Efficacy of Parental Application of Eutectic Mixture of Local Anesthetics for Intravenous Insertion

Jeffrey L. Koh, MD*‡; Debra Fanurik, Ph.D*‡; JoAnne Stoner, MD*; Michael L. Schmitz, MD*‡; and Maryelle VonLanthen, MD‡

ABSTRACT. *Objective.* **To demonstrate that parent application of eutectic mixture of local anesthetics (EMLA) results in equal reduction of the pain of intravenous (IV) placement compared with clinician application of EMLA, and to assess potential difficulties with parental application.**

Study Design. **A 2 × 2 randomized block design was used, with 41 children divided into two age groups (5–12 years vs 13–18 years) and randomized to one of two experimental groups (parent-applied EMLA vs clinician-applied EMLA).**

Methods. **All children were scheduled to have outpatient gastrointestinal endoscopies with IV sedation. EMLA was placed at least 60 minutes before IV insertion either by the parent or a clinician, depending on the experimental group assignment. Outcome measures were child pain ratings and observed behavioral distress ratings. Parents and children were interviewed to determine parent and child anxiety levels in anticipation of the IV insertion, previous needle stick experience, and previous difficulty coping. Feasibility outcomes included technical difficulty with application of EMLA and appearance of the EMLA cream and occlusive covering.**

Results. **Pain ratings and behavioral distress ratings were generally in the low to moderate range for all groups and were consistent with previous empiric reports of EMLA outcome. There were no significant differences in pain or distress ratings for either the age or the experimental groups. Parent ratings of their child's previous difficulty coping was related to the level of behavioral distress exhibited before ($r = .50$), during ($r = .32$) and after ($r = .44$) the IV insertion. In addition, children's anxiety ratings about IV insertion seemed to differ among groups (although not statistically significant for post hoc comparisons), with the most anxiety reported by the younger children when clinicians applied the EMLA and by older children when parents applied the EMLA.**

Conclusion. **Parent application of EMLA appears to be as effective as clinician application in reducing children's pain and distress associated with IV insertion. Permitting parents to apply the EMLA at home can allow children who are having procedures on an outpatient basis to benefit from topical anesthesia without having to arrive early to the clinic or hospital. Additionally, application by parents may result in less anticipatory anxiety for younger children.** *Pediatrics* **1999;103(6). URL: http://www.pediatrics.org/cgi/content/full/103/6/e79;** ***pain, children, topical anesthetic, venipuncture, EMLA.***

ABBREVIATIONS. EMLA, eutectic mixture of local anesthetics; IV, intravenous; GI, gastrointestinal; VAS, visual analog scale.

Needle sticks are frequent and necessary aspects of pediatric health care. Unfortunately, even a brief painful procedure such as a blood draw or an immunization can result in significant pain and distress for a child.[1–3] Previous work has also suggested that younger children may experience a higher level of pain and distress with needle sticks than older children.[2] Local anesthetics can help decrease pain, but frequently they are not used for brief procedures such as blood draws and immunizations. For intravenous (IV) insertion, infiltration with local anesthetic may be helpful, but it requires another needle stick and may produce pain with infiltration. Children who do not cope well with IV insertion are likely to be equally distressed by the local anesthetic infiltration. Therefore, researchers have searched for a method of providing effective topical anesthesia that is painless.

In 1980, the first description of the use of a new topical anesthetic, subsequently named eutectic mixture of local anesthetics (EMLA), was published.[4] During its initial evaluation and in the time period after, EMLA has been shown to be effective for reducing the pain from needle sticks, including blood sampling, and lumbar punctures.[5–7] Its use continues to expand with reports of good analgesia for procedures such as laser surgery,[8] debridement of ulcers,[9] skin testing,[10] and skin graft harvesting.[11] Current recommendations state that the EMLA should be applied for a minimum of 60 minutes[12] before the procedure to provide adequate anesthesia, although it has been suggested that a longer application time may be advantageous for certain procedures.[5,11] Consequently, the use of EMLA for outpatient procedures is not considered frequently, because there may not be enough time for the necessary duration of application after the child arrives at the health care facility.

