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THE EVALUATION OF PAIN EXPERIENCED BY CHILDREN UNDERGOING SIMPLE EXTRACTION USING 2% LIDOCAINE VERSUS ORAQIX TOPICAL ANESTHETIC GEL

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SIMPLE EXTRACTION USING 2% LIDOCAINE VERSUS ORAQIX TOPICAL

ANESTHETIC GEL

A Thesis submitted in partial fulfillment of the requirements for the degree of Masters of Science in Dentistry at Virginia Commonwealth University.

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Abstract

The Evaluation of Pain Experienced by Children Undergoing Simple Extraction Using 2% Lidocaine versus Oraqix Topical Anesthetic Gel.

By John Jason Haffner, DMD

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Purpose: The purpose of this study is to examine the pain response experienced by children undergoing simple tooth extractions using 2% Lidocaine injection versus Oraqix topical anesthetic gel.

Methods: This study is being conducted at VCU pediatric dentistry clinic. The sample size will consist of 15 children ages 7-12 undergoing a simple extraction procedure. Each participant is randomly assigned to one of two groups, the lidocaine injection group or the Oraqix topical group. The pain level will be measured at four key

events during the procedure. The first event will evaluate the pain at baseline. The second event will measure pain during the anesthetic injection or Oraqix topical gel application. The third event will record the response after the tooth has been extracted and the final event will evaluate pain five minutes post operatively. The children are asked to rate their pain using the Facial Pain Scale after all four events. The dentist and an independent observer watching a video of the extraction will also examine and rate the pain responses of each child at each of the four events.

Results: The first two participants received lidocaine injection and experienced some pain upon injection. This pain was supported by what the dentist rated as well. One child felt pain on extraction and the other felt nothing. The dentist rated both children as feeling pain. The Oraqix child felt nothing upon application but felt pain during the extraction and post-operatively. The dentist rated the child as feeling nothing during the entire procedure.

Conclusions: It appears that the lidocaine injection group's pain rating matches the pain rating given by the dentist. The Oraqix patient experienced no pain upon application, but did feel pain upon extraction and five minutes post-op. The dentist's rating contradicted this by rating the child as feeling no pain through the entire procedure. This study is limited by the number of participants and needs more patients to further evaluate other children's pain responses.

INTRODUCTION

There is one constant symptom dentists see when treating children and that symptom is pain. Often, the primary reason a patient seeks treatment is due to their dental pain.1 It is often difficult for children to convey their feelings of pain due to its subjective nature and be able to separate it from other symptoms like fear, anxiety, or fatigue.[1,2] Most pain studies have been done with adults due to their ability to reliably convey how they feel.[3] The severity of pain in children has been assessed in the past using parents, observers, or the dentist.1 There are several studies showing that children as young as ages 4-6 are indeed capable of reliably expressing their pain.[1,2,3] A study by Acs et al. stated that "children represent a group in which the subjective nature of the pain response may be minimized due to minimal exposures to pain." It may be difficult for a child to report in words how they feel due to their limited life experiences.

A study by Acs et al., examined the extent of surgical trauma and post extraction pain in children. A survey was completed by parents who were instructed to ask their children about pain. 37.6% of children in the study group reported pain. There was a control group consisting of 20 children who received prophylaxis and fluoride treatment. This group reported no pain. This was considered significant. The authors found that the older the group of children the more likely to report pain. As the number of extractions

increased so did the number of children reporting pain. Only 34.8% of children receiving 1-2 extractions reported pain, but that number increased to 60% when 3 teeth were extracted. The dentist rated each extraction case by a degree of difficulty (DOD). As the DOD increase so did the report of pain. 60% of patients undergoing a more complex single tooth extraction reported pain. They concluded that the DOD was a predictable method to asses post operative pain in children.

