# Scientific Article

## The effect of electronic dental anesthesia on behavior during local anesthetic injection in the young, sedated dental patient

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## Abstract

**Purpose:** The purpose of this study was to evaluate the effectiveness of the 3M Electronic Dental Anesthesia (EDA) finger electrode on reducing sedated patient responsiveness during local anesthesia administration.

Methods: Thirty patients between the ages of 24 to 48 months, ASA I, and in need of treatment of maxillary anterior teeth using local anesthesia were used in this study. Each of the patients received chloral hydrate (CH) and hydroxyzine (50 mg/kg and 2 mg/kg, respectively). The patients were divided randomly in two groups. The experimental group received activated electronic dental anesthesia (AEDA) while the control group had a nonactive EDA (NAEDA). Physiological parameters were recorded and behavior was videotaped and rated using the Ohio State University Behavior Rating Scale. A repeated-measures ANOVA, Student's t tests, and descriptive statistics were used.

**Results:** The results indicated that the heart rate and diastolic blood pressure of both groups were significantly affected as a function of time and dental procedures. A significant effect in the percent change of heart rate between groups was noted during local anesthetic injection with the NAEDA group having an increased heart rate. There was a higher occurrence of movement in the NAEDA compared to the AEDA.

**Conclusion:** The EDA appears to be beneficial in reducing the discomfort, as judged by behavioral and physiologic observations, associated with local anesthetic administration in young sedated dental patients. (Pediatr Dent 21:12–17, 1999)

ocal anesthetic injections have been reported as one of the dental procedures that provokes disruptive, crying behaviors in sedated children.<sup>1-4</sup> Local anesthetic injections are accepted as necessary, in most cases, for the comfort of sedated children during restorative procedures because of the following reasons: a) some popular sedative agents for children do not have sufficient analgesic properties, b) the duration of potential discomfort associated with rubber dam application and tooth preparation outlasts that of local anesthetic administration, and c) local anesthetic administration is perceived consistent with the published goals of sedation of the American Academy of Pediatric Dentistry (AAPD) guidelines for the elective use of sedation.<sup>5</sup>

In recent years, the use of electronic dental anesthesia (EDA) has been suggested as a potential alternative to the conventional method of local anesthesia.<sup>6–13</sup> In principle, EDA is related to a well-known physical therapy technique called transcutaneous electrical nerve stimulation (TENS). TENS has been an extremely useful physical therapy technique for pain relief.<sup>14–16</sup>

Abdulhamed et al.<sup>17</sup> showed that EDA increased tooth pain threshold and reduced the cardiovascular stress during placement of a rubber dam clamp in children. Others have reported positive results of effectiveness and acceptance in children and parents with the use of EDA.<sup>18–20</sup> However, some studies have inconclusive results<sup>7</sup> and others report that EDA is not effective with invasive dental procedures.<sup>21, 22</sup>

Most of the studies highlight some factors common to the outcome of the EDA. EDA is more effective in anterior than posterior teeth.<sup>23, 24</sup> Also, the depth of the restoration makes a difference on the pain perception and effectiveness.<sup>22, 23, 25</sup> EDA is highly successful in periodontal procedures,<sup>9, 10, 23</sup> but is mainly unsuccessful in surgical and endodontic procedures. To our knowledge, EDA has not been evaluated as an adjunct in administering local anesthesia in children sedated for dental treatment.

The purpose of this study was to evaluate the effectiveness of the 3M EDA finger electrode in reducing sedated patient responsiveness during local anesthesia administration. More specifically, the study was done to determine if the EDA, when active, eliminates or reduces the percent of a sedated patient's disruptive behaviors of crying, movement and/or struggling, as measured by the Ohio State University Behavioral Rating Scale (OSUBRS) when a dental injection is given compared with a nonactivated EDA instrument.

## Methods

#### Patients

Thirty dental patients ranging in age between 24 to 48 months were used in this study. They were a convenience sample of patients who were the first in order among patients in the clinic population meeting the inclusion criteria: patients who were healthy, had no known allergies nor contraindications to sedation, had no or minimal tonsillar tissue, and were in need of treatment of maxillary anterior teeth using local anesthesia. The need for sedation was based on the patient's behavior during an initial examination (i.e., uncooperative, disruptive behaviors consistent with Frankl 1 category). The parent or guardian gave informed consent for the institutionally approved study.

#### Equipment

The EDA used was a 3M Dental Electronic Anesthesia Model System 8670 (St. Paul, MN). The stimulator/control unit had a battery-operated pulse generator that transmitted electrical impulses through a finger pad held against soft tissue in the mouth. The pulse rate and width parameters were fixed and the amplitude was adjusted at chairside. The stimulator could provide continuous, burst, or modulated impulses, but the continuous impulse mode was used in the study.

