Effectiveness of electronic dental anesthesia for restorative care in children

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Abstract

The effectiveness of electronic dental anesthesia (EDA) for pain control during restorative procedures was compared with local anesthetic injection (LA) in 32 children aged 6 to 12 years. Each child selected had two antimere primary or permanent molars requiring similar-sized Class I or Class II restorations. The pain levels during restorative treatment were assessed using a visual analogue scale. Heart rates and behavior were also recorded. A crossover design was used with each child acting as his/her own control. The results showed that overall, EDA was less effective than LA for cavity preparation. The reported pain scores for EDA were higher in permanent teeth for the deeper cavities, and with one of the operators. The pre- or post-treatment anxiety scores were not found to differ significantly between the two restorative appointments. However, children with the highest pretreatment scores were more likely to report higher pain scores with EDA. Despite this, 63% of the children preferred EDA to LA. Dental anxiety, cavity depth, the tooth being treated, and operator attitude may also be important factors in determining the success of EDA. (Pediatr Dent 20:2 105–111, 1998)

Pain control is an important part of pediatric dentistry. Although most children can cope with local anesthetic injections, a few children are needle-phobic, and giving them an injection presents a challenge to the dentist. For other children, the paresthesia which may linger for hours after the completion of the dental procedure is more objectionable than the injection. In the past decade, there has been renewed interest in the applications of electronic pain control in dentistry and several electronic dental anesthesia machines are currently being advertised and used.[1–3]

Mechanism of action of transcutaneous electrical nerve stimulation

In 1967, Shealy[4, 5] first introduced the use of transcutaneous electrical nerve stimulation (TENS) to help control chronic pain. The explanation of the mechanism by which TENS produces anesthesia is based on several theories describing mechanisms of pain trans-

mission. The gate control theory states that activity generated by myelinated primary afferent fibers (the A fibers) inhibits the transmission of activity in the small unmyelinated primary afferent fibers (the C fibers), acting via inhibitory circuits in the dorsal horn.[6] In addition to activating local inhibitory circuits, one possible explanation for the effectiveness of TENS is that the electrical stimulation causes release of pituitary and hypothalamic opioid peptides into the systemic circulation or into the cerebrospinal fluid.[7] Another theory is that serotonin, dopamine, and nor-adrenalin, which may have roles in the effects of electrically produced analgesia, are produced.[8] Drugs affecting these neurotransmitters have been shown to alter analgesia produced by stimulation or opioids. The exact mechanism of TENS remains unknown and may be a combination of one or more of the theories. Woolf and Thompson[6] believe that the most likely mechanism is the activation of segmental inhibitory circuits in the spinal cord supplemented by descending inhibitory pathways.

Effectiveness of electronic anesthesia in dentistry

TENS devices have been used to control the pain of trigeminal neuralgia or atypical facial pain, and to relieve muscle spasms in myofascial pain dysfunction.[1] Results of clinical studies are limited and extremely varied.[1, 2] In the mid-1980s, several devices were developed for dentistry. These were TENS units modified for intraoral use. Malamed et al.[9] used the term electronic dental anesthesia (EDA) when referring to the application of TENS to dentistry. In their study, they reported a success rate of more than 80% for shallow and moderately deep restorations. The success rate for deep restorations was 60%. The EDA device is a modified TENS unit which uses lower currents and higher frequencies.

One reported indication for EDA is for needle-phobic children even though only a few studies have tested its effectiveness in children. In a double-blind study of the effect of EDA in 30 children using electric pulp testing and rubber dam clamp application as the stimuli, Abdulhameed et al.[10] found a significant rise

in the pain threshold when EDA was used. The subjective pain scores of the children and the assessment of the children's pain levels by the investigator were not significantly different from measurements when an inactive machine was used. Harvey and Elliot[11] evaluated pain perception in 20 children during Class I amalgam preparations on permanent mandibular first molars. They reported a significant decrease in pain perception with EDA compared with a placebo inactive machine. Reported pain with EDA increased when deeper cavity excavation was necessary.

teDuits et al.[12] compared the effectiveness of EDA with conventional local anesthesia for restorative procedures in 27 6- to 12-year-old children. They found no significant differences between the effectiveness of EDA and local anesthesia. The dental procedures were rubber dam application and preventive resin restorations, which may be painless without anesthesia. In another study, Jedrychowski and Duperon[13] tested the effectiveness of EDA in restorative procedures on 40 children. Only two children reported moderate discomfort requiring injection of local anesthesia to complete treatment. These two children still reported discomfort after local anesthesia.