Pain Scales

The majority of pain studies used with children have used nonverbal scales of reporting pain. Some examples of these scales are the visual analogue scale or VAS, or the faces pain scale or FPS.[1,2,4-6] The VAS is a scale that uses numbers, color shading, or some other volume to represent the amount of pain with 0 at the bottom representing no pain all the way up to 10 or more representing more pain. This type of scale has been shown to be understood by children as young as 4.[1,6] The FPS uses faces with different expressions that represent pain levels and the child is asked to pick the face to represent how they feel.[1,2] A color analogue scale can was also used in conjunction with the VAS in one study to represent pain. The child would slide their level of pain up the color scale and it coincided with a nominal level on the VAS. In a study done by Barretto et al. that evaluated toothache severity in children using the visual analogue scale of faces (VASOF) found that 39% of the children experienced intense pain. This pain was associated with children who cried because of the pain, were awakened due to pain, and who could carry out normal tasks. Also the children with lower pain scores on the VASOF were shown to have conditions not associated with pathosis. There was no difference associated with age or

gender in this study. The study concluded that the scale was successful at assessing children's pain associated with a toothache.[1] In a study done by Versloot et al., an assessment of pain by the child, dentist, and independent observer during anesthetic injection was evaluated. In this study pain was clearly defined as any sudden change in behavior like crying, crying louder, or closing eyes. The authors wanted to separate this from distress, which was defined as a stress behavior that might not be the result of pain. This may include fear or fatigue. The child's pain during the injection was reported by the child to the dentist and to the parent independently. The dentist also rated their observation of pain and so did an independent observer watching a videotape of the pain. The dentist and observer rated each injection for pain and for distress. The results showed no correlation between age and gender for pain. Dentists assessed pain significantly lower than the observers, the children's report to the dentists, and the children's report to the parent. They concluded here that what others reported as pain, the dentist reported as distress. The authors discussed that health care professionals who do painful procedures often develop pain blindness. There was a strong correlation between the child reported pain and pain reported by the observer. The authors also reported a moderate correlation between the amount of stress and pain intensity reported by the child during the anesthesia phase. These authors concluded that the observation of a child by videotape was the best way to accurately assess pain and keep from discriminating from distress.[2]

Topical Anesthetics

There have been several studies that looked at using topical anesthetics to reduce the pain felt by children during a dental procedure. One study by Kreider discussed that if

you are able to reduce the injection pain for the child you will make the procedure more comfortable and easier on the patient.[7] Another study done by Primosch compared benzocaine 20% gel to EMLA cream (2.5% lidocaine and 2.5% prilocaine) in their ability to reduce palatal injection pain. Both agents showed similar pain responses by the patients on the VAS, but the benzocaine gel was preferred by the patients due to its better taste. The authors discussed the idea that topical anesthetics actual efficacy in reducing pain is still in dispute, but argued that acute pain can be influenced by several factors including fear, anxiety, and trust. If the patients believe that the topical anesthetic works, the anxiety felt by the patient before injection is reduced.6 One study done by Lim and Julliard evaluated the efficacy of EMLA topical and sealant placement using a rubber dam. This study is interesting because it looked at comparing a topical anesthetic to a placebo cream used in the same mouth of each child patient. The EMLA cream and the placebo cream were placed on opposite sides of the mouth before rubber dam clamp placement for 5 minutes. The pain response of the clamp placement was recorded after each clamp was placed using the facial pain scale. The authors found that the EMLA cream significantly reduced pain over the placebo cream used. They also concluded that age and gender were not significant in any way.[8] This study gave validity to the fact that topical anesthetics can benefit the pediatric patient.

The purpose of this study is to evaluate the pain responses of children undergoing a simple tooth extraction using 2% Lidocaine or Oraqix topical anesthetic gel. It is important to assess the pain experienced by children undergoing dental procedures. Any

information collected that could accurately measure a child's pain experience could benefit the child and the dentist making that experience or future experiences better for both.

Methods

Design

This study is a cross-sectional study. This study examines the pain responses of children undergoing simple tooth extractions using 2% Lidocaine injection or Oraqix topical anesthetic gel. Each participant is randomly assigned to one of two groups, the lidocaine injection group or the topical Oraqix group. The dentist extracting the tooth will be blinded to the anesthetic the patient receives. A separate dentist will administer the topical anesthetic (lidocaine injection or the Oraqix gel). The pain level will be measured at four key events during the procedure. The first event will evaluate the pain at baseline. The next event will evaluate pain after the anesthetic injection or Oraqix gel application. The third event will record the response after the tooth has been extracted. The fourth event will evaluate any pain felt five minutes post operatively. The children, dentists, and observer will all rate each pain interval using the Wong-Baker faces pain scale. This scale is shown in figure 1. The independent observer will rate the pain of the child while watching a videotape of the procedure.

