Reducing children's injection pain: lidocaine patches versus topical benzocaine gel

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Abstract

Purpose: The purpose of this study was to compare the effectiveness of lidocaine patches and topical anesthetic gel in reducing injection pain in children.

Methods: Thirty-two children received bilateral greater palatine injections of 0.2cc of 2% lidocaine with 1:100,000 epinephrine at the same visit. Injections followed a 15 minute application of DentiPatch™ (20% lidocaine) or a 1 minute application of topical anesthetic gel (Topex, 20% benzocaine). Each child completed a Faces Pain Scale and Visual Analog Scale after each injection and was asked which injection hurt more. Injections were videotaped and two independent evaluators, using the Sounds, Eyes, and Motor Scale, rated observed pain-related behavior. Inter-rater reliability was established at 96%.

Results: A significant difference was shown in observed pain-sounds favoring use of the DentiPatch (P<.003, Wilcoxon Sign Rank Test). Using Wilcoxon Sign Rank Test and paired t-tests, no significant differences were shown in either reported pain or observed pain-motor.

Conclusions: A statistically significant decrease in observed verbal indicators of injection pain was found when the DentiPatch was used 20%: compared to a 1 minute application of topical anesthetic gel. However, no significant difference was found between the two study groups in either reported pain or observed pain-motor responses. (Pediatr Dent 23:19-23, 2001)

Reducing injection pain in children may help to provide overall comfort and well being during the entire dental experience. Pediatric dentists are constantly searching for tools which may provide a more comfortable dental procedure. The challenge is to find an effective method that can be utilized in the pediatric population. A recent study by Wilson et al[1] demonstrated the benefits of electronic dental anesthesia in reducing discomfort as judged by both behavioral and physiological parameters in young sedated dental patients. Topical anesthetics function by blocking signal transmission in the terminal fibers of sensory nerves. Their effects are limited to the control of painful stimuli occurring in or just beneath the mucosa. The literature reports mixed results regarding the efficacy of topical anesthetics in reducing injection pain. Of seven published placebo controlled trials reviewed by Martin, et al,[2] three studies[3-5] found topical anesthetic superior to a placebo, while four studies[6-9] found no difference in the effectiveness of topical anesthetic and a placebo.

Two similarly designed studies[3,8] compared effectiveness of topical anesthetic vs. placebo during injection of 0.3 ml of 2% lidocaine near the greater palatine canal. Bilateral injections were completed at the same appointment after application of either topical anesthetic or placebo. Yaacob[3] reported that topical anesthetic (5% lidocaine) was superior to the placebo while Keller[8] found no difference between topical anesthetics (18 or 20% benzocaine) and placebo in reducing injection pain. Keller alternated injection order and which quadrant received the topical anesthetic while Yaacob did not. Martin et al[2] found injection order influenced patient perception of pain with the second injection being perceived as more painful than the first. However, in pediatric dentistry the use of a topical anesthetic agent is considered commonplace prior to the administration of local anesthesia.

The Noven DentiPatch™ is a non-invasive pain control patch which provides site-specific delivery of anesthesia.[11,12] The current FDA-approved indication for the DentiPatch™ system is the production of mild topical anesthesia of the mucous membranes of the mouth prior to superficial dental procedures. The manufacturer notes that the patch may reduce the pain of injections into the gingiva. The DentiPatch contains 46.1mg of lidocaine (20% concentration) or 23.1 mg lidocaine (10% concentration) which diffuses into the mucosa. Hersch et al[13] found systemic absorption of lidocaine for the 20% lidocaine patch was approximately 10% of that which results from an infiltration injection of 36 mg lidocaine with .018 mg epinephrine. This must be considered in the total calculation of local anesthetic dosage.[14,15] The patch may be left in place up to 15 minutes,[11] at which time maximal anesthesia is produced.[13] Both 10% and 20% lidocaine patches have been found superior to placebo patches in reducing reported pain after insertion of a 25 gauge needle apical to the mucogingival junction in the premolar area in adults.[13,16]

The benefit of the new lidocaine patch delivery system has yet to be evaluated in children. The purpose of this study was to compare the effectiveness of intraoral lidocaine patches and topical anesthetic gel in reducing injection pain in children as measured by a reduction of pain, fear, and anxiety experienced by children during the administration of local anesthesia.