Recently, the 3M company introduced an EDA device which uses extraoral electrodes (3M Dental Electronic Anesthesia System 8670). The extraoral electrodes eliminate the inconveniences of intraoral electrodes such as difficulty in application, obstructed field of operation, and easy detachment. Croll and Simonsen[14] reported use of the system in 45 children aged 3 to 13 years. Thirty-seven children having procedures including extraction of primary teeth with resorbing roots or Class II restorations were successfully treated with EDA alone. No control group was used. More recently, Segura et al.[15] investigated the effectiveness of EDA for "moderate" procedures (14 Class II restorations and one stainless-steel crown) in primary molars of 15 children aged 7 to 12 years. The children's past experiences with restorative procedures under local anesthesia were used as the control. Minimal pain was reported in most procedures and 14 of the 15 children said they preferred EDA to local anesthesia. Sasa and Donly[16] compared the effectiveness of EDA to local anesthesia in 17 children aged 6 to 14 years. The procedures included Class II restorations or stainless-steel crowns with and without pulpotomies. Sixty percent of the patients stated that they preferred LA to EDA, which was only abandoned in four cases. Of the children who preferred LA, 70% received restorative procedures in the mandible, including stainless-steel crowns and pulpotomies.

Methods

The present study was carried out in the clinics of the Healthcare Otago School Dental Service in Dunedin, New Zealand. After obtaining approval from the Southern Regional Health Authority Ethics Committee, 32 healthy children aged 6–12 years who had two primary or permanent antimere molars with similarly sized carious lesions were selected. The teeth had no recorded history of trauma or pulpitis. Informed written consent was given by the parents and the children were invited to take part and give their assent. Dental treatment was provided by three dental therapists (school dental nurses) trained by the principal investigator to use the 3M Dental Electronic Anesthesia System 8670.

A crossover study design was used. The antimere teeth were restored in two separate visits with random selection of use of EDA or LA. The principal investigator was present at each appointment to ensure the set procedures were followed and to record the observations and measurements. For the control visits, anesthesia was given by infiltration for the maxillary teeth and inferior nerve block for the mandibular teeth. Throughout the study, local anesthesia was referred to as sleepy juice ("shot" is not a term known by these children). Cavity preparation began after 5 min. Injections were repeated if the anesthesia was not effective.

EDA was referred to as using the "funny stickers" throughout the study. When using EDA for mandibular primary teeth, the electrodes were placed over each mental foramen and for mandibular permanent molars, they were placed over the apices of the last molar and over the mental foramen ipsilaterally, with at least 0.5 in in between. For maxillary primary molars, the electrodes were placed over the apices of the primary molars just below each zygoma and for permanent maxillary molars the electrodes were placed over the apices of the last molar and just below the ipsilateral zygoma, with at least 0.5 in in between.

The EDA machine was set to the maximum frequency (140 Hz) and pulse width (250μs) as recommended by the manufacturer. A pilot study carried out prior to the main study established that acceptance was greatly improved when the children were allowed to control their own current output. The children were asked to increase the output from the EDA until they felt significant tingling. The amplitude was reduced slightly for 20 s with the principal investigator's guidance and then gradually increased again until there were signs of involuntary muscle movements near the electrodes. The amplitude was kept at this level if the child reported they were comfortable. Cavity preparation began immediately and the children were told to increase the amplitude if they felt pain during the procedure.

