Original Article

The Use of a Topical Refrigerant Anesthetic to Reduce Injection Pain in Children

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Abstract
Early childhood experiences with painful injections may lead to anxiety and fear. These reactions need not develop if steps are taken to reduce the pain associated with injections. The purpose of this study was to assess the efficacy of a refrigerant topical anesthetic in reducing injection pain in preschool children experiencing routine diphtheria-pertussis-tetanus (DPT) immunizations. This double-blind placebo-controlled study was conducted in community health clinics in conjunction with ongoing immunization programs. Ninety subjects, aged 4–5.5 years, were randomly assigned to one of three groups: (a) refrigerant topical anesthetic; (b) placebo topical spray; and (c) no-spray control. Pain was measured subjectively using a four-point visual analogue scale. Both the refrigerant topical anesthetic spray and the placebo spray significantly reduced injection pain. Age was found to be an important factor influencing pain response in this study. Parental anxiety was not a significant factor influencing pain response. In addition, parents were not good at predicting their child's pain. The results of the study support the use of an intervention, such as refrigerant topical anesthetic, as a practical, simple, and effective treatment strategy for reduction of short-term painful procedures like injections. J Pain Symptom Manage *1995;10:584–590.*

Key Words
Injection pain, topical anesthetics, preschool

Introduction

Despite recent advances in the delivery of medications, children continue to receive injections for immunizations, suturing, local anesthetic infiltration, and postoperative analgesia administration. Injections remain a source of distress and pain for many children and are still one of the most common sources of medically induced pain that will be experienced.[1–6] The degree of behavioral distress and lack of cooperation observed during an injection often ranges from nuisance to major management problems. Behavior such as crying, screaming, and physical resistance creates additional stress for parents, clinicians, and other children present.[7] Experiencing a procedure that is painful often leads to feelings of anxiety and fear, and a vicious circle of fear, anxiety, and pain may develop.[8–14] One method of dealing with this fear and anxiety may be through avoidance behaviors. A descriptive study by Eland[15] indicated hospitalized children often will not verbally complain

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of pain if they know it will result in a needle. This is consistent with findings by Mather and Mackie,[16] in which children experienced moderate-to-severe postoperative pain rather than receive the "dreaded needle." Pain control strategies are needed to reduce fears, anxieties, and avoidance behaviors.

Since the formulation of the Gate Control Theory,[8] researchers have viewed pain as a multidimensional construct leading to improvements and advancements of many interventions, both cognitive–behavioral and pharmacological, aimed at reducing or eliminating pain from noxious stimuli. Cognitive–behavioral treatment strategies, such as distraction,[17] providing preparatory information,[14,18] relaxation,[19] and hypnosis,[13] have demonstrated efficacy, but are not often employed in busy clinical settings due to time constraints and lack of training. Pharmacological treatment strategies, such as topical anesthetics, have proven to be effective and have the added advantage of being convenient and easy to use, thus making them more practical in many clinical settings.[20–28]

Most studies investigating the efficacy of topical anesthetics in the management of injection pain have been randomized clinical trials involving the use of a eutectic mixture of local anesthetics, lidocaine-prilocaine (EMLA). EMLA cream has proven effective in producing dermal analgesia before skin puncture, thus reducing pain associated with injections.[20–22] A limitation is that it must be applied at least 60 min prior to needle insertion, thus potentially minimizing its usefulness in a busy unit or clinic when only 10–15 min is allotted per person.[22,23]

Refrigerant topical anesthetic sprays have been found to reduce pain associated with minor surgical procedures, myofascial pain, dermabrasion, and injections.[24–26] However, these studies have been descriptive in nature, except for one randomized clinical trial supporting the use of refrigerant topical anesthetics for injection pain.[28] In this clinical trial, there were some methodological weaknesses that reduced both internal and external validity. Nevertheless, the fact that a refrigerant topical anesthetic can be so quickly applied and takes effect in only 10–15 sec makes it an easy and practical intervention strategy to employ in a clinical setting and warrants further investigation.