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Table 1. Sounds, Eyes, Motor Scale[17]

Observations	1 comfort	2 mild discomfort	3 moderately painful	4 painful
Sounds	no sounds indicating pain	non-specific sounds; possible pain indications	specific verbal complaints "OW" raises voice	verbal complaint indicates intense pain, e.g. scream, sobbing.
Eyes	no eye signs of discomfort	eyes wide, show of concern, no tears	watery eyes, eyes flinching	crying, tears running down face
Motor	hands relaxed no apparent body tenseness	hands show some distress or tension; grasps chair due to discomfort, muscular tension	random movement of arms or body without aggressive intention of physical contact, grimace, twitch	movement of hands to make aggressive contact, e.g. punching, pulling head away

Methods

Thirty-two patients between 6 and 15 years of age participated in this study. Criteria for inclusion were cooperative behavior, ability to complete the Faces Pain Scale and Visual Analog Scale, ASA Class I, no contraindications to lidocaine or other local anesthetics, and no history of contact dermatitis. The child must have exhibited bilateral maxillary posterior caries in need of operative and/or surgical treatment. The parent or guardian gave written informed consent for the institutionally approved study.

Materials used were the DentiPatch™ (20%) (Noven Pharmaceuticals, Miami, FL), 20% benzocaine topical anesthetic gel (Topex™, Sultan), 2% lidocaine with 1:100,000 epinephrine (Schein, New York), and 27-gauge short dental needles (Monoject, Sherwood Medical, St. Louis, MO). Physiologic monitoring equipment used was the Criticare pulse oximeter Scholar II (Criticare, Waukesha, WI). A Porter nitrous oxide delivery system was used. A wall-mounted video camera recorded behavior during injections.

After a review of the current health status with the parent/guardian, the child was seated in a private operatory and the pulse oximeter attached to the patient. Injection order and determination of which quadrant received the lidocaine patch or topical anesthetic gel was randomly determined. The lidocaine patch was applied to the area of the right or left greater palatine canal for 15 minutes. The nasal hood was placed and baseline heart rate recorded. The patient received 100% oxygen throughout the injection period and until baseline heart rate was attained in the post-injection period. Nitrous oxide was not administered at any time. After 15 minutes, the lidocaine patch was removed and a greater palatine injection of 0.2cc 2% lidocaine with 1:100,000 epinephrine completed. The highest heart rate in the immediate post-injection period was recorded. When baseline heart rate was attained, the nasal hood was removed and the patient completed the Faces Pain Scale and Visual Analog Scale for that injection. The patient was returned to the supine position, the nasal hood placed, 100% oxygen administered for 5 minutes, and baseline heart rate recorded. Approximately 0.1 ml of topical anesthetic (Topex, 20% benzocaine) was applied for 1 minute to the area of the greater palatine canal of the contra-lateral quadrant and the greater palatine injection of 0.2cc of 2% lidocaine with 1:100,000 epinephrine completed. A new 27-gauge needle was used for each injection. The highest heart rate post-injection was recorded. When heart rate returned to baseline, the patient completed the Faces Pain Scale and Visual Analog Scale for that injection. The child was then asked which injection hurt more.

All injections were completed by the principal investigator who attempted consistency in rate of injection and verbal instructions to the patient. This was established by utilizing the lidocaine patch on several patients prior to the initiation of the study. In each instance, the needle was inserted into the tissue with the bevel facing the periosteum. The nasal hood was placed and 100% oxygen was administered to serve as a placebo, a distraction technique, and a visual block of the syringe. Once the greater palatine injections were given, the study portion of the appointment was complete. Buccal infiltrations were then given and necessary dental treatment completed. Verbal post operative instructions were given to the parent and child. The study phase of the treatment was videotaped using a standard video camera mounted on the wall in the dental operatory. The videotape of each session was independently reviewed later by two members of the pediatric dentistry faculty and the patient's behavior during each injection evaluated according to the Sounds, Eyes, Motor Scale as previously outlined by Wright[17] (Table 1). Intra-rater reliability was established at 100% by reviewing a series of videotapes in a training session prior to evaluation of the study videotapes. The following parameters were utilized to evaluate patient's reported pain, physiological pain, and observed patient pain:

Table 2. Statistical Comparisons of Measurements of Pain Response (Lidocaine Patch versus Topical Anesthetic Gel)