Sample and Data Collection

The study is being conducted at the VCU School of Dentistry Pediatric Dental clinic. The sample size will consist of n=30 (n=15 for each type of anesthetic) children ages 7-12 undergoing a simple extraction procedure. Each child requires youth assent and

parental informed consent to be able to participate in the study. Pain for the purposes of this study is defined as any sudden change in behavior during or right after the tooth extraction. After the tooth is extracted, the child will be shown the facial pain scale and asked to pick the face that relates to his or her pain experience. The dentist performing the extraction will also assess the child's pain experience using the Wong-Baker pain scale. An observer watching a videotape of the extraction will also rate the child's experience using the same Wong-Baker pain scale. In addition to pain response the child's age, gender, use of nitrous, and tooth number extracted will be recorded. Each participating child will be assigned an individual identification number for confidentiality. The clinical research form (CRF) will not contain any individual identifiers.

Analysis

Data is collected from the child's pain response and also the responses of the dentist performing the extraction and the observer watching the video tape. The pain responses between types of anesthetic will be compared using a Chi-square analysis.

Results

At this point, three patients have enrolled in the study. The children were asked to evaluate their pain experience four times during the procedure using the Wong-Baker faces pain scale (Figure 1). Table 1 shows each child's response to the injection/Oraqix application at each interval. An example of Oraqix application can be seen in figure 3. Table 2 shows each child's response to the extraction. Table 3 shows the dentist's evaluation of pain during the injection and during the extraction. For the patient that was successfully videotaped, the observer's evaluation of pain during the injection and during the extraction is included in table 2 as well.

Discussion

Each patient was asked to choose the face that represented their pain and those were recorded on the clinical data sheet. Both patients were injected with 2% lidocaine and another operator extracted each tooth. As expected both patients pointed to the face that represented "no pain" or score 0 for before injection and both also picked score 3 or "hurts even more" for during the injection. The other scores were the same except for the interval of during the extraction where one child picked 2 for "hurts a little more" and the other child picked 0 representing "no pain." This was interesting because the dentist extracting picked the selection 3 representing "modest pain" for during the injection. The patient's facial expression changed and she groaned a little during the extraction. An observer or operator would most likely relate this reaction as a pain reaction, but the child picked no pain. It was the operator's opinion in this case that the child may have been trying to please the dentist and give them a positive response. If this had been videotaped, the observer would have been able to independently give their opinion. The last case was successfully videotaped. One dentist used Oraqix and extracted the tooth. The child gave all answers coinciding with "no pain" until he was asked about pain during and after extraction. At these intervals the child gave answers of "hurts even more" and "hurts a whole lot" respectively. This differed from what the operator rated the pain during these time periods. The operator gave the child a 1, which represented "no pain." The

independent observer rated the child's pain experience the same as the dentist in this situation.

A limitation to the study that needs to be addressed is the rating scale of the dentist and observer. The Wong-Baker scale uses numbers that coincide with each face on the scale. These numbers represent an amount of pain with 0 representing no pain and 5 representing the worst pain. There are other pain scales that may be more suitable to provider/observer ratings of pain such as the FLACC scale which rates both pain and movement and responses to procedures.[9] Each of the five categories for the FLACC scale are: (F) Face; (L) Legs; (A) Activity; (C) Cry; (C) Consolability is scored from 0-2, which results in a total score between zero and ten.

Another limitation is the inability to get reliable data on some patients who are just too fearful during the procedure. These patients have too much anxiety before the procedure begins and this anxiety can influence their responses. These patients should be excluded from the study. The purpose of this study is focused on a patient's pain response and not their response to fear or distress. Distinguishing between pain and anxiety is beyond the scope of this study.