The influence of age and parental fears and anxieties on a child's pain response is beginning to be systematically investigated in pain studies. Age appears to be negatively correlated with pain response.[1,18,20] Parental anxiety has been positively correlated with the child's distress.[11,12,30,31] Likewise, parents have been able to predict their child's pain.[1,12,31]

The purpose of this study was to assess the efficacy of a refrigerant topical anesthetic[a] in reducing injection pain in preschool children, aged 4–5.5 years, who were undergoing routine diphtheria-pertussis-tetanus (DPT) immunization. It was hypothesized that subjects who received a refrigerant topical anesthetic spray would have significantly less pain from the injection than subjects in both a placebo group and a no-treatment group. Further, subjects who received the placebo spray would be found to have significantly less pain than the control subjects. It was also hypothesized that age would be inversely related to pain response. Last, it was hypothesized that parental anxiety and parental prediction of the subject's pain would be positively related to the subject's reported pain.[1]

Methods

Design and Subject Selection

This double-blind, placebo-controlled study was conducted in community health clinics in conjunction with ongoing immunization programs. Ninety subjects, aged 4–5.5 years, were randomly assigned to one of three groups: (a) refrigerant topical anesthetic spray; (b) placebo topical spray; and (c) no-treatment control. The dependent measure was the child's self-report of pain.

[a] There are several types of refrigerant topical anesthetics on the market such as Ethyl-chloride, Frigiderm and Fluro-ethyl. Fluro-ethyl was chosen because of its accessibility to health professionals in Canada without a doctor's prescription. To date, there have been no documented side effects that have resulted from the use of Fluro-ethyl.

To control for past experiences and level of cognitive development, the children selected met the following criteria: age 4–5.5 years; English-speaking; not hospitalized within the past year; no known skin allergies or skin condition; experienced routine immunization injections in the past; and demonstrated an understanding of the concept of pain as assessed by three vignettes.

All parents and children meeting the above eligibility criteria were asked to participate in the study. A total of 93 subjects were approached; there were three refusals. Two parents refused to participate in the study due to time constraints and lack of interest; one child refused to participate. A written consent was obtained from the parents and a verbal consent from the child. Once consent was obtained, the children were randomized to treatment groups.

Measures

Pain was measured subjectively by each child using a four-point visual analogue scale (VAS).[17] To eliminate color biases, the measurement tool had a grey background with four white boxes on an anchored line. Each box was the same size, equal distances apart, and assigned a numerical value from 0 (on the far left) to 3 (on the far right). Box 1 was assigned 0 and represented "no pain/hurt;" box 2 was assigned 1 and represented "a little bit of pain/hurt;" box 3 was assigned 2 and represented "a lot of pain/hurt;" and box 4 was assigned 3 and represented "the worst pain/hurt ever."

Parental rating of how anxious needles make them, as well as their prediction of how much pain their child would experience from the injection, were measured subjectively using a horizontal 10-cm VAS. For parental ratings of anxiety, the VAS had "no anxiety" at one end, and "most anxiety ever" at the other end. For parental predictions of their child's pain, a VAS was also used with "no pain" at one end and "worst pain ever" at the other end.

Procedure

Once consent to participate was obtained from the parent and child, Research Assistant #1 assessed each child's comprehension of the concept of pain by presenting the following three vignettes and having the child point to the box on the four-point VAS that most closely represented anticipated pain in each situation. These vignettes were randomly administered so that the direction of the intensity was not consistent. These vignettes also helped to detect response bias and provide reliability and validity for the pain scale.

Vignette 1. You are out playing and spot a big pile of leaves. How much do you think it would hurt to jump in the big pile of leaves?

Vignette 2. You are outside riding on your bicycle and suddenly fall off and skin your knee and it's bleeding. How much would skinning your knee hurt?

Vignette 3. You are getting out of the car, but accidentally slam your fingers in the door. How much would slamming your fingers in the car door hurt?

While this research assistant was assessing the child's concept of pain, Research Assistant 2 was obtaining parental ratings of anxiety and pain. The parent was asked to (a) draw a point on the line that best describes how anxious you are when you have a needle, and (b) draw a point on the line that best describes how much pain you think your child will experience from this needle. The parent was also asked to refrain from asking how the child felt after the injection until the research assistant obtained the child's pain rating of the injection. All the children demonstrated an understanding of the concept of pain and the pain scale as determined by the vignettes.

