17), and blinded observer (buffered lidocaine: 2.0 ± 1.4 ; ELA-Max: 2.5 ± 1.8 ; *P* = .2) (Fig 2). There were also no statistically significant differences in anxiety during IV insertion between buffered lidocaine and ELA-Max groups reported by children (buffered lidocaine: 2.9 ± 3.2 ; ELA-Max: 2.0 ± 2.0 ; *P* = .18), parents (buffered lidocaine: 2.6 ± 2.7 ; ELA-Max: 2.2 ± 2.0 ; *P* = .50), and blinded observer (buffered lidocaine: 3.3 ± 2.5 ; ELA-Max: 3.3 ± 2.5 ; *P* = .96) (Fig 3). There were no statistically sig-

Fig 1. Anticipated pain for upcoming IV.

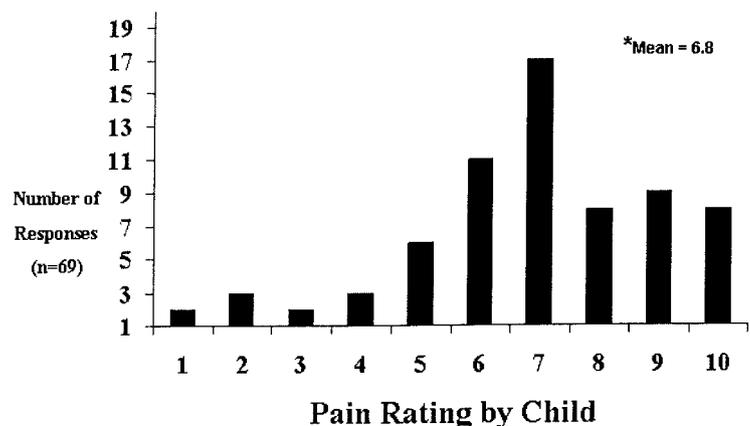


Fig 2. Pain during IV insertion.

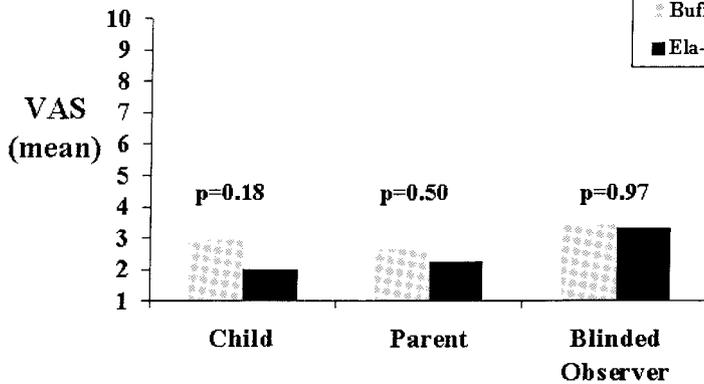
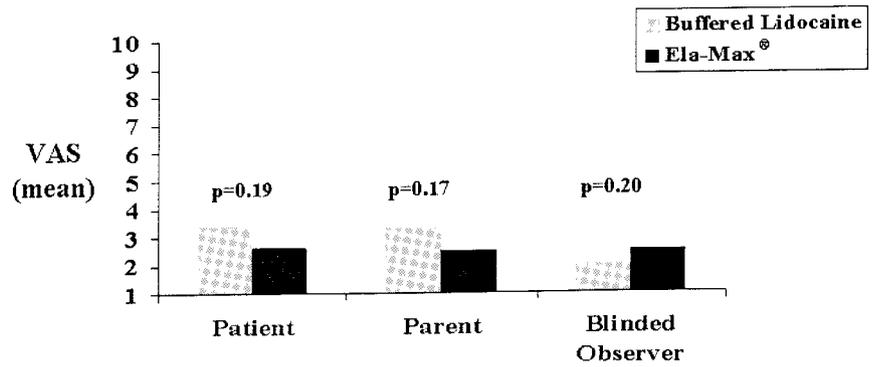


Fig 3. Anxiety during IV insertion.

nificant differences between buffered lidocaine and ELA-Max groups in technical difficulty of (buffered lidocaine: 2.6 ± 2.3 ; ELA-Max: 2.6 ± 2.4 ; $P = 1.0$) and overall satisfaction with (buffered lidocaine: 8.0 ± 3.0 ; ELA-Max: 8.8 ± 2.1 ; $P = .19$) the procedure per nursing self-report (Fig 4). Scores for each question ranged from 1 to 10.

DISCUSSION

Venipuncture is one of the most anxiety-producing events children encounter in the setting of a hospital or physician's office.⁸ Our results confirm that children anticipate significant pain before IV insertion. Therefore, measures to reduce pain and anxiety associated with IV insertion should be considered in all children.

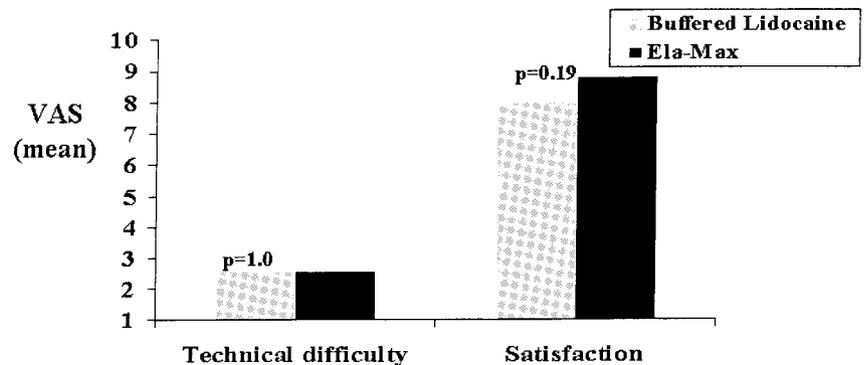
Subcutaneous injections of buffered lidocaine before IV insertion can make this procedure painless. Although we frequently use this method, there are some barriers that prevent more universal use. Because this method relies on subcutaneous injection,

many perceive the procedure to involve an "extra stick." Our experience suggests using a 30-gauge needle, injecting into the subcutaneous region, and injecting the lidocaine quickly, which usually results in painless delivery. Ineffective administration may result in pain both during local anesthesia administration and IV insertion.

ELA-Max is a 4% liposomal lidocaine cream that is available over the counter. The liposomal delivery system enhances penetration and increases the concentration and residence time of the drug in the dermis and epidermis.⁹ A 30-minute application of ELA-Max has been demonstrated to be as effective for reducing pain associated with venipuncture in children as a 60-minute application of eutectic mixture of local anesthetics.⁶ In addition, ELA-Max has been shown to produce less vasoconstriction and result in a lower serum lidocaine level.^{9,10}

Package labeling for ELA-Max does not state that an occlusive dressing should be used. To help keep the cream in place, we chose to use a Tegaderm

Fig 4. Nurse assessment of technical difficulty and satisfaction associated with IV insertion.



occlusive dressing. Interestingly, many of the children who received ELA-Max and rated overall procedure pain as high, described the pain as being associated with removal of the occlusive dressing and not with the IV insertion. Additional research is needed to evaluate the use of an occlusive dressing when applying ELA-Max on children.

The prevention of pain during medical procedures is essential. Children should have the opportunity to have a local anesthetic applied before IV insertion. ELA-Max topically applied 30 minutes before IV insertion is as effective as injected buffered lidocaine in reducing pain. Providing health care workers with options for local anesthesia may improve acceptance of this practice.

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