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Clinical effectiveness of 1 and 2% lidocaine in young pediatric dental patients

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Abstract

Clinical effectiveness of the double-blind administration of 1 and 2% lidocaine solutions was evaluated for restorative and surgical procedures on primary molars of children 4.5 to 10.5 years old. This effectiveness was measured by changes in the child's heart rate, the child's self report of pain, and the operator's assessment of the anesthesia's effectiveness. Although the incidence of anesthetic failure was higher for the 1% solution (31.3%) than for the 2% solution (11.1%), no statistically significant difference between the solutions was found. During the performance of pulpotomies and extractions, a higher failure rate was recorded for the 1% solution (62.5%) than for the 2% solution (28.6%), but these differences were not statistically significant. For minor restorative procedures, the 1% solution was equally successful in achieving anesthesia. The results suggested that 1% lidocaine should be used when multiple minor procedures are performed and potential toxicity in the young dental patient is a concern.

Introduction

More than 500,000 local anesthetic injections are given by dentists each day in the United States (Milam and Giovannitti 1984). Systemic toxic reactions from these injections are considered rare in adults. Young children, however, are more likely than adults to experience toxic reactions, because of their lower body weight. Small or precooperative children often are sedated with pharmacologic agents for dental treatment. The potential for toxicity increases when local anesthetics are used in conjunction with sedation medications. Goodson and Moore (1983) reported that in 86% of pediatric dental sedations in which patients experienced adverse reactions, the recommended dosage of local anesthetic had been exceeded. In a survey of reported pediatric dental sedations, Aubuchon (1982) found a direct linear relationship between the number of carpules of local anesthetic administered and the frequency of severe adverse reactions. Animal studies tend to support these findings. In 1964, Smudski and coworkers found increased toxicity when narcotic drugs were used in combination with local anesthetics. The study demonstrated that mice premedicated with a narcotic showed significantly reduced convulsive thresholds to lidocaine.

This previous research suggests the need to reduce the dose of local anesthetic when treating pediatric patients premedicated with sedative agents. Strong evidence supporting the selective use of a 2% solution of lidocaine over other concentrations is lacking in the dental literature. Bjorn and Huldt (1947) conducted the study that paved the way for use of a 2% lidocaine solution. They found that 100% of maxillary lateral incisors in adult patients lost the ability to respond to electrical stimulation when anesthetized with 2% lidocaine, while teeth anesthetized with 1% lidocaine were unresponsive 97.3% of the time. Brynolf (1947) showed that painless tooth preparation may be accomplished in anesthetized permanent teeth despite continued sensitivity to electric current. This finding would indicate that the dose of lidocaine necessary to achieve clinical anesthesia is less than the dose required to eliminate sensitivity to electrical stimulation. Furthermore, Hammond et al. (1984) reported that primary teeth may be less responsive to cavity preparation than permanent teeth.

Previous research showed no difference between 1 and 2% mepivacaine with 1:100,000 adrenaline for removal of mandibular third molars (Dahl and Lindqvist 1967). In a recent report, both 1 and 2% lidocaine solutions were evaluated for effectiveness in the induction of profound local anesthesia in adolescents (Rozanski et al. 1988). The ability to extract healthy premolars was measured in a cross-arch design using paired premolars. The efficacy of 1% lidocaine was found not to be significantly different from 2%

lidocaine. The results suggested that 1% lidocaine may be considered for selective use in the young child patient to reduce the possibility of local anesthesia toxicity.

It can be concluded that there is a need in pediatric dentistry for a local anesthetic agent with a greater margin of safety than the currently employed 2% solution. Since preliminary data indicated that 1% lidocaine may produce clinical success comparable to 2% lidocaine for extraction of healthy premolars, further testing in a pediatric population with routine restorative and surgical procedures performed on primary teeth was warranted. The purpose of this study was to determine the clinical effectiveness of 1% compared to 2% lidocaine for restorative and surgical procedures on primary molars of healthy children aged 4 to 11 years old. Changes in the child's physiological (heart rate) and psychological (self report of pain) response to the dental procedure were analyzed for comparison to the operator's assessment of anesthesia effectiveness.

Methods

The subjects were selected from the patient population presenting for routine care at the pediatric dentistry clinic of the University of Florida. To be included in this study, patients were required to:

1. Be healthy medically (ASA =1)
2. Be between 4 and 11 years old
3. Have a behavioral rating (Frankl et al. 1962) of "positive" or "definitely positive," determined at the previous dental visit
4. Be able to use the "faces" scale (McGrath et al. 1985a)
5. Have at least one primary molar needing restoration, pulpotomy, or extraction
6. Have no more than one-third physiologic root resorption present on nonextraction teeth.