	Wilcoxon Sign Rank Test *P* value	Paired t-Test *P* value
Faces pain scale	.2573	.3621
Visual analog scale	.7329	.8258
Heart rate change	.2034	.2122
Heart rate change Topical as 1st injection	.0151•	.0234•
Heart rate change Patch as 1st injection	.6776	.7592
Observed pain-sounds•	.0027•	.0016•
Observed pain-motor	.8438	.6898

•Statistically significant

Reported pain / observed pain

Faces pain scale: Each of the 5 faces on the Faces Pain Scale is assigned a value from 1 (smiling) to 5 (crying). The use of the Faces Pain Scale in children has been validated as a reliable indicator of pain following major surgery.[18]

Visual analog scale: The VAS is a 100 mm line anchored by the words "no pain" at 0 mm and by "worst pain possible" at 100 mm. Scoring is accomplished by measuring in mil-

Fig 2. Reported Pain Visual Analog Scale Results

Gel	33 mm
DentiPatch	34 mm

Paired *t*-test *P*=.83

Fig 3. Heart Rate Change by Injection Order

• 1st injection gel: HR increase 2nd injection patch: HR increase	18% 9% *P*=.02
• 1st injection patch: HR increase 2nd injection gel:HR increase	15% 14% *P*=.76

limeters from 0 to the mark the child made representing the pain perceived during the injection.

Verbal rating: Upon completion of the second injection, the child was asked which side hurt more.

Heart rate changes: Baseline heart rate and the highest heart rate in the post-injection period were recorded for each injection. The percent increase or decrease in heart rate was calculated for each injection. An increase in heart rate has been shown to be a reliable physiologic response to perceived painful stimuli.[19]

Sounds, eyes, motor scale: The score in each category ranged from 1 (none) to 4 (intense). A lower score represents less physical reaction to the injection stimulus than does a higher number. Wright[17] reported that the SEM Scale (Table 1) corresponded favorably to the Frankl Behavior Rating Scale. Two independent evaluators viewed the videotapes and evaluated the patient's behavior during each injection. Pain related behavior in the categories of sounds and motor was rated. Eye indications of pain were not rated due to inability to accurately observe such signs on the videotape. Inter-rater reliability was excellent, as established by a kappa statistic of 96%.

Results

Participants in the study had an average age of 9 years, 2 months (± 30 months) with an age range of 6 years, 2 months to 15 years, 9 months and included 17 females and 15 males. The numerical difference in the score for each child's pair of injections was analyzed using the Wilcoxon Sign Rank Test and the paired *t*-test. Results of statistical analyses are shown in Table 2. There was no statistically significant difference between injections which followed topical anesthetic gel or the lidocaine patch in the Faces Pain Scale ratings (*P*=.2573, WSRT). The Visual Analog Scale mean value for topical anesthetic was 32.5 mm, the mean value for the lidocaine patch was 33.9 mm (± 38.2mm) and was not statistically significant (*P*=.7329, *t*-test). Nine children rated the injection which followed topical anesthetic as more painful, 9 rated injections following the lidocaine patch more painful and 14 rated the injections the same. Percentage heart rate change from baseline for all injections was not statistically significant (*P*=.2122, *t*-test). However, when the first injection followed topical anesthetic gel application, the heart rate change for the second injection was significantly decreased (*P*=.0151, WSRT). Injections which followed lidocaine patch application resulted in less intense verbal indications of pain compared to topical anesthetic gel for 12 of the 32 pairs of injections (Fig 1). Figure 1 indicates the differences between the scores of the Sound, Eyes, Motor Scale for the patch and topical anesthetic gel. For example, for three children the observed pain-sounds score for the patch was two rankings lower than for the topical gel. Topical anesthetic gel application resulted in less intense verbal indications of pain for 1 pair of injections. The observed pain-sounds result was found to be highly statistically significant (*P*=.0027, WSRT, Table 2). Observed pain-motor was not statistically significant (*P*=.8438, WSRT).

Discussion

Results showed children made fewer sounds indicating pain when injections followed lidocaine patch application than injections which followed topical anesthetic gel application. This finding is significant and should offer the patch as a viable option for reduction of discomfort during dental injections. Use of the lidocaine patch could lead to reduced stress for the child, parents, staff, dentist, and other children in the office who may benefit through modeling. The use of each patient as his/her own control helps support the findings since the variability in a patient's response to pain is addressed. The comparison of palatine injections also contributes to strength of the findings since this is an injection that is perceived to be of relatively greater discomfort.