Analgesic effectiveness was measured using a visual analogue scale (VAS) where one end represented "no pain" and the other represented "worst pain". The children positioned a sliding bar to indicate their lev-

els of pain. The degrees of pain were recorded as the distance from zero when the tooth was probed by an explorer. The procedure was halted to allow the children to score after the cavity preparation was complete and after the restoration had been placed and completed. The children were encouraged during the procedures to concentrate on adjusting the EDA machine to obtain the best comfort. Children's anxiety levels were recorded at the beginning and end of each visit using the Venham Picture test.[17] Information about their previous dental experiences were also recorded. This was obtained from the clinic records and from the therapist if she had met the child previously. The children were asked if they had had local anaesthesia or TENS/EDA previously for dental or medical treatment. The TENS/EDA was shown and described to help the children's memories. Behavior was assessed throughout the procedure using the Frankl Scale.[18]

Pulse rates were recorded using a pulse oximeter (Pulse Oximeter 503, Criticare System Inc) to evaluate changes in physiological arousal (Table 1).

The depths of the cavities were measured with a graduated periodontal probe and the cavities in permanent teeth were classified according to the criteria by Malamed et al.[9] as shallow, medium, or deep (< 0.5 mm, 0.5–2 mm, or > 2 mm into dentin, respectively). The classifications for primary teeth were slightly modified to shallow, medium, and deep (< 0.5 mm, 0.5–1.5 mm, or > 1.5 mm into dentin, respectively).

After both visits were completed, the children were asked about their preferred method of anesthesia and the reasons. They were asked if they preferred the funny stickers (EDA) or the sleepy juice (LA). As previously mentioned, children in New Zealand do not use the term "shot" for an injection. At the completion of study, each dental therapist's reactions to the use of EDA were evaluated. Their responses were correlated with the acceptance of EDA by the children.

The data were analysed as a crossover trial using ANOVA and adjusting for a period effect using SAS System (SAS Institute Inc.). Changes in heart rate were examined by including pretreatment heart rate as a covariate in the model. The effects of age, anxiety, operator, cavity

TABLE 1. RECORDING OF MEASUREMENTS DURING DENTAL TREATMENT

	Before	Probe Speed	High Speed	Slow	Hand Finish	Cavity Band	Matrix	End	Out of Chair
Anxiety Score (0–8)*	X								X
Pain (0–100)†		X				X		X	
HR	X	X	X	X	X	X	X	X	
Behavior (1–4)‡	X	X	X	X	X	X	X	X	
Cavity Depth§						X			

* Venham anxiety test,[17] † Visual analogue scale, ‡ Frankl scale of behavior,[18] § Measured by graduated periodontal probe.

TABLE 2. STUDY POPULATION

Gender	N	Age Range (Years)	Teeth Treatment (Cavity Classification)						
			3/14	19/30	18/31	A/J	B/I	L/S	K/T
Female	14	6–12	4 (4 cl II)	4 (4 cl I)	4 (2 cl I)	8 (8 cl II)	8 (8 cl II)	2 (2 cl II)	
Male	18	6–12	10 (6 cl I 4 cl II)	6 (4 cl I 2 cl II)	–	6 (2 cl II 4 cl II)	4 (4 cl II)	4 (2 cl II 2 cl II)	4 6 (2 cl I 4 cl II)

cl I : class I amalgam, cl II : class II amalgam.

depth, tooth type, and tooth position on the differences in the pain scores between EDA and LA during cavity preparation were compared. The results are presented as differences between the methods of anesthesia and their 95% confidence intervals. Before the study was carried out, it was estimated from results of previous studies that using a 5% level of significance, 33 subjects would provide an 80% chance of showing a difference in reported pain scores of half a standard deviation between EDA and LA.

Results

A total of 32 children (14 females, 18 males) aged 6 to 12 years (mean 8.8 ± 2.0 years), each having paired restorations, completed the study. Twenty-five had previous experiences of dental treatment under local anesthesia. None of the children had ever experienced EDA or TENS for any previous dental or medical treatment. The restorative procedures included 40 Class II and 24 Class I restorations. Thirty-eight primary mo-

lars (26 maxillary, 12 mandibular) and 26 permanent molars (14 maxillary, 12 mandibular) were treated. Two cavities were measured as shallow, 36 as medium, and 26 as deep. Details of the restorative procedures are shown in Table 2.