The procedures and their possible discomforts, risks, and benefits were explained fully to the human subjects involved, and their informed consent was obtained before the investigation, as approved by the University's Institutional Review Board. The characteristics of the study population according to age, sex, race, arch, and type of procedure were collected. The type of procedure was assigned after the clinical treatment was completed. Pulpotomies and extractions were defined as major procedures, while all other restorative therapies were defined as minor procedures.

One per cent lidocaine (Xylocaine ® — Astra Pharmaceutical Products Inc, Westboro, MA) solution with 1:100,000 epinephrine was obtained from multidose vials for use as the test anesthetic solution. Under sterile conditions, the contents of standard 2% lidocaine (Xylocaine) carpules were expressed and the emptied carpules then were reloaded with the 1% test solution. In accordance with the study reported by Cowan (1964), the volume of each standard (2%) and test (1%) carpule was adjusted to 1.5 ml for mandibular teeth and 0.8 ml for maxillary teeth. Double-blind conditions were obtained by coding identically appearing carpules of both solutions; this was done by an individual unassociated with the clinical procedures.

All anesthetic and surgical procedures were performed by the same operator using standard techniques. For mandibular teeth, a 1.5", 27-gauge needle was used to deposit approximately 1.0 ml of anesthetic solution for the inferior alveolar nerve block, 0.2 ml for the lingual nerve block, and 0.3 ml for the long buccal nerve. For maxillary teeth, a 1.0", 30-gauge needle was used to deposit approximately 0.6 ml of anesthetic solution for apical infiltration and 0.2 ml to anesthetize palatal soft tissues. Aspiration was performed before each injection to minimize the possibility of intravascular injection.

The effectiveness of the local anesthetic solutions was evaluated by the operator at four levels of increasing stimulus during the dental procedure. The presence of satisfactory anesthesia was verified if the operator elicited no pain response from the patient for the following sequence of events:

Level 1. Clinical signs of anesthesia by patient report after operator inquiry

Level 2. Explorer penetration into interdental gingival papilla (all 4 line angles of the test tooth)

Level 3. Enamel preparation with a high speed 330 bur or tooth luxation with straight elevator

Level 4. Dentin or pulp penetration with a high speed 330 bur or tooth extraction with forceps.

Failure at any level required patient reassurance, followed by a 5-min delay before repeating the test. A second failure at any level required reinjection with 2% lidocaine, and the anesthesia was recorded as a failure. If reinjection was warranted, then it was assumed the child received the more concentrated 2% solution. As with all pediatric patients, the maximum recommended dose of 4.4 mg/kg was never exceeded (Malamed 1986).

All dental treatment was performed in the customary manner, except rubber dam placement, which was deferred until after completion of the test procedure, but before preparation refinement, or placement of the formocresol pellet. The child's level of discomfort was gauged using three measurements: 1) physiological (heart rate), 2) child's self-report ("faces" scale), and 3) operator's assessment. Performance of the procedures and data collection adhered to a strict schedule to ensure standardization along temporal intervals (Table 1; see next page).

TABLE 1. Timetable for performance of procedures and data collection

Time (min)	*Procedure*	*Heart Rate*	*Child's Report*	*Operator's Report*
0	Enter operatory, dicuss procedure, attach probe			
5	Baseline measurements	X	X	
10	Topical anesthesia applied			
12–14	Local anesthesia injected	X		
15	Postanesthetic measurements		X	
20–25	Dental procedure	X		
30	Postoperative measurements		X	X

Heart rate was monitored using a pulse oximeter (Model N-100—Nellcor, Haywood, CA). A noninvasive probe was attached to the patient's right index finger. The patient's mean heart rate was recorded at baseline, during administration of the local anesthesia, and during the individual treatment procedure selected at point of maximum stimulation (Level 4). A mean heart rate was generated by recording the patient's heart rate every 30 sec for a duration of 2 min (five recordings).

If an anesthetic failure occurred at any level during the procedure before Level 4, the test was terminated and a heart rate of 120 bpm was assigned to the patient. A heart rate of 120 bpm, which is slightly less than two standard deviations above normal for the chronological age range of the population studied, was assigned on the assumption that if the procedure were permitted to continue to Level 4, significant tachycardia would be recorded. An arbitrary value for heart rate among the anesthetic failures was deemed necessary to ensure a statistical comparison to the group of anesthetic successes.