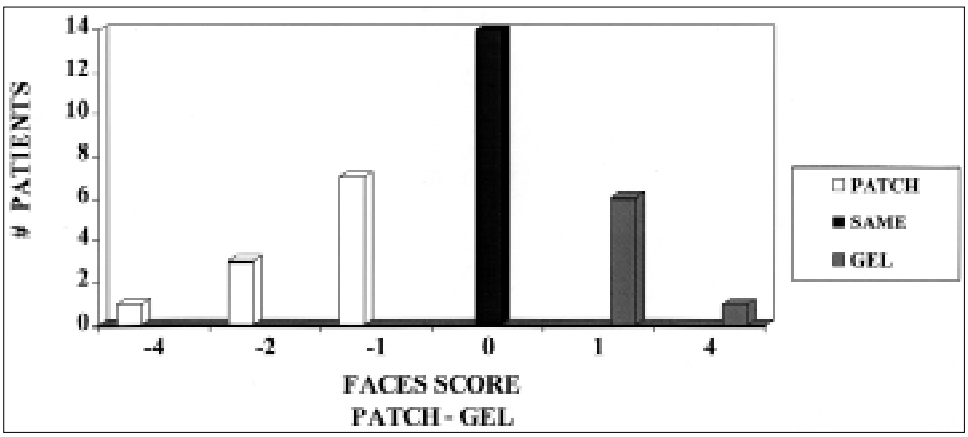

Fig 1. Individual Faces Pain Scale Results. Wilcoxon Sign Rank Test P=.26

Change in heart rate has been shown to be a reliable indicator of a patient's response to pain. Results showed when the first injection followed topical anesthetic gel, there was a significant lessening of heart rate increase for the second injection which followed patch application. Second injections have been found to be more painful than first injections.[2] The results obtained indicate the patch was able to provide superior anesthesia, which negated the expected increased heart rate.

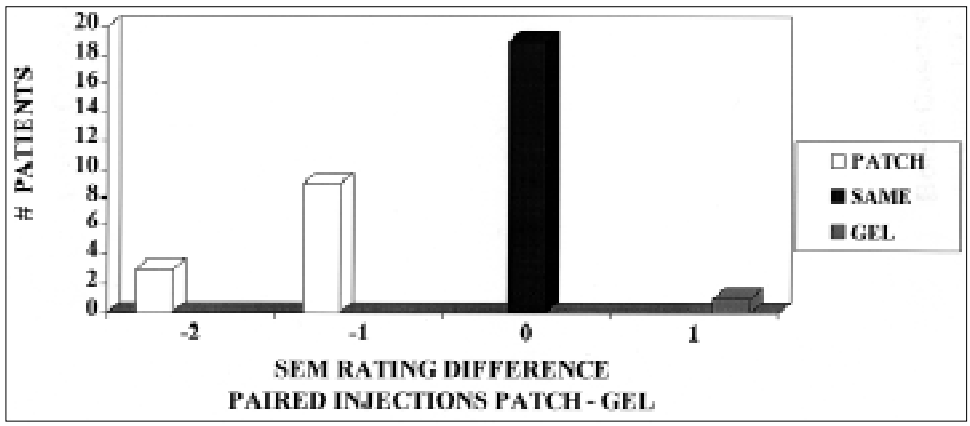

Fig 4. Individual Observed Pain-Sounds Results. Wilcoxon Rank Test *P*=.0027

The time required for maximum effectiveness of the lidocaine patch presented some clinical problems. Several children cried quietly during much of the 15 minute patch application period. The results of the study might be different for very apprehensive children versus calm children and a pre-operative assessment of the child's anxiety level could be included in future studies to determine if the lidocaine patch is suitable for use in anxious children. The patch is easily dislodged during the 15 minutes application period if not kept dry. Further studies could determine if a shorter lidocaine patch application period would provide the same results.

Evaluation of the data gathered from the Faces Pain Scale and the Visual Analog Scale indicates self-evaluation of pain, while documented in several studies post-surgery, may not be a valid measurement of perceived pain in pediatric dental patients. In this study, the Faces Pain Scale and Visual Analog Scale were completed after the painful event while studies which have found self-evaluation of post-surgery pain to be a reliable indicator of pain involve completing the scales during the painful event. [10,18]

Many patients made no sounds indicating pain during injections following lidocaine patch application until very near the end of the injection. When sounds indicating pain were observed following topical application, the sounds were often made almost immediately upon needle insertion through mucosa. A possible explanation may be that the lidocaine patch provided more profound anesthesia than topical anesthetic. However, pain was experienced near the end of the injection when the volume of anesthetic exceeded the area anesthetized by the patch. The Sounds, Eyes, Motor Scale does not differentiate between the onset of indications of pain.

