Vapocoolant Spray Is Equally Effective as EMLA Cream in Reducing Immunization Pain in School-aged Children

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ABSTRACT. *Background.* **Untreated immunization pain causes undue distress and contributes to underimmunization through physician, and possibly parental, resistance to multiple simultaneous injections.**

Objective. **To compare the efficacies of two pain management methods in reducing immediate immunization injection pain and distress in school-aged children.**

Design. **A randomized, controlled clinical trial of eutectic mixture of local anesthetics (EMLA) cream and vapocoolant spray.**

Patients. **Children aged 4 to 6 years and scheduled to receive diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) during health supervision visits.**

Interventions. **Enrolled children were randomized to one of three treatment groups: 1) EMLA cream + distraction; 2) vapocoolant spray + distraction; or 3) distraction alone (control). The specific pharmacologic pain control interventions consisted of EMLA cream (2.5% lidocaine, 2.5% prilocaine [Astra Pharmaceutical Products, Inc, Westborough, MA] $15.00/patient; applied 60 minutes before injection) and vapocoolant spray (Fluori-Methane [Gebauer Company, Cleveland, OH] $0.50/patient; applied via spray-saturated cotton ball for 15 seconds immediately before injection).**

Main Outcome Measures. **The blinded investigator (BI) measured (by edited videotape) cry duration and the number of pain behaviors using the Observational Scale of Behavioral Distress. Pain visual analog scales (linear and faces scales) were completed by the child, parent, nurse, and the BI.**

Results. **Sixty-two children, aged 4.5 ± 0.4 years (mean ± SD) were randomized. The three treatment groups had similar subject characteristics. All pain measures and cry duration were similar for EMLA and vapocoolant spray. Both EMLA and spray were significantly better than control. Results for spray vs control: cry duration (seconds): 8.5 ± 21.0 vs 38.6 ± 50.5; number of pain behaviors: 1.2 ± 1.9 vs. 3.1 ± 2.1; child-scored faces scale: 2.0 ± 2.4 vs. 4.1 ± 2.3; parent-scored faces scale: 1.6 ± 1.6 vs. 3.0 ± 1.7; nurse-scored faces scale: 1.6 ± 1.2 vs. 3.1 ± 1.4; and BI-scored faces scale: 1.0 ± 1.5 vs. 2.4 ± 1.4.**

Conclusions. **When combined with distraction, vapocoolant spray significantly reduces immediate injection pain compared with distraction alone, and is equally effective as, less expensive, and faster-acting than EMLA cream. As an effective, inexpensive, and convenient pain control method, vapocoolant spray may help overcome physician and parent resistance to multiple injections that leads to missed opportunities to immunize.** *Pediatrics* **1997;100(6). URL: http://www.pediatrics.org/cgi/content/full/100/6/e5;** ***pain control, EMLA cream, vapocoolant spray, immunization.***

ABBREVIATIONS. AHCPR, Agency for Health Care Policy and Research; EMLA, eutectic mixture of local anesthetics; DTaP, diphtheria and tetanus toxoids and acellular pertussis vaccine; VAS, visual analog scales.

Despite recent advances in the assessment and management of acute pediatric pain, outlined in the clinical practice guideline of the Agency for Health Care Policy and Research (AHCPR),[1] children continue to be subjected to the pain and distress of immunization injections.[2–6] Parents, as well as their children, experience distress related to untreated immunization pain.[6]

In addition to undue pain and distress, lack of pain control for injections is a barrier to immunization. Many physicians withhold scheduled vaccines out of concern for the excessive pain of simultaneous immunizations.[7–11] We recently showed that children scheduled for three immunization injections were significantly more likely to miss a vaccine than children scheduled for fewer than three.[12] This finding suggests that the number of scheduled injections during well-care visits is independently associated with missed opportunities to immunize. Parents' concerns about injection pain may also contribute to underimmunization through their poor compliance with preventive health care visits.[10,13,14] Missed opportunities by physicians combined with appointments not kept account for nearly the total underimmunization rate,[15] which far exceeds the target levels set by *Healthy People 2000*,[16] especially among disadvantaged youth.[17,18]