A patient's self report of discomfort was determined using the "faces" scale described by McGrath et al. (1985a). This scale consisted of nine different faces representing a range of discomfort from "no hurt" to "hurt." These ratings were taken immediately following the recording of the child's heart rate. Children were tested for comprehension of the "faces" scale before the day of the procedure. The child was asked to identify the faces that represented "no hurt" and "hurt." If the child identified the correct faces within one face, he was included in the study. If an anesthetic failure occurred during the procedure, the score representing the most discomfort (face #9) was assigned to the patient.

The operator's assessment was based upon a score of 1–9 corresponding to the operator's interpretation of the "faces" scale. No attempt was made to define in operational terms the number assigned, but was rather used as a subjective relative assessment of the pain experienced by the child based upon behavioral outcomes. The operator's assessment was no more objectively based than the child's assessment of his own perceived pain through use of the "faces" scale. The operator recorded his assessment of the child's pain experience for the procedure before solicitation of the child's report using the "faces" scale.

Results

Table 2 provides the characteristics of the study population according to age, sex, race, arch, and type of procedure performed according to concentration of anesthetic solution administered. No statistically significant differences in the group characteristics were found.

TABLE 2. Characteristics of study population

Characteristics	*Lidocaine Concentration* 1%	2%	*Total*
Mean age (months) ± SD	88±19	96±21	92±20
Number of subjects*	16	18	34
Male (N)*	8	9	17
Female (N)*	8	9	17
White (N)*	11	14	25
Black (N)*	5	4	9
Maxillary arch (N)*	7	8	15
Mandibular arch (N)*	9	10	19
Minor Procedure (N)*	8	11	19
Major Procedure (N)*	8	7	15

*No significant differences as determined by Chi-square analysis

Regression analysis indicated no correlation between heart rate and the faces score (child's report of pain) with the introduction of a potential pain stimulus created by the injection of local anesthesia (R = 0.001). During the test procedure, heart rate also failed to correlate with either the faces score or the operator's assessment of the child's pain reaction. Only a weak positive correlation (R = 0.221) was found between the faces score and the operator's assessment after the dental procedure was performed.

The results obtained for the changes in mean heart

rate and faces score occurring during the treatment session according to the lidocaine concentration administered are illustrated in Fig 1 and 2. There was no statistically significant difference between 1 and 2% solutions for either the child's heart rate or faces score at baseline, during injection, and during the performance of the dental procedure. There was a trend, however, toward increased heart rate and faces score at the time of local anesthesia injection when compared to the mean values obtained at baseline. When successful anesthesia was achieved, mean heart rate and faces score revealed decreasing values, but still remained higher than those values obtained at baseline. When anesthetic failures were incorporated into the analysis, the standard 2% solution demonstrated a smaller decrease in mean heart rate, while the 1% test solution actually elevated mean heart rate and faces score beyond that recorded during the injection.

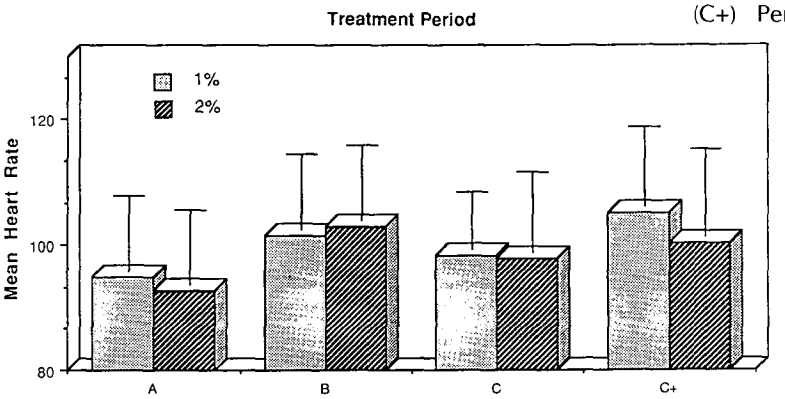

Fig 1. Comparison of mean heart rate during the treatment session according to lidocaine concentration recorded at:
(A) Baseline, prior to initiation of the dental procedure
(B) Injection of anesthetic solution
(C) Performance of selected dental procedure under conditions of successful anesthesia (N = 27)
(C+) Performance of selected dental procedure for entire population (N = 34) which includes anesthetic failures (N = 7) having adjusted values.