The patch as manufactured is 8mm X 26mm. A change in the patch configuration to 16 mm X 13 mm might result in decreased pain during injection by reducing pain caused if the volume of anesthetic injected exceeds the periphery of the patch as currently manufactured. Such a patch modification would not change the amount of lidocaine in the patch.

It was noted after removal of the lidocaine patch the area anesthetized was not readily evident while tissue anesthetized by topical anesthetic gel was easier to visualize. The incorporation of a dye or other indicator into the patch could facilitate injection. Since the present study was the first to evaluate the patch delivery system in children, additional studies are needed to investigate these modifications.

Conclusions

1. There was a statistically significant difference favoring the use of the lidocaine patch (20%) in the category of observed pain-sounds. However, there were no statistically significant differences in reported pain (Faces Pain Scale, Visual Analog Scale, Verbal Rating), overall heart rate increase, or observed pain-motor when comparing the lidocaine patch and topical anesthetic gel (20% benzocaine).
2. When second injections followed lidocaine patch application, the increase in heart rate was significantly lessened.
3. Although the Dentipatch™ clearly has limitations in pediatric dentistry, further studies are needed to determine its clinical usefulness.

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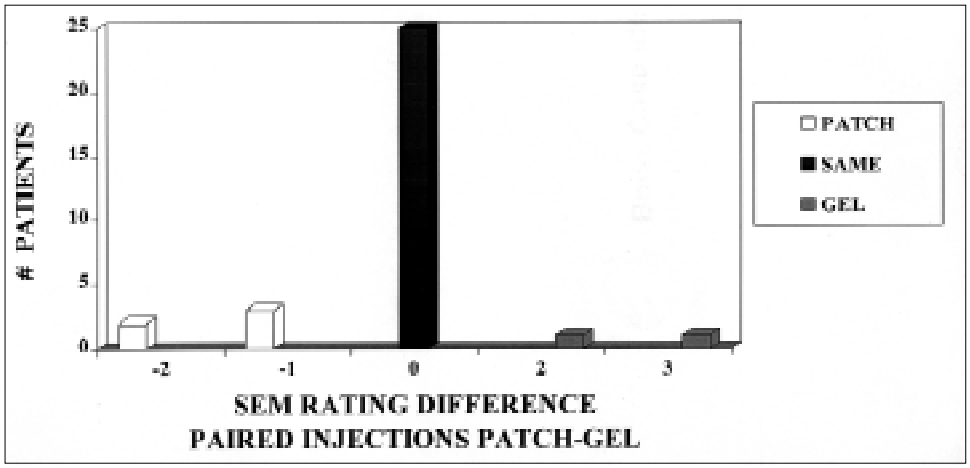

Fig 5. Individual Observed Pain-Motor Results. Wilcoxon Sign Rank Test *P*=.8438

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Abstract of the Scientific Literature

Day Care Attendance and Risk of Asthma During Childhood

Both the incidence and prevalence of asthma among children have increased dramatically in the last three decades. Young children with older siblings and those who attend day care are at increased risk for infections which may in turn protect them from the development of allergic diseases, including asthma. In this study, 1035 children, followed since birth as part of the Tucson Children's respiratory study, were evaluated to determine the relationship between a physician's diagnosis of asthma and the prevalence of frequent wheezing to the number of siblings at home and attendance at day care during infancy.

The presence of one or more older siblings at home protected against the development of asthma between age 6-13 as did attendance at day care in the first six months of life. Interestingly, while children with more exposure to older siblings or other children had more episodes of wheezing at age 2 than children with little or no exposure, they were less likely to have frequent wheezing at age 6-13. The authors conclude that exposure of young children to older children at home or other children at day care may protect against the development of asthma and frequent wheezing later in childhood.

Comments: This paper presents a rather interesting conclusion that emphasizes the complex interactions between upper respiratory infections in childhood and allergic phenomena such as asthma. It also offers yet another perspective on the health implications of early attendance at day care. CH

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