A limitation with using this product to deliver anesthesia to children is the fact the delivery system looks almost exactly like a typical syringe with needle attached to it. This is shown in figure 2. The delivery tip is basically a hollow tube with no point attached to the delivery system. This tube looks exactly like a needle; it just doesn't have a point on it. The drug is expressed out the hollow tube into the area of intended use. Most children will not be able to differentiate this from a typical syringe and may become very fearful if

allowed to see this coming. If all the data suggests that this is indeed a safe product for children, then a more child friendly delivery system may need to be developed. With a little imagination and creativity, a more child friendly system could easily be created. This would further alleviate any anxiety the child may already be going through and further enhance the possibility of this product being a better alternative to local anesthetic injection in certain procedures.

The manufacturers of Oraqix recognize the fact that their product can be used off label in pediatric dentistry to alleviate the pain and anxiety related to dental treatment. Currently, Oraqix does not have safety information on children under 18. There is no current data that exists that shows how much of the drug is absorbed into the blood stream of pediatric patients. Although it is believed to be very small compared to a perioral injection, no true levels have been recorded. A study to assess the pharmokinetics of Oraqix is needed. This proposed study is the beginning of what could be a new way to deliver anesthesia to children. It will provide the scientific data needed to prove whether this drug is safe for children.

Literature Cited

Literature Cited

1. Barretto, E. (2004). Evaluation of Toothache Severity in Children Using a Visual Analogue Scale of Faces. Pediatric Dentistry, 26(6), 485-491.

2. Versloot, J. (2004). Assessment of Pain by the Child, Dentists, and Independent Independent Observer. Pediatric Dentistry, 26(5), 445-449.

3. Acs, G. (1988). The Extent of Trauma and Post extraction Pain in Children. Pediatric Dentistry, 10(3), 210-214.

4. Needleman, H. (2000). Reports of Pain by Children Undergoing Rapid Palatal Expansion. Pediatric Dentistry, 22(3), 221-226.

5. Roghani, S. (1999). Evaluating the Efficacy of Commonly Used Topical Anesthetics. Pediatric Dentistry, 21(3), 197-200.

6. Primosch R. (2001). Comparison of Topical EMLA 5% Oral Adhesive to Benzocaine 20% on the Pain Experienced During Palatal Anesthetic Infiltration in Children. Pediatric Dentistry, 23(1) 11-14.

7. Kreider, K. (2001). Reducing Injection Pain: Lidocaine Patches Versus Topical Benzocaine Gel. Pediatric Dentistry, 23(1), 19-23.

8. Lim, S. (2004). Evaluating the Efficacy of EMLA Topical Anesthetic in Sealant Placement With Rubber Dam. Pediatric Dentistry, 26(6), 497-500.

9. The FLACC: A behavioral scale for scoring postoperative pain in young children, by S Merkel and others, 1997, Pediatric Nurse 23(3), p. 293-297.