Reasons for inadequate pain control for immunization are unclear. One possible explanation is that physicians may have negative attitudes toward the applicability of available pain control methods. A topical anesthetic cream, EMLA, or eutectic mixture of local anesthetics, (2.5% lidocaine, 2.5% prilocaine, [Astra Pharmaceutical Products, Inc, Westborough, MA]), is approved for use in reducing the pain of pediatric procedures, including injection. Despite its proven efficacy,[19–22] EMLA cream has not been widely accepted for control of immunization pain possibly due to its delayed onset of anesthesia (60

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minutes) and expense (approximately $15.00 per 2-dose tube). Another pain management intervention offers promise. In 1955, a vapocoolant spray of a volatile refrigerant liquid (ethyl chloride) was shown to provide cutaneous anesthesia in seconds at a fraction of EMLA's cost (current cost $0.50 per patient).[23] To date, these interventions have not been compared with regard to their efficacy in controlling pediatric immunization pain and distress. Therefore, the present study was designed to assess the relative efficacies of two methods of pain control, EMLA cream and vapocoolant spray, in reducing immediate immunization injection pain and distress among school-aged children.

METHODS

This randomized, controlled trial of immunization pain control interventions was approved by the Human Rights Committee of the Children's Hospital of Pittsburgh.

Subjects

Children aged 4 to 6 years and scheduled to receive diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) at the Children's Hospital of Pittsburgh Primary Care Center were eligible for the study. Parents of these children were approached in the registration area. After the study was explained, interested parents gave written informed consent for their children to participate and children gave assent. Children for whom the use of EMLA cream or Fluori-Methane (Gebauer Company, Cleveland, OH) was contraindicated were excluded. Contraindications to EMLA cream consisted of: known history of sensitivity to amide anesthetics (lidocaine, prilocaine); glucose-6-phosphate deficiency; congenital or idiopathic methemoglobinemia; severe hepatic or renal disease, or use of Class I antiarrhythmic drugs. Contraindications to Fluori-Methane consisted of: known history of sensitivity to dichlorodifluoromethane and/or trichloromonofluoromethane.

Pain Control Treatments

Subjects were randomly assigned to one of the three treatment groups: EMLA cream + distraction; vapocoolant spray + distraction; or distraction alone (control). For subjects scheduled for multiple injections, the same pain control intervention was used for all injections. However, measurements were limited to the target immunization (DTaP), which was administered first.

EMLA Cream

EMLA cream was applied in the waiting room according to manufacturer's instructions: 2.5 g applied to the injection site in a thick layer and covered with the occlusive dressing. The cream was left undisturbed for 60 minutes, then removed before cleaning the skin with alcohol. The injection was then performed as described below.

Vapocoolant

Fluori-Methane spray was selected as it is the nonflammable alternative to ethyl chloride. A cotton ball saturated with Fluori-Methane was applied immediately before injection. Using forceps, to avoid cooling the assistant's fingers, the saturated cotton ball was held firmly on the injection site for 15 seconds. After the liquid was allowed to evaporate (1 to 2 seconds), the skin was cleaned with alcohol and the injection was performed as described below. Of note, although the vapocoolant may be sprayed directly on the injection site, the cotton ball technique was chosen as some patients experience the direct spray as a noxious stimulus.

Distraction

To standardize the distraction technique during immunization, subjects were instructed to blow on a pinwheel that they or their parents held.

Injection Procedure

Immunization injections were performed according to the standard nursing protocol. 0.5 mL of DTaP vaccine (Connaught, Swiftwater, PA) was drawn into a 1-mL syringe under aseptic technique and administered intramuscularly in the deltoid at a 90° angle to the skin with a 26-gauge, ½-inch needle. Before initiation of the study, the nursing staff participated in an in-service demonstrating the standardized injection procedure. Injection administration was monitored by the investigator periodically to ensure compliance with standard procedure.