Physiologic monitoring equipment used was: Critikon Dinamap Vital Signs Monitor (Tampa, FL), 1846SX (blood pressure); Nellcor Pulse Oximeter and Printer, Model N-100 and N-9000, respectively (heart rate and peripheral  $O_2$  saturation); Datex Carbon Dioxide Monitor, Model 223 (expired CO<sub>2</sub> concentration). The Porter MXR nitrous oxide (N<sub>2</sub>O) delivery system was used. Intraoperative behavior was recorded using a video camera.

## Procedure

Each of the 30 patients were scheduled for conscious sedation and received a standard therapeutic dose, per weight, of chloral hydrate (CH) and hydroxyzine (50 mg/kg and 2 mg/kg, respectively). The sedative agents were prepared using a flavoring agent and either administered by cup or needleless syringe to the patient. All sedations followed the sedation guidelines of the AAPD.<sup>5</sup>

After a 60-min latency period, the dental treatment was initiated. The patient was separated from the parent and laid on a restraint board. (Patients were not restrained unless it was necessary to complete the dental procedure.) Physiologic probes were attached and  $N_2O/O_2$  delivery initiated.  $N_2O/O_2$  inhalation was set to 50% concentration and delivered using a nasal hood. Supportive and gentle encouragement was given to alay the child's fears.

Prior to the study the patients were divided in two groups, those receiving AEDA and those with an NAEDA, by random assignment with the flip of the coin until an equal number of patients was attained per group (15/group). Following a period of 5 min under N<sub>2</sub>O, the EDA finger electrode was placed on the buccal mucosa overlying the teeth to be anesthetized according to manufacturer's instructions. Because the operator and patient were blinded, the dental assistant was responsible for controlling the EDA equipment. The manufacturer's instructions were followed and the EDA was increased every 20 s by the dental assistant with the direction of the operator.

Topical anesthesia was not used because a recent study indicated that topical anesthesia is less effective than EDA in reducing discomfort during local anesthetic administration<sup>28</sup> and this study was designed to assess only the effectiveness of electronic anesthesia on behavior of sedated children. A minimum of 2 min passed before local anesthesia was delivered to the maxillary buccal vestibule via a dental syringe using a 30-gauge, ultrashort needle. One Carpule (2% Xylocaine with 1:100 000 epinephrine) was deposited slowly with the injection period being not less than 1 min per both central and lateral incisors on either side of the labial frenum. Once anesthesia was obtained, routine dental care was delivered.

The same operator was used throughout the study. Consistency in administration of local anesthesia (i.e., rate of injection) and use of the EDA were established by the operator practicing on several cooperative patients requiring similar operative procedures prior to study initiation.

#### Behavior

Intraoperative behavior was videotaped using a standard video camera mounted on the wall in the sedation room. The video camera was turned on just prior to the patient and operator entering the operatory and was continued until tooth preparation with the high-speed handpiece began.

The videotape of each session was reviewed later and the behavior analyzed using the OSUBRS as has been previously reported.<sup>3</sup> In summary, a rater (blinded to

## TABLE 1. BEHAVIOR CODES DURING **INTRAOPERATIVE EVALUATION**

Key	Behavior Codes	Definition of Codes
Q	quiet	quiet, no movement or crying
M	movement	no crying, movement only
C	crying	crying only
S	struggles	cries, screams, struggles

## TABLE 2. DEFINITIONS OF THE TIME PERIODS OF EACH VISIT **DURING WHICH PATIENTS WERE EVALUATED**

Time Period	Evaluation Included •
Baseline I	Initial assessment of patient HR, BP, OS, RR, B
Baseline II	Initial assessment intraoperatively HR, BP, OS, RR, B
EDA	EDA finger-assist probe placed on the mucosa HR, BP, OS, RR, B, V
Injection	Local anesthesia injection HR, BP, OS, RR, B, V

· HR=Heart rate; BP=Systolic and diastolic blood pressure; OS=Oxygen saturation; RR=Respiratory rate; B=Behavior; V=Videotape.

A FUNCTION OF TIME AND EDA				
Variable	f	Р		
O <sup>2</sup> saturation	0.15	0.703		
Time	1.42	0.241		
Time x EDA	0.06	0.9811		
Heart rate	1.02	0.320		
Time	3.08	0.032		
Time x EDA	1.66	0.182		
Respiratory rate	0.14	0.716		
Time	1.99	0.122		
Time x EDA	1.99	0.122		
Systolic blood pressure	0.72	0.405		
Time	0.81	0.493		
Time x EDA	1.12	0.345		
Diastolic blood pressure	0.08	0.780		
Time	10.31	0.000		
Time x EDA	1.74	0.165		

TABLE 3. ANOVA OF THE PHYSIOLOGICAL PARAMETERS AS

conditions) used a VCR, monitor, and computer with software that determined the frequency, duration, and mean duration of defined behaviors to evaluate the tapes of the procedures. The software program was the Automated Counting System (ACS) (Version 1.0 JAGTECH, Rockville, MD).