Figure 1: Wong-Baker faces pain rating scale

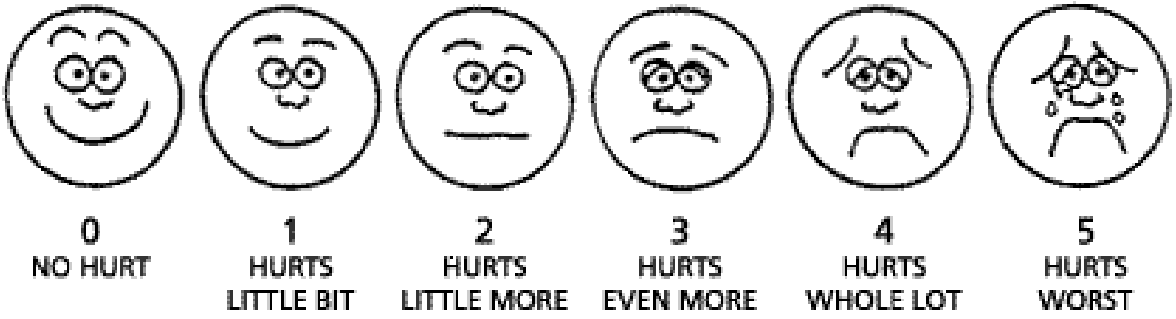

Figure 2: Oraqix Applicator

Figure 3: Oraqix Application

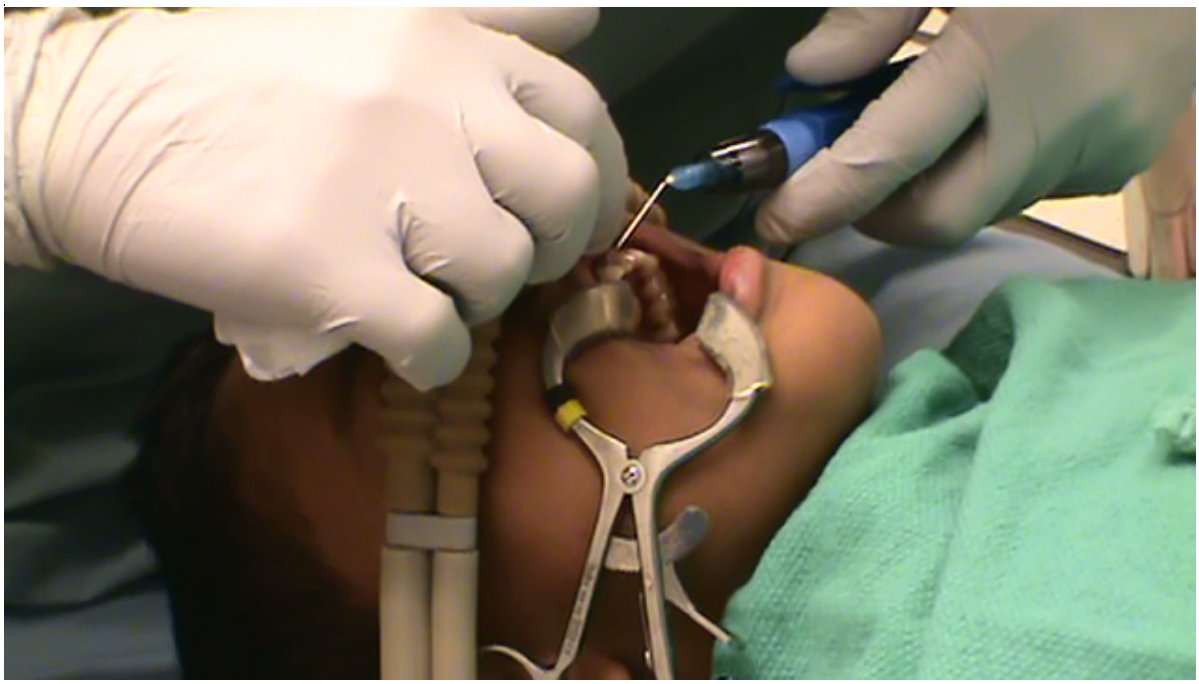

Table 1: Children's injection/Oraqix pain rating using Wong-Baker faces pain scale

Baseline	Before injection	During injection	5 min. post injection
0	0	3	0
0	0	3	0
0	0	0	0

Table 2: Children's extraction pain rating using Wong-Baker faces pain scale

Baseline	Before extraction	During extraction	5 min. post op.
0	0	2	0
0	0	0	0
0	0	3	4

Table 3: Dentist and observer's pain rating using Wong-Baker Pain Scale

Child	Dentist rating during injection	Dentist rating during extraction	Observer rating during injection	Observer rating during extraction
1	3	1	NA	NA
2	3	3	NA	NA
3	1	1	0	0

VITA

Dr. John J Haffner was born June 11th, 1975 in Shreveport, Louisiana. He spent most of his life growing up in his hometown of Alpharetta, Georgia. Dr. Haffner received a bachelor's degree in business from Florida State University in 1998. In 2007 Dr. Haffner graduated from the Medical College of Georgia School of Dentistry with a degree of Doctor of Dental Medicine. On June 30, 2009, Dr. Haffner will receive his Masters of Science in Pediatric Dentistry from Virginia Commonwealth University School of Dentistry.