In an effort to overcome this limitation, parents are asked often to apply EMLA before arriving for their child's procedure, obviating the need for the family to arrive over an hour early for their child's appointment. Parental application has become more ac-

From the Departments of *Anesthesiology and ‡Pediatrics, Arkansas Children's Hospital, University of Arkansas for Medical Sciences, Little Rock, Arkansas.

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Reprint requests to (J.L.K.) Arkansas Children's Hospital, Pediatric Anesthesia and Pain Management, 800 Marshall St, Slot 203, Little Rock, AR 72202-3591. E-mail: kohjeffreyl@exchange.uams.edu

cepted in hospitals that serve a large geographical area, in which families may travel several hours to reach the hospital.

A possible drawback to parental application is that applying EMLA can be somewhat challenging, especially for those who have not used it previously. Half of the contents of a 5 g tube are placed on each of two identified sites for the IV insertion and then covered with an occlusive dressing. Application of EMLA on young children may be difficult if they are not cooperative throughout the process. However, a study by Guttormsen et al[13] suggested that parents are both interested in and capable of applying EMLA at home before day-surgery. This particular study did not measure directly outcome variables such as pain of IV insertion or child behavior to determine the effectiveness of parental application. Outcome variables related directly to analgesia or behavioral distress with parental application remain to be evaluated.

Therefore, in the absence of any previous systematic evaluation of parental application of EMLA, this study was designed to evaluate the hypothesis that parents can apply EMLA with equal effectiveness as clinicians (as measured by pain report and behavioral distress) and to assess the feasibility aspects of parental application.

METHODS

Subjects

A total of 41 children who were scheduled to undergo elective outpatient gastrointestinal (GI) endoscopy with IV sedation participated in this study with parental consent and subject assent. Subjects ranged in age from 5 to 18 years of age (mean age = 11.5 years) with 20 male subjects and 21 female subjects. None of the children in this study had previous experience with EMLA.

Design

Children were assigned to one of two age groups (5–12 years vs 13–18 years) and randomized to one of two experimental groups (parent-applied EMLA vs clinician-applied EMLA). Thus, a 2×2 randomized block design was used to evaluate the effects of age and the person applying the EMLA. The mean ages for the younger age groups were 8.8 years (parent applied) and 8.5 years (clinician applied), and for the older age groups 14.3 years (parent applied) and 14.8 years (clinician applied). The study design called for the exclusion of children if they could not demonstrate understanding of the visual analog scale (VAS) scale. All children recruited for the study demonstrated appropriate understanding of the VAS before initiating study procedures. All children had EMLA in place for at least 60 minutes.

Measures

Outcome Measures

The primary outcome measures used were the children's report of pain and observed behavioral distress. Pain ratings were obtained after the IV was taped in place and before administration of the sedative, with the child rating the amount of pain experienced from the IV insertion using a 100-mm VAS (from no pain at all to the worst pain ever). Three behavioral distress ratings were recorded on a 6 point numerical scale (0 = not at all distressed; 5 = extremely distressed) by one of two GI nurses. The ratings were obtained for the following times 1) anticipatory, behavior from treatment room entry until the tourniquet was placed; 2) insertion, the behavior at the time of the needle stick; and 3) recovery, behavior from taping of the IV until sedative medications were given. A score of 0 was assigned if the patient had no sign (verbal or physical) of distress and cooperated with IV placement. A score of 5 was assigned if the patient was hysterical and required significant physical restraint to place the IV. Scores in between represented distress levels between these two extremes. This scale is similar to those that were used in previous studies[14–16] A second researcher independently rated behavioral distress for approximately a third (27%) of the subjects for reliability. All personnel were trained in the use of the behavioral distress scale before study implementation after the primary investigators piloted the behavioral investigation scale. Reliability between observers was calculated with weighted κ coefficients. Coefficients were .83 for anticipatory distress, .59 for insertion distress, and .92 for recovery distress. The lower coefficient between observers for the insertion rating may likely be attributable to how difficult it was for the independent observer to see the child's face at this time.