Only three children exhibited negative behaviors (Frankl category 2) throughout the study. One child exhibited negative behavior during cavity preparation with EDA. Two children exhibited negative behavior during both visits. The measurements and observations of pain and anxiety are summarized in Table 3. Because the distribution of the pain scores with probing and the pre- and post-treatment anxiety scores were skewed toward the lower end, natural logarithms were used to normalize data. A significantly higher mean reported pain score was found during cavity preparation with EDA than in cavity preparation with LA ($P < 0.01$). There were no significant differences between the pain scores at the two visits at the beginning or at completion of each restoration.

TABLE 3. MEASUREMENT DIFFERENCES BETWEEN ELECTRONIC DENTAL ANAESTHESIA AND LOCAL ANAESTHESIA

Meaurements	EDA Mean ± SD	LA Mean ± SD	Differences (EDA – LA)	95% Confidence Intervals	Significance[*]
Anxiety (pre-op)	1.7 ± 2.2	1.7 ± 2.2	1.0[†]	0.7–1.5[†]	NS
Anxiety (postop)	1.1 ± 2.3	1.3 ± 2.1	0.9[†]	0.6–1.2[†]	NS
Pain (probe)	9.3 ± 17.0	4.9 ± 10.5	1.5[†]	0.7–3.1[†]	NS
Pain (cavity finished)	47.8 ± 35.5	25.1 ± 25.9	22.9	6.9–38.9	$P < 0.01$
Pain (completion)	14.3 ± 15.2	13.2 ± 20.0	1.0	– 8.9–10.9	NS
Heart rate (pre-op)	92.8 ± 11.3	92.8 ± 10.1	– 0.1	– 5.6–5.4	NS
Heart rate (high speed)	102.0 ± 10.7	104.5 ± 12.7	– 2.5	– 8.5–3.6	NS
Heart rate (slow speed)	94.8 ± 10.7	98.4 ± 12.5	– 3.7	– 10.2–2.7	NS
Heart rate (cavity finished)	90.3 ± 11.1	91.7 ± 11.2	– 2.0	– 7.9–3.9	NS
Heart rate (completion)	87.1 ± 10.7	88.7 ± 10.9	– 1.7	– 7.1–3.8	NS

[*] Differences adjusted for period effect between EDA and LA visits. [†] Differences expressed in terms of ratios of $^{EDA}/_{LA}$ after using log transformation. [‡] NS Statistically not significant ($P > 0.05$).

The pre- or post-treatment Venham anxiety scores were not found to differ significantly between the two visits. Twenty-two children scored 3 or less at each measurement time in both visits. Twenty-eight children had similar pretreatment scores between visits and 29 had similar post-treatment scores. No significant differences were found in absolute heart rates or in changes in heart rate between the two visits. All children showed the highest heart rates during high-speed cavity preparation and the lowest heart rates at the completion of treatment. All children except for two showed pretreatment heart rates within the normal resting heart rates for their ages.[19]

Six treatment procedures using EDA were interrupted because of insufficient pain con-

trol and treatment was completed using local anesthesia. Four of those children showed high pre-treatment anxiety scores. Of the six restorations, two were in maxillary second primary molars, two in maxillary first permanent molars, and two in mandibular permanent first molars. Cavity depths were deep in four and medium in two teeth. Two children reported "worst pain" for the cavity preparations even after LA was administered and one reported the same "worst pain" for cavity preparation of the antimere molar when LA was used.

Table 4 summarizes the pain scores for EDA and LA. Reported pain scores during cavity preparation with EDA were found to be significantly higher than those with LA for permanent teeth ($P < 0.01$), deep cavities ($P < 0.01$,) and with one of the operators ($P < 0.01$). When the pretreatment anxiety was included as a covariate in the model of ANOVA, the reported pain score during cavity preparation was found to be significantly related to pretreatment anxiety ($P < 0.05$). No statistically significant relationships were found between the effectiveness of EDA or LA in controlling pain and the location of teeth (maxillary or mandibular), sequence of treatment, age of children or previous dental experience with LA.