Outcome Measurements

Numerous pain and distress scales were completed by four informants. The nonblinded informants included the child, parent, and nurse administering the immunizations. In order to add a blinded observer, a large subset of subjects (60%) were videotaped during immunization. The videotapes were edited to show only the injection and the immediate recovery period so that information regarding the treatment group was not evident. All videotapes were scored by one investigator (E.C.R.), who was blinded to treatment group assignment.

The measures used to assess the five outcome domains, the time of assessment, and the identity of the informant are shown in

TABLE 1. Observations and Measurements

Outcome Domains	Measure	Assessment Period	Informant
Anticipatory distress-Child	Prior experience VAS	E	P
	Global Mood Scale	E	I*
		−1 m	I*
Pain-Child	Observational Scale of Behavioral Distress	0	I
	Pain VAS:		
	Linear	+1 m	I, N, P
	Faces	+1 m	I, N, P, C
	Cry duration	0	I
Postprocedural distress-Child	Global Mood Scale	+1 m	I
		+5 m	I
Distress-Parent	Parental distress VAS	+5 m	P
Satisfaction-Parent	Comparison VAS	+5 m	P
	Parental preference VAS	+5 m	P
	Willingness to pay	+5 m	P

VAS indicates visual analog scale.
Key for assessment period information is as follows: E, Enrollment in waiting room; −1 m, 1 minute before immunization administration; 0, during immunization administration; +1 m, 1 minute after immunization administration; +5 m, 5 minutes after immunization administration.
Key for informant information is as follows: C, Child; I, Investigator, blinded; I*, Investigator, nonblinded; N, Nurse; P, Parent.

Table 1. Descriptions of each outcome measure are given below. All visual analog scales (VAS) were scored by measuring the distance from 0 (at the extreme left) to a vertical line drawn by the respondent on the horizontal scale.

Prior Experience VAS. To assess a child's prior experience with injections, parents were asked to complete a 100-mm linear VAS, (range, 0 = "usually not at all upset with shots" to 100 = "usually extremely upset with shots.") This scale was completed at enrollment.

Global Mood Scale. Originally created by Vernon, Foley, and Schulman,[24] this ordinal scale is noted to be of practical utility in applied clinical settings and has been used to measure distress in several studies of children undergoing various medical interventions.[25] Interrater reliability is excellent.[26] Scores range from 1 (eg, attentive, contented, interested in play) to 7 (eg, intense and constant crying). This scale was used to assess the degree of the child's distress and was completed at the following times: 1) enrollment (before randomization) by a nonblinded research assistant; 2) 1 minute before immunization (by the research assistant); 3) 1 minute after the last immunization (by the blinded investigator); and 4) 5 minutes after the last immunization (by the blinded investigator).

Observational Scale of Behavior Distress. This scale was developed by Elliot, Jay, and Woody[27] to measure behavioral responses to painful medical procedures in children aged 3 to 13. Interrater reliability is excellent.[26] A composite score is calculated based on the occurrence/nonoccurrence of 11 pain behaviors (eg, cry, verbal resistance, physical restraint). The blinded investigator completed this scale at the time of the target immunization to assess the child's pain reaction to the DTaP injection.

Pain VAS. Two VAS were also used to assess injection pain and were completed by the parent, the nurse administering the vaccine, the blinded investigator, and the patient (faces scale only). The first was a 100-mm linear scale (range, 0 = "no pain" to 100 = "worst pain possible.") The second, a ratio faces scale developed by Bieri et al,[28] consists of 7 cartoon faces (range, 0 = "no pain" to 6 = "worst pain"), one of which was selected by each informant to represent the severity of the child's pain with the DTaP injection. These pain scales were completed 1 minute after the last immunization was administered.

Cry Duration. Cry duration (seconds) was measured by the blinded investigator using the edited videotape. Initiation of cry was set as the time of needle puncture of the skin with the first (DTaP) injection. Crying was considered terminated when the child ceased crying for more than 3 seconds.