Anxiety Meaures

Shortly after arriving at the hospital, children were asked to rate their levels of anxiety about having an IV placed by completing a 100-mm vertical VAS ("Using this scale, please tell us how anxious you are about having an IV placed"), with anchors of "not nervous at all" and "extremely nervous." At the same time, parents rated the degree of their own anxiety about their child having an IV placed by completing a similar 100-mm vertical VAS ("Using this scale, please tell us how anxious you are about your child having an IV placed").

Previous Needle Stick Experience

Parents were asked for 1) the number of needle sticks (blood sampling, IV placements, and immunizations) that their child had experienced in the last 2 years and 2) their child's level of difficulty coping with these previous sticks on a 100-mm VAS (anchors of "not at all difficult" to "extremely difficult").

Feasibility Measures

Parents who applied EMLA answered a series of questions rating the degree of difficulty (100-mm VAS) in 1) obtaining EMLA, 2) applying the EMLA cream and occlusive covering, and 3) understanding the package instructions. In addition, the anesthesiologist who was to place the IV rated the appearance of the occlusive covering (intact, partially off, or completely off), and the amount of EMLA cream (dollop of white cream present, cream present but not a substantial dollop, or no cream present).

Procedures

The clinic specialty nurses (or attending GI physician) recruited the family into the study in the outpatient GI clinic, if it was known at that time that an endoscopic procedure would be scheduled. Researchers and GI specialty nurses in the endoscopy suite recruited families with children who needed to be scheduled for endoscopic procedures by telephone. Children were assigned randomly to experimental groups (blocked by age). Parents of children in the parent applied group were provided a prescription for EMLA (5-g tube, single-dose pack) and were instructed by a nurse or physician from the GI service to apply half of the tube of EMLA to the back of both of their child's hands and then to cover the EMLA with the occlusive covering provided in the EMLA pack. The specific instructions provided were consistent with those provided in the EMLA package insert and any questions regarding EMLA application were answered at this time. Parents were instructed to apply the EMLA $\geq$60 minutes before the scheduled time of the GI procedure, to note the time of application, and to arrive at outpatient admissions 30 minutes before their scheduled procedure. Parents of children in the clinician applied group were also provided with a prescription for EMLA by the GI service and instructed to bring the package with them $\geq$60 minutes before the procedure so that one of the investigators (all experienced with the application of EMLA) could apply the EMLA. The investigator who applied the EMLA cream was not involved with subsequent outcome measurements. On arrival at the hospital, families from both groups were met by one of the investigators who immediately applied the EMLA for the children in the clinician applied group. Research questionnaires were administered to obtain anticipatory anxiety ratings (parent and child). All children remained in the primary hospital waiting area before being brought to the GI waiting area ~10 minutes before the procedure.

When it was time for the endoscopic procedure, the child was taken from the GI waiting area into the treatment room. A GI nurse began conducting observations of behavioral distress imme-

TABLE 1. Anxiety Measures and Needle Stick History

	Parent Applied						Clinician Applied					
	Younger (n = 11)			Older (n = 10)			Younger (n = 10)			Older (n = 10)		
	M	(SD)	Md	M	(SD)	Md	M	(SD)	Md	M	(SD)	Md
Parent anxiety*	20.2	(38.3)	0	34.4	(32.6)	25.0	40.3	(32.0)	38.5	25.5	(24.0)	19.0
Child anxiety*	14.4	(29.3)	0	37.4	(36.7)	21.5	49.1	(35.0)	52.0	17.2	(20.0)	11.0†
Number of previous needle sticks	5.6	(5.7)	4.0	2.2	(1.5)	2.0	6.1	(5.2)	6.0	8.4	(9.2)	6.0
Previous difficulty coping*	39.1	(36.1)	41.0	52.9	(44.6)	54.0	43.9	(34.2)	39.0	31.7	(30.7)	25.0