When asked whether they would prefer EDA (funny stickers) or LA (sleepy juice), 20 children (63%) said they preferred EDA to LA. Eleven of them preferred EDA because there was no need for injection, three liked to control the anesthesia, four liked the feeling with EDA, and one preferred EDA because there was no paresthesia after treatment. Twelve children preferred LA because they found LA more effective for pain control. There were differences in the children's acceptance of EDA between the three operators. The

numbers were too small to make statistical conclusions. The operators' support for EDA varied. One was very positive and planned to continue to offer EDA. The other two were more sceptical and felt they would only offer EDA for small cavities in primary teeth or to children who were needle-phobic.

Discussion

The criteria to determine success of EDA have differed between studies. In Hochman's study,[20] success was a self-report of at least 90% pain relief. Other studies using self-report pain scales have allowed some pain in the lower part of the scales.[9, 15, 21] In most studies, success has been determined by whether the procedure was completed with EDA alone.[22, 23] In our study, 81% of procedures were completed with EDA alone, which is similar to the 82% success in the clinical report of Croll and Simonsen[14] but lower than the 100% reported by Harvey and Elliot[11] and the 95% by Jedrychowski and Duperon.[13] Differences in study design and restorative procedures prevent exact comparison, but it should be noted that in Harvey and Elliot's study, only two of 10 children reported "no pain" after the procedure, which suggests that profound analgesia may not be necessary for EDA success. Similarly, Quarnstrom defined the success with EDA as "either the absence of pain, or an acceptable level of pain that the patient tolerates to avoid receiving local anesthesia".[3]

The results of the present study showed a relationship of reported pain scores during cavity preparation with pretreatment dental anxiety, which has also been reported by Quarnstrom and Milgrom[23] and Hochman[20] in adults. The Venham Picture Test, a

TABLE 4. PAIN SCORES RECORDED DURING CAVITY PREPARATION

Subgroups	N	EDA Mean ± SD	LA Mean ± SD	Differences (EDA – LA)	95% Confidence Intervals	Significance[†]
Tooth						
primary	19	36.8 ± 32.8	20.3 ± 23.8	16.8	- 3.0–36.6	NS
permanent	13	63.9 ± 34.3	30.4 ± 25.9	37.5	11.2–63.8	$P < 0.01$
Cavity Depth						
medium/shallow	20	36.0 ± 30.0	23.2 ± 20.5	13.8	- 3.3–30.8	NS
deep	12	67.5 ± 36.4	26.4 ± 31.5	41.1	9.9–72.3	$P < 0.01$
Operator						
A	13	38.8 ± 27.5	24.0 ± 23.2	15.2	- 7.3–37.6	NS
B	9	78.9 ± 27.7	29.1 ± 31.4	53.0	17.4–88.6	$P < 0.01$
C	10	31.4 ± 35.6	20.6 ± 21.9	8.7	- 25.5–42.8	NS

* Differences adjusted for period effect between EDA and LA visits. † NS Statistically not significant ($P > 0.05$).

projective measurement of the children's self-report anxiety which was used in our study, has been shown to be a valid and reliable measurement of situational anxiety in children.[17, 24] No other studies have looked at the influence of children's dental anxiety on the effectiveness of EDA, and the results suggest that measuring pretreatment anxiety may be useful in screening children to determine their possible acceptance of EDA.

The present study employed a crossover design in which children served as their own controls. This design reduced the response variability inherent in studies using separate treatment and control groups. In the study of teDuits et al.[12] placing PRR restorations, there were no significant differences reported between EDA and LA. However in Sasa and Donly's stainless-steel crown and Class II restoration study,[16] the reported pain scores with EDA were significantly higher. With restorative procedures involving the dentin, we found the success rate of EDA to be between the two previous studies. For both pain and anxiety measurements there were large standard deviations which were explained by the fact that the distribution of both scores was positively skewed. For the pain scores there was one extreme outlier and for the anxiety scores there were only three children who scored very differently to the others. Because of the positively skewed distributions, the analyses involved log transformation of the scores which were then analyzed and presented in terms of ratios.