Parental Distress VAS. A linear scale, 100-mm long, (range, 0 = "not at all upset by the immunization" to 100 = "very upset by the immunization") was completed by the parent to denote his/her own level of immunization-related distress 5 minutes after the last injection.

Comparison VAS. In answer to the question "How much pain did your child have with the first shot today compared with previous immunizations?", a linear scale, 100-mm long, (range, 0 = "much less pain today" to 50 = "the same pain" to 100 = "much more pain today") was completed by the parent 5 minutes after the last injection.

Parental Preference VAS. In answer to the question "Would you prefer that your child receive his/her shots the same way in the future?", a linear scale, 100-mm long, (range, 0 = "definitely would prefer" to 100 = "absolutely would not prefer") was completed by the parent 5 minutes after the last injection.

Willingness to Pay. Parents in the EMLA and spray groups were asked how much they would be willing to pay to have their child receive the same pain control for future injections.

Data Analysis

Summary data was obtained for each treatment group by calculating mean values for continuous and ordinal level data and proportions for nominal level data. Histograms were prepared for the main outcome variables, the subject pain measures. As these histograms revealed that the data were not distributed along a normal curve, nonparametric tests were used to assess differences between treatment groups. Specifically, for continuous and ordinal level data, the Kruskal-Wallis test was used to test for differences between all three groups, and the Mann Whitney test was used to test for differences between two groups (ie, EMLA vs spray). The χ^2 test was used to test for differences in nominal level data.

Assessment of the statistical significance of the findings necessitates consideration of the multiple between-group comparisons for each outcome. By conservative Bonferroni correction, P values $<.016$ would be considered significant.

RESULTS

Subject Characteristics

Sixty-two children, aged 4.5 ± 0.4 years (mean ± SD) were randomized. As shown in Table 2, subject characteristics for the three treatment groups were comparable. Of note, patients in the three groups had similar prior experience with injections and similar levels of distress noted at enrollment. In addition, most patients received more than the one target injection, most commonly the measles, mumps, and rubella vaccine.

Child Pain and Distress

Nonblinded Informants

Using the linear and faces VAS scales, parents and nurses rated both EMLA + distraction and vapocoolant spray + distraction as significantly better than distraction alone (control) in reducing children's immunization-related pain (Table 3). Scores for the control group were approximately twofold higher than for the other two groups. Furthermore, mean scores for the EMLA and spray groups were equivalent. Notably, the children self-reported that vapocoolant spray significantly reduced injection pain relative to control; however, self-reported pain scores for EMLA cream were not significantly different from the control group.

Of note, as most of these significant differences reached the .01 level of significance, our findings are not substantially affected by the consideration of multiple comparisons.

Blinded Observer

The blinded investigator also scored both EMLA and vapocoolant spray as significantly better than control in reducing pain, using the linear and faces VAS scales (Table 4).

The more objective measures scored by the blinded investigator, Observational Scale of Behav-

TABLE 2. Subject Characteristics by Treatment Group

	EMLA (n = 21)	Spray (n = 20)	Control (n = 21)
Mean age (y)	4.5 ± 0.5	4.5 ± 0.5	4.4 ± 0.3
Gender (% female)	53	30	67
Race (% black)	75	83	83
Mean VAS score–prior experience	58.2 ± 30.2	43.4 ± 30.0	47.2 ± 30.9
Mean GMS score–enrollment	1.5 ± 1.0	1.4 ± 0.8	2.0 ± 1.4
Mean GMS score: −1 minute	2.4 ± 1.6	2.4 ± 1.7	3.1 ± 1.9
Multiple injections (%)	90	90	90
Total injections	2.2 ± 0.7	2.2 ± 0.6	2.1 ± 0.5
Measles, mumps, rubella (%)	91	80	81
Varicella (%)	24	25	19
Hepatitis B (%)	10	15	10

VAS indicates visual analog scale; GMS indicates Global Mood Scale.
There were no significant differences between the three groups.