Abbreviation: Md, median.
* 0–100 mm VAS.
† Age by experimental group interaction; $P < .01$.

diately after the child entered the room. Parents and children in both experimental groups were encouraged to do what they would typically do to cope in the situation. An age-appropriate book was left on the stretcher; however, only a few parents picked up the book to read or to look at pictures with their children. In these cases, the book was used only briefly. One of four experienced pediatric anesthesiologists rated the appearance of the EMLA application, then placed the IV. After insertion of the IV, the child was asked by the GI nurse to rate the pain experienced. Pain ratings were not obtained for 5 subjects in the younger age group. The missing ratings resulted from the child being too distressed to complete the VAS scale or from the sedative being administered before the researcher could ask the child for his or her rating. All other data from these 5 subjects are included in the results.

The study design called for blinding of the GI nurse and anesthesiologist to the experimental group. Parents and children were asked to avoid making any statements about who applied the EMLA. Blinding was maintained for most subjects; however, on a number of occasions, the nurse who scheduled the procedure (and thus assigned the patient to the experimental group) was the one who assisted with the IV insertion and GI procedure. After the child's procedure, the nurses were asked whether they remembered the study group assignment. Nurses indicated that they did not remember which experimental group the child was assigned to, which was not surprising because of the high number of patients scheduled for endoscopies (eg, 4–6 each day) and the time frame between the day that an appointment was scheduled and the day of the procedure. In addition, there were two occasions when parents were dispensed the EMLA without an occlusive dressing, resulting in an improvised dressing (ie, plastic wrap with tape) that suggested parental application.

Statistical Methods

Data analyses included univariate ANOVA to examine potential study group differences on the independent variables of child anxiety, parent anxiety, parent predication of child distress, number of previous IVs, and previous difficulty coping with IVs. Associations between these variables were examined by correlational analyses. Heterogeneity of pain ratings was detected among experimental groups (Levene's test; $P < .005$); therefore, nonparametric methods (Kruskal Wallis) were used to evaluate age and experimental group differences on this outcome measure, as well as on the behavioral distress scores that were treated conservatively as ordinal data. Nonparametric analyses were also used in any analyses (eg, correlations) containing these dependent measures (ie, pain and behavioral distress scores).

RESULTS

Preliminary Analyses

The means, medians, and SDs for parent and child anxiety, number of previous sticks, and the parent's report of their child's difficulty coping with previous needle sticks are presented in Table 1. Group differences were found only for child anxiety in anticipation of the IV insertion. Specifically, an experimental group–age group interaction was found ($F(1,35) = 7.73$; $P < .01$). Examination of the means and medians shows that the younger children who had clinician-applied EMLA and the older children who had parent-applied EMLA reported the highest levels of anxiety in anticipation of their IV insertion. Group comparisons suggested that the younger clinician applied group differed from the younger parent applied group ($P < .02$) and the older parent applied group ($P < .03$); however, these levels of significance do not exceed those values needed when correcting for multiple post hoc comparisons (Bonferroni critical level = .008). There were no other experimental or age group differences on these variables.

Spearman rank correlations were calculated between the dependent variables (pain ratings and behavioral distress ratings) and those variables in Table 1. Correlational analyses revealed that the child's previous level of difficulty with coping scores (as rated by parents) was correlated with the child anxiety ratings ($r = .34$; $P < .05$). To examine whether previous difficulty coping would account for the age by experimental group difference on child anxiety ratings, an analysis of covariance was conducted with previous difficulty coping entered as the covariate. Results indicated that when previous difficulty coping was controlled for, the interaction between age and experimental group became more significant ($F(1,31) = 14.25$; $P < .001$) with the same group differences. The child's previous difficulty in coping