Research Assistant 1 randomly assigned the children to one of the three treatment groups prior to the injection procedure. The group assignment was not known to the clinic nurse, parent, child, or Research Assistant 2. If the child was assigned to either the refrigerant topical anesthetic or placebo spray group (placebo was compressed air with freon in same size can as the anesthetic spray), Research Assistant 1 would follow this protocol:

1. Tell the child that, "I am going to put something on your arm that will feel cool, but may really make the needle hurt less."
2. Spray the sterile cotton ball with the spray for a count of ten. Lightly hold the cotton ball against the injection site for 10 sec (tell-

ing the child it would be there for a count of 10 and would the child count out loud with me), then remove the cotton ball.

3. As soon as the cotton ball is removed, the clinic nurse administers the injection.
4. After the injection is complete, Research Assistant 1 leaves and Research Assistant 2 enters and asks the child to show her how much the needle hurt by pointing to one of the four boxes on the VAS introduced prior to the study.

If the child was assigned to the no-spray control group, Research Assistant 1 still entered the room and left when the injection was complete, but the child did not receive an intervention prior to the injection. Research Assistant 2 still asked the child to rate the hurt of the needle following step 4 as outlined above.

Variables related to the injection procedure that were held constant were the type and amount of injectable solution, needle size, and the deltoid muscle as the site of injection. The needle length and the injection technique varied among clinics. Due to random assignment, the groups are assumed to be comparable.

Results

Characteristics of the Sample

The sample consisted of 90 children (51 boys, 39 girls) who attended five separate health clinics throughout a western Canadian province. Ages of the subjects ranged from 48 to 66 months, with a mean of 52.42 ± 4.67 months. The treatment groups did not differ significantly on gender ($\chi^2 = 0.81$, $P = 0.66$), clinic ($\chi^2 = 9.82$, $P = 0.28$) or age ($F(2, 87) = 1.85$, $P = 0.16$). In addition, there were no significant differences between clinics for gender ($\chi^2 = 2.08$, $P = 0.72$) and age ($F(4, 85) = 2.54$, $P = 0.05$). Consequently, the groups can be considered to be homogenous on these variables.

Effect of Refrigerant Topical Anesthetic Spray on Injection Pain

The treatment group main effect was significant for pain response ($F(2, 87) = 4.44$, $P = 0.01$). Post-hoc comparisons (Scheffé, $P = 0.05$) indicated that only two of the three groups were significantly different. Examination of the group means (Table 1) indicated that children who received the refrigerant topical anesthetic spray reported significantly less pain from the injection than children who did not receive any spray. Likewise, children who received the placebo spray reported significantly less pain from the injection than children who did not receive any spray. There was no significant difference between the refrigerant topical anesthetic and placebo spray for children's reported pain although the means were in the predicted direction.

Table 1
Mean Pain Scores by Treatment Group

Group	Mean pain score ± standard deviation	*N*
Anesthetic spray	1.37±0.96	30
Placebo spray	1.43±0.97	30
No spray	2.03±0.93	30
Total	1.61±0.99	90

Relationship of Age to Pain Response

Pearson correlation was used to determine the relationship between age and pain response of subjects. This correlation ($r = 0.24$, $P = 0.01$) suggested that as age increased so did reported pain from the injection. This correlation was not in the predicted direction, warranting a closer examination. As there were no reported pain studies on children ranging in age from 48 to 53 months, age was divided into two categories for closer inspection of pain responses (Table 2).

The trends observed in the means indicated that older subjects (54–66 months) reported more pain from the injection than younger subjects (48–53 months) and were more likely to be boys. Of the girls, most were younger (48–53 months). Due to the small number in the older age group, more elaborate statistical analysis examining the age/gender interactions could not be performed.

Relationship of Parental Anxiety and Predicted Pain to Subjects Pain Response

It had been hypothesized that parental rating of anxiety about having an injection and subject's reported pain response from the injection would be positively and significantly related. Pearson correlation did not support this hypothesis ($r = 0.02$, $P = 0.41$).

Table 2
Mean Pain Scores by Age Group and Gender

Age group/ gender	Mean pain score ± standard deviation	*N*
48–53 months	1.53±0.97	62
Boys	1.18±0.87	34
Girls	1.96±0.92	28
54–66 months	1.79±1.03	28
Boys	1.71±1.05	17
Girls	1.91±1.04	11
Total	1.61±0.99	90

It was also hypothesized that parental predicted ratings of their child's pain from the injection and the subject's reported pain response from the injection would be positively and significantly related. Pearson correlation did not support this hypothesis ($r = 0.02$, $P = 0.16$).