Predefined behavioral categories (quiet, crying, movement, and struggling with crying) were used for the OSUBRS (Table 1). The rater used a computer keyboard, and while rating the tape depressed one of four keys with each representing one of the defined behaviors. Any change from one behavioral category to another was noted by pressing the appropriate key. Behavioral categories were mutually exclusive and only one was identified for any given period of time. The defined segments in this study were the pre-EDA period, EDA administration, and local anesthetic administration (Table 2). Because the rated period of the sedation visit varied slightly in length, the data was converted to a percent of each defined clinical segment.

Previous studies have indicated that intra- and inter-rater reliability for the OSUBRS, using this technology and measured by a correlation analysis, was 95–99%.<sup>2,3</sup> An individual who was blinded and trained in the use of this technology rated each tape twice.

In conjunction with each procedure/episode of treatment, a clinical assessment of behavior was recorded based on the following scale: 1=quiet (Q); 2=sleeping (SL); 3=crying (C); 4=struggles (S). Percentages for each behavior observed also were analyzed.

## **Statistics**

Descriptive statistics were used to characterize the patient's demographic information (e.g., male/female and age). An independent *t*-test was used to determine any difference between groups (placebo and study group) for age, weight, dose of CH, and dose of hydroxyzine. A repeated-measures ANOVA as a function of EDA activation for each physiologic category was used to determine any significant differences by group and the individual variance across the rated segments. A chi-square analysis was used to determine any difference in the frequency of occurrence for behavioral categories (quiet, crying, movement, and struggling) as a function of AEDA versus NAEDA. Pearson's correlation coefficient was used to determine the association between behavioral categories rated in the two trials by the rater. An a priori level of statistical significance was set at P < 0.05.

## Results

Physiologic and behavioral data were collected from 30 sedation visits involving 13 males and 17 females. The mean age of the population was 33.8 months. A Student's *t*-test revealed no significant difference between experimental and control groups for age, weight, amount of CH, and hydroxyzine.

#### **Physiologic Measures**

A repeated-measures ANOVA revealed no statistical differences in any physiologic parameter as a function of AEDA or NAEDA; however, a time-related, significant difference was found for heart rate and diastolic blood pressure across the procedures (f=3.08, P=0.032; f=10.31, P=0.001, respectively; Table 3). The heart rate for the AEDA group slowly decreased from baseline I through injection. Initially, a similar trend was noted for the NAEDA group except during the injection procedure when the mean heart rate increased.

A parallel pattern was observed with the diastolic blood pressure. For the AEDA group the diastolic blood pressure decreased slowly from baseline I through injection. Likewise, for the NAEDA, a mean decrease in diastolic blood pressure was noted until the injection, when it increased.

An independent *t*-test revealed a statisically significant difference between the AEDA and NAEDA group in the mean percent change in heart rate in the injection phase (*t* statistic=2.15, P<0.05). There were no differences found for the percent change of other physiologic parameters.

## **Behavioral Measures**

#### Intraoperative behavior ratings

Behavioral data was recorded at chairside for baseline I (preoperative), baseline II (intraoperative), EDA, and dental injection. Chi-square analysis of the behavior during procedures revealed no statistical difference in observed behavior as a function of NAEDA or AEDA group.

#### Videotape behavior analysis

Intrarater reliability was consistently high according to Pearson's product-moment correlation coefficient comparing first and second viewing for duration (trial 1 versus trial 2, r=0.9938) and for frequency (trial 1 versus trial 2, r=0.9589) of behaviors.

ANOVA showed no difference in the mean percent duration of observed behavior. However, a chi-square analysis was done to determine the frequency of occurrence of each behavior category as a function of AEDA group vs NAEDA group. A significant difference ( $X^2$ =3.96, *P*=0.046) was noted for movement as a function of AEDA versus NAEDA. There was a significantly greater number of NAEDA patients who moved compared with the AEDA group. Also it was noted that the occurrence of crying for the AEDA group was less compared to that of the NAEDA group ( $X^2$ =3.35, *P*=0.067).

## Discussion

The purpose of this study was to evaluate the effectiveness of the EDA finger electrode on reducing sedated patient responsiveness during local anesthesia injection. There was no statistically significant difference between AEDA versus NAEDA group in regard to sex, weight, dose of CH and hydroxyzine. This would suggest that both groups were statistically similar and not likely to add any confounding effects to the analysis.