TABLE 2. Outcome Measures

	Parent Applied								Clinician Applied							
	Younger				Older				Younger				Older			
	M	(SD)	Md	n	M	(SD)	Md	n	M	(SD)	Md	n	M	(SD)	Md	n
Behavior Distress Rating	1.0	(1.3)	1.0	11	1.4	(1.0)	1.0	10	2.1	(1.7)	2.0	10	.7	(.7)	1.0	10
Anticipatory Insertion	1.0	(1.5)	1.0	11	1.5	(1.4)	1.5	10	2.6	(1.6)	2.5	10	.7	(.8)	.5	10
Recovery	.6	(.9)	0	11	1.1	(1.2)	1.0	10	1.2	(1.5)	1.0	10	.2	(.4)	0	10
Pain rating	15.1	(19.8)	5.0	8	25.7	(29.6)	8.5	10	45.4	(36.6)	42.0	8	17.7	(13.5)	14.0	10

Abbreviation: Md, median.
0–100 mm VAS.

was correlated moderately with the behavioral distress ratings (anticipatory $r = .50$, $P < .01$; insertion $r = .32$, $P < .05$; recovery $r = .44$, $P < .01$). All three behavioral distress ratings were correlated with pain ratings (anticipatory $r = .45$, $P < .01$; insertion $r = .63$, $P < .0001$; recovery $r = .50$, $P < 01$).

Outcome Measures

Table 2 displays the means, medians, and SDs of the pain ratings and behavioral distress ratings for each experimental and age group.

Pain Ratings

As presented in Table 2, the mean and median pain ratings were within a low to moderate range. Pain ratings did not differ significantly when analyzed by age group or by experimental group. A total of 4 children (11%), ages 11 to 14 years, indicated a VAS score of 0.

Behavioral Distress

As shown in Table 2, the means and medians for behavioral distress were in the low to low/moderate range for all experimental groups. No significant age or experimental group differences were found for anticipatory distress, insertion distress, or recovery distress, when analyzed by Kruskal-Wallis procedures.

Feasibility of Parent Application of EMLA

Appearance

The appearance of the EMLA cream and occlusive covering is described in Table 3. The majority of both parent and clinician applications were rated as having an intact occlusive dressing and a substantial dollop of EMLA cream. Although clinician application was more likely to result in an intact occlusive covering and clear dollop of cream than parent application, there was 1 child in the clinician application group whose occlusive covering had come partially off and 1 child whose cream either had leaked out partially or had been absorbed. The child in the parent applied group without cream present was still included in the study, because the blanching was observed over the IV site indicating the presence of the cream at some point. The 5 patients whose occlusive dressing had come off partially before the procedure all had pain ratings below the mean for their group.

Difficulty With Application

Parent ratings of the difficulty of the separate aspects of the application process are presented in Table 4. Overall, the mean rating for difficulty of application was in the low range. The portion of the application process rated the most difficult was placement of the occlusive covering (mean = 23.29). Additionally, there were a number of parents who noted that their local pharmacies needed to special order the EMLA. In a number of circumstances, parents met the challenges of application with creative solutions. In two instances, parents received the larger multidose tube rather than the unit dose pack. This particular packaging does not include the occlusive dressing and, as mentioned previously, parents improvised by using plastic wrap and tape. Other parents solved the problem of their young child pulling at the dressing by placing mittens on their hands. Most of the comments expressed by parents were related to difficulties with the applications of the occlusive covering. For example, "I didn't know all the paper was supposed to come off"; " I couldn't determine which side was up when putting on the adhesive"; or "I put it on upside down and crumpled the right hand patch."