The patient's pain-control preference has also been used as one of the criteria of success.[15, 21, 25] Twenty children (63%) in this study preferred EDA to LA for further treatment. This is lower than the 78% in the study by teDuits et al.[12] but higher than the 40% in Sasa and Donly's study.[16] The variation in preference may be due to the severity of the different procedures. The results of the present study suggest that the effectiveness of EDA may be lower in deeper cavities, which agrees with Malamed et al.[9] Both Donaldson et al.[25] and Malamed et al.[9] have reported that the effectiveness of EDA may be tooth-dependent in adults. Our results suggest that EDA is effective in primary teeth, but we found no differences between maxillary and mandibular molars, which was also reported by Abdulhameed et al.[10] and teDuits et al.[12]

No radiographs were exposed for the diagnosis of caries in this study as they are not routinely used in this school dental service. In further studies, radiographs may allow cavity depths to be matched more closely. EDA and LA could be compared with a nonanesthesia group, although this does not allow antimere teeth to be used and it may not be possible to recruit enough children prepared to have restorative treatment without pain control.

The pattern of heart rate changes we found, where heart rate increased at the beginning of cavity prepa-

ration, was similar to that reported by Myers et al.[26] Decrease in heart rate during cavity preparation with either EDA or LA may reflect relaxation when the patient realizes that anesthesia is adequate and the cavity preparation is not painful. There was no relationship between heart-rate changes and reported pain in Abdulhameed and coworkers' study.[10] They queried the sensitivity and validity of using a visual analogue scale in children. However, in a series of studies examining children's ability to use visual analogue scales to measure dimensions of their pain, McGrath[27] found that children older than 5 years of age were able to use visual analogue scales in a reliable and valid manner to describe their perceptions, independent of their sex, age, or health status.

One problem common to all visual analogue scales is the limitation imposed by extremes. If a patient rates pain at the worst end of the scale and then it gets worse, the measurement stays the same. This was not a major problem in the present study as only one child reported maximum pain in both visits. As each child evaluated treatment under both EDA and LA, the differences in the pain scores between the two visits were more important than the actual scores. Additionally, the children were reminded of what they had scored previously so that they could attempt to make a deliberate comparison of the pain. In some studies, subjects do not see previous scores. This may introduce errors, especially when there is delay between the two treatment times in a paired study and patients may overestimate pain severity.[28] The high standard deviations of pain scores reported during cavity preparation may be due to variations in pain perception or threshold in different children.

Both Quarnstrom[5] and Croll and Simonsen[14] suggested children younger than 9 years should not be allowed to control their own EDA amplitude, as younger children may increase the amplitude rapidly out of curiosity. In the present study, the children were asked to control their own EDA current output after it was found that this gave the best acceptance in the pilot study. There were no problems with even the younger children having this control. One possible explanation was that the children in this study controlled the EDA units under close supervision and very careful instructions and explanations were given at the start of the procedure.

The success of EDA was somewhat dependent on the operator acceptance of the method, although numbers were too small to draw definitive conclusions. Hochman[20] suggested that the attitude of operators is an important factor as one of the mechanisms of EDA may be a placebo effect. Observation that not all of the operators would continue to use EDA suggests that in future studies the operator's experience or belief in EDA, their behavior-management techniques, their method of introducing the EDA, and their treatment

techniques should be more closely evaluated, as these factors may play an important role in how well patients accept EDA. Various methods of introducing the EDA should also be evaluated.

Conclusions

1. Overall, EDA was less effective than LA in controlling pain during cavity preparation in children aged 6 to 12. Sixty-three percent of the children preferred EDA to LA for future dental treatment.

2. This study suggests that the effectiveness of EDA is related to children's dental anxiety, the depth of the restoration, operator attitudes, and whether the teeth are permanent or primary.

3. EDA can be a useful adjunct to providing pain control during restorative dental care in children.

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