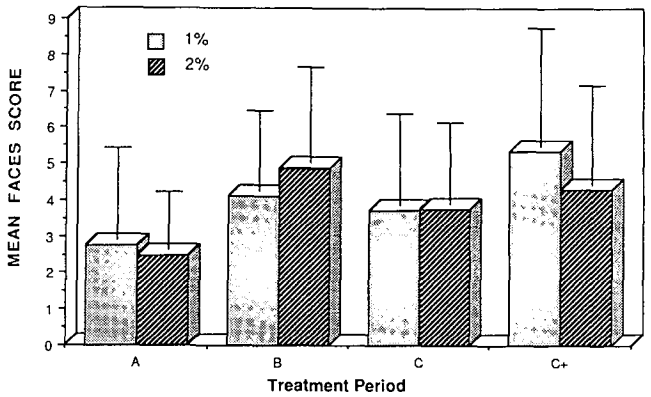

Fig 2. Comparison of mean faces score during the treatment session according to lidocaine concentration recorded at:
(A) Baseline, prior to initiation of the dental procedure
(B) Injection of anesthetic solution
(C) Performance of selected dental procedure under conditions of successful anesthesia (N = 27)
(C+) Performance of selected dental procedure for entire population (N = 34) which includes anesthetic failures (N = 7) having adjusted values.

The results obtained for 1 and 2% solutions of lidocaine are summarized in Table 3 (se next page). Five anesthetic failures occurred with the 1% concentration, while only two failures resulted with the 2% concentration. Chi-square analysis indicated no statistically significant differences between the effectiveness of the two solutions, but 1% lidocaine demonstrated a higher percentage of anesthetic failures.

Potential factors that may have contributed to these failures are shown in Table 4 (see next page). No significant differences were noted for age, sex, race, or arch. Evaluation of anesthetic failures by Chi-square analysis revealed a significant difference ($P = .001$) between minor and major procedures. Major procedures were defined as pulpotomies or extractions; minor procedures were defined as all other restorative therapies. Analysis by lidocaine concentration, however, revealed a trend ($P = .189$) toward decreased anesthetic effectiveness when performing major procedures with 1% lidocaine as compared to 2% lidocaine (Table 5, see next page).

Discussion

One of the most difficult challenges confronting health professionals is the reliable assessment and valid measurement of pain in children. The assessment of children's pain experience is clouded by their changing, and relatively limited, ability to understand measurement instructions and to articulate descriptions of their pain (McGrath et al. 1985b). Similar to adult pain measurements, pain measurements for children may be classified as physiological, psychological, or behavioral (McGrath 1987). Since acceleration in heart rate has been demonstrated with invasive, potentially painful dental procedures (Rape et al. 1988) and since an interval face scale assists children to describe their pain in a meaningful way (McGrath et al. 1985a), both measurements were selected to augment the operator's assessment of the pain experience. The test conducted with the four sequential levels of anesthesia during the dental procedure was devised to identify obvious anesthetic failures. The heart rate and child's report using the "faces" score assisted in the determination of relative anesthesia effectiveness and to compare the validity of the operator's assessment. Heart rate determination and patient's report were col-

TABLE 3. Incidence of local anesthesia failures by concentration

Lidocaine Concentration	*Incidence of Failures**	*Per cent Failures*
1%	5/16	31.3
2%	2/18	11.1
Total	7/34	21.0

*Probability of failure differences = 0.147 (NS) as determined by Chi-square analysis

TABLE 5. Incidence of local anesthesia failures by procedure

	Lidocaine Concentration		
Procedure	*1% (% Failures)*	*2% (% Failures)*	*Significance**
Minor	0/8 (0.0)	0/11 (0.0)	P= 1.00 (NS)
Major	5/8 (62.5)	2/7 (28.6)	P= .189 (NS)

*Probability determined by Chi-square analysis

lected at both baseline and injection to provide a relative comparison of pain experienced during the actual dental procedure.

The results of this investigation suggested that changes in the child's heart rate may not be a uniformly sensitive measurement of pain when compared to self report or to the operator's assessment of the child's pain experience. In a review of the multiple dimensions of pain assessment in children, McGrath (1987) stated that there was insufficient evidence to conclude that physiological responses such as heart rate correlated directly with pain experience. Physiological changes during noxious and invasive dental procedures in children may represent their physical (behavioral) and emotional (psychological) distress, rather than a pure pain experience. Further investigation will be necessary to help clarify the interrelationships among these variables.