TABLE 3. Appearance of EMLA Application for Parent Application Group

	Parent Applied *n* (%)	Clinician Applied *n* (%)
Occlusive dressing		
Intact	17 (81%)	19 (95%)
Partially off	4 (19%)	1 (5%)
Cream		
Dollop present	13 (62%)	19 (95%)
Some cream present	7 (33%)	1 (5%)
No cream present	1 (5%)	0 (0%)

DISCUSSION

This study provides empiric support that parents can apply EMLA effectively on their child's potential IV sites. Child pain ratings and observed behavioral distress ratings were similar for both experimental groups and were comparable to the findings of other researchers with similar age groups. Specifically, children's pain reports have been shown to be in the low range for IV insertion using EMLA.[15,17] Behavioral distress ratings have not been included in most previous studies examining outcome with EMLA; however, one recent study[15] did show generally low behavioral distress scores similar to those in this study.

Although outcomes were comparable for both the parent and clinician-applied groups, children's anticipatory anxiety appeared to differ between experimental groups. Younger children reported the most anticipatory anxiety for IV insertion when the EMLA was placed by clinicians. The lack of standardized waiting time may contribute in part to the difference observed in anxiety levels, because children who had clinician applied EMLA arrived 60 minutes early (vs 30 minutes for the parent applied group). Perhaps the longer waiting time for younger children increased their anxiety. However, ratings were obtained immediately on the child's arrival and we doubt that the children were aware of the waiting time. More likely, we speculate that younger children were more comfortable with their parents ap-

TABLE 4. Parent Ratings of Difficulty With Aspects of Applying EMLA

	Mean	SD	Range	Median
Difficulty obtaining EMLA	18.0	28.0	0–93	4.0
Difficulty understanding application	6.0	11.0	0–41	.0
Difficulty in applying cream	9.0	22.0	0–100	2.0
Difficulty in applying occlusive dressing	23.0	29.0	0–100	9.0

All responses were made on a 0–100 mm VAS.

plying the EMLA cream rather than a clinician (the white coat phenomenon). Older children may react differently and feel more comfortable allowing a health care provider apply the EMLA. Additionally, children's previous difficulty coping, as rated by the parent, was associated with their behavioral distress before, during, and after the IV insertion. Investigations evaluating methods to decrease anxiety and to promote positive coping behavior in children who are undergoing painful procedures, even with the use of EMLA, may be an important focus for future research. In addition, evaluation of the use of the new EMLA patch (recently released in the United Stated and not available at the time of the study) by parents may resolve some of the technical problems identified in this study.

The biggest obstacle for parent application of EMLA may be the availability of the drug, especially in rural locations. This obstacle may be overcome by making EMLA available at a clinic visit before the date that the procedure is performed. At our hospital, physicians encourage parents to fill their prescriptions at the hospital pharmacy during the visit when it is decided that a procedure is necessary. Parents can also be encouraged to call ahead to their local pharmacy so that there is ample time to order the EMLA if necessary. Hopefully, with increased demand and awareness of the efficacy of EMLA, more pharmacies will have this medication in stock.

This study was limited by the relatively small sample size, which may have resulted in group differences that were obscured by the variance in responses. Specifically, because most of the pain and distress ratings were in the low to moderate range, group differences may not have been revealed because of the low number of subjects. However, because the efficacy of EMLA in reducing the pain from needle sticks has been proven in multiple studies and because our results suggest that parent application is very similar in appearance and efficacy to clinician application in most cases, it is unlikely that a higher number of subjects would change this result. The differences seen in anxiety are intriguing, but no definitive conclusions can be drawn because of the small sample size. These results might have been more concrete with a larger number of subjects.

CONCLUSION

In summary, parental application of EMLA can be effective in reducing the pain and distress associated with IV insertion and should be considered for any type of outpatient procedure involving a needle stick. This procedure allows the child to have the benefit of effective topical anesthesia without having to arrive excessively early to the hospital or clinic. In situations requiring the child to arrive at least 1 hour before the procedure, preplanning should allow for the parent or a clinician to apply the EMLA after he or she arrives. Finally, including the use of behavioral interventions for decreasing anxiety and distress may enhance the effectiveness of EMLA and is an area for future empiric investigation.

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