TABLE 3. Child Injection Pain Measurements (Parent, Child, and Nurse Observations)

	EMLA (n = 21)	Spray (n = 20)	Control (n = 21)
Mean scores			
Linear VAS-parent	23.5 ± 20.6†	20.5 ± 26.0†	43.3 ± 24.3
Linear VAS-nurse	21.6 ± 16.4†	23.6 ± 22.4†	47.2 ± 19.1
Faces VAS-parent	1.9 ± 1.6*	1.6 ± 1.6†	3.0 ± 1.7
Faces VAS-nurse	1.8 ± 1.6*	1.6 ± 1.2†	3.1 ± 1.4
Faces VAS-child	3.0 ± 2.4	2.0 ± 2.4†	4.1 ± 2.3

VAS indicates visual analog scale.
* $P < .05$, † $P < .01$ for comparison between this treatment group and control.
There were no significant differences between EMLA and spray groups.

TABLE 4. Child Injection Pain and Distress Measurements (Blinded Investigator Observations)

	EMLA (n = 12)	Spray (n = 12)	Control (n = 12)
Mean scores			
Linear VAS	14.9 ± 19.9*	15.4 ± 26.6*	38.9 ± 25.4
Faces VAS	1.1 ± 1.2*	1.0 ± 1.5*	2.4 ± 1.4
OSBD†	1.3 ± 1.6*	1.2 ± 1.9*	3.1 ± 2.1
Cry duration (sec)	10.3 ± 16.5	8.5 ± 21.0*	38.6 ± 50.5
GMS (+1 m)	2.4 ± 1.2*	2.5 ± 1.4*	4.0 ± 1.7
GMS (+5 m)	1.7 ± 1.2	2.0 ± 1.2	2.5 ± 1.6

VAS indicates visual analog scale; GMS indicates Global Mood Scale.
* $P < .05$ for comparison between this treatment group and control.
† Observational Scale of Behavioral Distress: number of observed pain behaviors.
There were no significant differences between EMLA and spray groups.

ioral Distress and cry duration, revealed that the children in the control group exhibited twice as many pain behaviors and cried nearly 30 seconds longer than the children in the vapocoolant spray group. Although average cry duration for the EMLA group was shorter than for the control group, this difference did not reach statistical significance ($P = .10$). Of note, although EMLA and spray were both significantly more effective than control in reducing immediate postinjection distress (Global Mood Scale +1 minute), this difference did not persist at 5 minutes postinjection.

Parent Distress and Satisfaction

As shown in Table 5, parents reported that children who received EMLA or spray had significantly less pain during the study visit compared with previous immunizations, whereas children in the control group had a mean "comparison VAS" score approaching 50 ("the same pain as previous shots"). This finding is consistent with the other pain outcome measures. Levels of parental distress were not significantly different among treatment groups, although there was a trend toward less distress among parents whose children received EMLA or spray. Of interest, parents of all three groups had similarly strong preferences for their children to receive the same pain treatment again for future injections. This may be due to parental perception that all treatment methods, including distraction, were preferable to standard practice (ie, no attention to pain control).

TABLE 5. Parent Satisfaction Measurements

	EMLA (n = 21)	Spray (n = 20)	Control (n = 21)
Mean scores			
Comparison VAS*	27.9 ± 28.3†	24.0 ± 28.8†	46.0 ± 12.8
Parent distress VAS	12.1 ± 18.5	14.1 ± 24.0	22.1 ± 20.9
Preference VAS	22.5 ± 31.5	16.4 ± 26.6	31.2 ± 34.7

* VAS indicates visual analog scale.
† $P < .01$ for comparison between this treatment group and control.
There were no significant differences between EMLA and spray groups.

Parents of children in the EMLA and spray groups were asked about the monetary value of the pain treatment received. On average, parents responded that they would be willing to pay $11.90 for EMLA and $8.40 for vapocoolant spray for future injections.