## **Physiologic Measures**

A significant difference in the mean heart rate, percent change of heart rate, and diastolic blood pressure was noted between the NAEDA and AEDA groups during injection phase. It is likely that these patterns of decreased heart rate and diastolic pressure during the initial phase of the operative appointment reflect the patient's relaxation and reduction of fear associated with the pharmacologic action of the sedatives used.

Changes in the heart rate are expected to reflect patient responsiveness to procedures, especially during stressful experiences. Salient stimuli like pain will result in an increased heart rate which is the primary mode of cardiovascular response in young children to perceived stressful conditions.<sup>26, 27</sup> As less responsiveness of the cardiovascular system was noted for the group that received EDA, this finding would suggest a masking of the discomfort during local anesthetic injection.

Wilson<sup>1</sup> reported that accentuated physiologic responses are most notable during local anesthesia injection, but responses tend to be dampened as CH doses are increased. He noted that this observation was most likely attributable to a deeper level of sedation imparted by increased CH dosage and that a significantly higher dose of CH would be necessary to overcome the stimuli of most dental procedures. Such a practice could lead to deep sedation and compromise patient safety.

Results of this study suggested that improved responses to procedures may not require higher doses of CH. If one can decrease the perception of localized, noxious stimulation with a relatively innocuous mechanism, improvement in sedation techniques can be achieved without compromising patient safety, as associated with higher drug doses.

The result of this study can be compared to that found by Abdulhameed et al.<sup>17</sup> in his study with nonsedated children. They reported that using the EDA in placing a rubber dam clamp on oral soft tissue, a relatively noxious stimulus, decreased cardiovascular responses without altering comfort levels. In other words, the EDA stimulator had the apparent effect of increasing pain thresholds of the soft tissue for clamp placement with minimal or no change in heart rate.

#### **Behavioral Measures**

The strong correlation between the two trials of rating videotapes suggests that the rater was reliable in analyzing the videotapes for the behaviors studied. This finding is consistent with others.<sup>3</sup>

Some improvement in clinical behavior was noted for the categories of movement and crying during injection when the AEDA was used. Significantly fewer patients in the AEDA group were moving during injection than in the NAEDA group. Fewer patients cried in the AEDA group than in the NAEDA group during the injection; however, this was not statistically significant.

These results indicate that AEDA contributes to reduced overt expressions of some clinical behaviors, especially movement, during periods of salient stimulation from the dental procedure. Because movement can contribute to disruption of dental procedures and possibly cause increased discomfort and trauma to the localized tissues, EDA use may be indicated for young, sedated children who require injections in the maxillary anterior segments. Because less movement and dampened cardiovascular response were noted in the group receiving AEDA, one may predict an increased likelihood that some patients will be less disruptive for the remainder of the dental appointment. This hypothesis remains to be determined.

Another plausible explanation for the failure to find any dramatic difference in behaviors between the AEDA and NAEDA is the combination of sedative effects and operator technique. The sedative agents used typically result in quiet, sleeping children whose physiology remains stable.<sup>1</sup> Anecdotally, it is common knowledge that slow administration of local anesthesia results in reduced perceived discomfort. These two considerations may increase the likelihood that less responsiveness to the injection is notable in young children sedated with a sedative hypnotic agent. The clinical relevance of this consideration is obvious, especially the slow administration of local anesthesia, and highly recommended.

Regarding EDA use, the finger probe was very easy to use for both the operator and assistant. The only difficulty was that the finger probe comes in only one size and was sometimes difficult to place in the buccal vestibular mucosa on the small children.

There are some limitations to this study. No topical anesthetic was used. It is possible that topical anesthesia may have produced a more profound effect than the EDA and thus would be a positive control in the study design; however evidence exists that the EDA produces significantly less pain and is preferred three to one over topical anesthesia.<sup>28</sup>

The study design focused on the patient's behavior surrounding the injection of local anesthesia. It is possible that an evaluation would demonstrate a difference in behavioral categories in comparing the experimental to the control group. It is conceivable that the experimental group may have had significantly less disruptive behaviors for the entire visit compared to the control group because of less arousal during the injection phase when the EDA was used.

## Conclusion

Under the conditions of this study, the following can be concluded:

- 1. No physiologic variable was found to be significantly affected by EDA; however, the heart rates and diastolic blood pressures of both groups were significantly affected as a function of time and dental procedures.
- 2. A significant effect in the percent change of heart rate between groups in going from the EDA phase to the local anesthetic injection phase was noted, with the NAEDA group having an increased heart rate.
- 3. The frequency of occurrence as measured by videotaped analysis of the OSUBRS was significantly affected by the EDA during dental injection. There was a higher frequency of movement occurrence in the NAEDA compared to the AEDA.

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