Discussion

Effect of Refrigerant Topical Anesthetic Spray on Injection Pain

The purpose of this study was to evaluate the effectiveness of a refrigerant topical anesthetic spray as a noninvasive intervention to reduce injection pain in children. The results support the main hypothesis that a refrigerant topical anesthetic significantly reduces injection pain. Observations made during this study also support the use of a refrigerant topical anesthetic as an acceptable treatment for children. From repeated observations, there also appeared to be a latency to startle with subjects in the anesthetic group compared to the other groups.

The placebo spray was equally effective in reducing injection pain. Since placebos cannot possibly act through a pharmacological route,[32] the influence of cognitive processes on pain perception and response becomes more evident in this study. It is possible the suggestion statement alone was strong enough to produce the observed placebo effect. However, the effects of suggestion were indirectly controlled by standardizing the suggestion statement throughout both treatments and employing a no treatment control group. Other studies have found that suggestion alone did not significantly reduce reported pain from injections in children.[17,28] Melzack and Wall[10] indicate that suggestion itself is not sufficient to produce the entire placebo effect; the belief that something is being done to reduce pain, coupled with the suggestion, provides a stronger placebo effect.

It becomes difficult to separate out the effect of suggestion on placebo response. Many factors can occur together to elicit the placebo effect, such as diminished anxiety, expectation of pain relief, and faith in the person administering the treatment.[31] In addition, the children in this study are in the preoperational stage of cognitive development, which is characterized by prelogical and magical thinking.[33] Therefore, the placebo effect observed in this study may be related to the cognitive level of the children. The suggestion statement that a magic spray was going to be used that might make the needle hurt less coupled with the mechanical intervention, may have heightened the credibility of the pain strategy in the child's mind. Although it is not known how placebos actually work, this study provides further support of their effectiveness in reducing pain.

The finding that pain responses were significantly lower in the placebo-spray group compared to the no-treatment control group provides further evidence of the effectiveness of placebos in reducing pain. This finding was expected because after any treatment that a patient or caregiver perceives as potentially effective, a placebo effect will be observed.[32,34,35]

Relationship of Age to Pain Response

The finding that older children reported more pain from the injection than younger children in this study is contrary to the recent literature.[1,17,29] Due to the restricted age range in this study, the small number of children in the older age group, and a significant but low correlation of 0.24 with pain response, this finding of a positive correlation between age and pain must be interpreted cautiously. Parental presence may have influenced the child's report of pain. Although the parent was asked not to prompt the child about the amount of pain, nonverbal cues may have been communicated to the child.

Relationship of Parental Anxiety and Predicted Pain to Subjects Pain Response

The finding of no significant correlation between parental anxiety and pain response

was surprising because the literature suggests parental anxieties and attitudes toward pain affect the child's perception and reaction to pain.[1,11,12,30,31] There are several possible explanations for this lack of correlation. The lack of variability in the parental rating of anxiety in this study could indicate that a response bias has occurred; mothers in general did not rate themselves as very anxious about receiving an injection. It is possible the mothers did not want to appear to be fearful and anxious about injections when indeed they were. Another possible explanation is the VAS may not have been a sensitive enough measure of anxiety.

The lack of correlation between pain responses of children and the parents' predicted rating suggests that parents are poor at predicting their child's pain. If pain is a subjective experience, this makes sense. The studies supporting accuracy of parental prediction of pain deal with behavioral measures of distress and pain.[1,12,31] It is possible that children, through social learning, model behavior the way their parents expect, but actually experience something quite different.

Overall, the results of this study support the use of a refrigerant topical anesthetic spray to reduce injection pain in children. Subjects who received a treatment intervention (either anesthetic or placebo spray) reported less pain from the injection than subjects who did not receive a treatment intervention. This finding also demonstrated the power of cognitive pain strategies in reducing injection pain. Utilizing positive suggestion statements (for example, "This may really help the needle hurt less") often enhances the pain-relieving effects of pharmacological pain interventions and should be employed together. The influence of age on pain response is inconclusive and cannot be fully explained with the data available.

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