DISCUSSION

Pediatricians are responsible for recognizing and relieving children's pain in all medical settings, including pain related to procedures. As directed in the AHCPR clinical practice guideline on acute pain management, appropriate relief for pediatric procedures should address both pain and anxiety, using pharmacologic and nonpharmacologic methods.[1]

Our current study of pain control for DTaP injections used both pharmacologic and nonpharmacologic interventions. Although cognitive-behavioral approaches, such as distraction, are effective in treating procedure-related pain and distress,[29,30] we found that adding EMLA cream or vapocoolant spray to the distraction technique was superior to using distraction alone.

As pain is a subjective experience, individual self-report is the gold standard. We obtained self-report using a child-scored faces scale, which has demonstrated test-retest reliability among 6-year-old children.[28] Given the young age of our patients, we also obtained pain assessments by adult observers, including parents, nurses, and an investigator blinded to treatment group. Of interest, these adult observers rated EMLA and vapocoolant spray as equivalent; however, the children rated the spray as superior to EMLA.

To date, injection pain has received little attention as a barrier to immunization, often omitted entirely in discussions of immunization policy.[31] Standard #8 of the *Standards for Pediatric Immunization Practices* directs that "providers administer simultaneously all vaccine doses for which a child is eligible at the time of each visit."[32] However, numerous studies have reported that physicians routinely withhold scheduled vaccines out of concern for the excessive pain of multiple, simultaneous injections.[7–11] A survey of 40 practices serving high-risk Baltimore census tracts found that only one complied with Standard #8.[33]

Inadequate pain control for immunization injections has several important implications. First, failure to simultaneously administer all indicated vaccines contributes to underimmunization. Recent studies have documented that implementing simultaneous administration alone could substantially im-

prove vaccine coverage,[34,35] achieving full second year coverage of 30% of underimmunized children.[35] Second, if parents do bring their children back to receive the postponed vaccines, these additional visits lead to increased health care costs.[36] In addition, untreated injection pain often leads to children's fear of pediatric visits and time-consuming struggles between patients and office staff.

Many reasons have been proposed to explain the lack of attention to injection-related pain. These include: 1) the myth that children do not experience or remember the pain of injections; 2) lack of assessment of children's and parents' distress; 3) physicians' and nurses' personal beliefs about the meaning and value of pain in the development of the child (eg, pain builds character); 4) lack of knowledge about possible pain treatments; and 5) negative attitudes toward the feasibility of applying pain control methods in practice.[5] In hopes of addressing this last concern, we designed our current clinical trial to identify an effective and practical pain control method for immunization injections. We found that vapocoolant spray is equally effective as EMLA cream in reducing immediate injection pain, yet it is faster-acting and much less expensive.

With the newly revised immunization schedule, including inactivated poliovirus vaccine and DTaP for infants,[37] the likelihood of multiple, simultaneous injections, and therefore the need for improved pain control, is considerably increased. As an effective, safe, convenient, and inexpensive pain control method, vapocoolant spray may help overcome the barrier of physician and parent resistance to multiple injections that leads to missed opportunities to immunize.

Although generalization of our findings is limited by our study of the DTaP vaccine in 4- to 6-year-old children, these results suggest that the use of vapocoolant spray may help overcome resistance to multiple immunization injections for infants. We are currently conducting a randomized clinical trial of vapocoolant spray versus control in young children, 2 to 24 months old.

SUMMARY

Sixty-two children, aged 4 to 6 years, were randomized to one of three pain treatment groups for administration of DTaP: EMLA cream + distraction; vapocoolant spray + distraction; or distraction alone (control). When combined with distraction, vapocoolant spray significantly reduces immediate injection pain compared with distraction alone, and is equally effective as, faster-acting, and less expensive than EMLA cream. As an effective, convenient, and inexpensive pain control method, vapocoolant spray may help overcome the barrier of physician and parent resistance to multiple injections that leads to missed opportunities to immunize.

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