An earlier study evaluating physiologic measures during dental treatment found an increased heart rate during the injection, followed by a gradual decrease during the dental procedure (Myers et al. 1972). The results for the 2% solution followed this heart rate pattern. The failure of the subjects injected with 1% solution to demonstrate a similar pattern during treatment may have reflected the increased level of anesthetic failure experienced in this group. The vasoconstrictor (epinephrine) employed in this study would not be expected to produce a clinical sympathomimetic action resulting in tachycardia because of the small volume/concentration used and the negative aspiration required before injection (Malamed 1980).

The anesthetic solution was maintained at a standard volume, varying only the concentration of the anesthetic, because of the concern that a reduced volume might increase the incidence of anesthetic failures reported. Local anesthetics are known to act at the nodes of Ranvier (Hille 1967), but they do not prevent the existing currents from passing along the surface of the myelin sheaths and thereby jumping to an adjacent node (Rood 1977). Blair and Erlanger (1939) have demonstrated that a certain distance of nerve fiber must be blocked in order for impulse transmission to be interrupted. This distance or "critical length" as they called it, was found to be equal to three consecutive nodes of Ranvier. The internodal length in the largest fibers in the human inferior alveolar nerve is approximately 1.8 mm (Brown 1981). On this basis, it would be necessary to expose around 6 mm of nerve trunk to anesthetic solution to achieve a total block. Therefore, a customary volume was maintained in this study to ensure adequate anesthesia.

TABLE 4. Incidence of local anesthesia failure in the study population according to variable factors

Factors	*Variable*	*Incidence of Failure*	*Per cent Failure*	*Significance**
Age	< 7.5 years old	4/15	26.7	*P* = .436
	>7.5 years old	3/19	15.8	(NS)
Gender	Male	3/17	17.6	*P* = .671
	Female	4/17	23.5	(NS)
Race	White	4/25	16.0	*P* = .270
	Black	3/9	33.3	(NS)
Arch	Maxillary	2/15	13.3	*P* = .353
	Mandibular	5/19	26.3	(NS)
Procedure	Minor	0/19	0.0	*P* = .001
	Major	7/15	46.7	

*Probability determined by Chi-square analysis

In the current study, the frequency of inadequate local anesthesia was 11.1% for the standard 2% concentration. This compared favorably with a previous study in children which showed a 12.8% failure rate (Kuster and Rakes 1987). An earlier study showed that 1% lidocaine was an effective local anesthetic when used for extracting healthy premolars in adolescents (Rozanski et al. 1988). The reported higher success rate (lower percentage of anesthetic failures) than in the present study using primary teeth may relate to the incomplete neural development found in immature permanent teeth selected for extraction. Threshold values for electrical stimulation increased by a factor of 2–3 when permanent teeth with immature root formation were compared to permanent teeth with completed root formation (Fulling and Andreasen 1976). The increased threshold value of immature teeth may be caused by the decreased number of myelinated axons (Johnsen and Johns 1978), or an immature relationship between odontoblastic processes and the nerve fibers (Fearnhead 1963).

Another factor that may have contributed to the lower success rate with primary teeth was the presence of periodontal and pulpal inflammation. It has been demonstrated that histamine-induced inflammation decreased the firing threshold by 10% at a site distal to the inflammation (Wallace et al. 1985). Since major procedures in this study were pulpotomies and extractions involving inflamed tissues, the higher anesthetic failure rate reported probably was influenced by the presence of inflammation.

When used in proper doses, complications from local anesthetics are considered rare. A review of adverse reactions by Goodson and Moore (1983) indicated a lack of consideration for a child's smaller body weight and a failure to decrease the dose accordingly. Most toxic effects were related to excessive blood concentrations that were reached through overdoses, rapid absorption from highly vascular spaces, or accidental intravascular injection (Covino and Vassallo 1976). The potential for toxicity was increased greatly when sedation medications were used in combination with local anesthetics. Aubuchon (1982) reported that 11% of dentists who used sedation techniques had observed a significant adverse reaction. He suggested that local anesthetics play a strong role in precipitating these reactions.

Prevention is the most important phase in the management of unwanted systemic reactions to local anesthetics. Adherence to proper injection technique and maximal dose calculations for local anesthetics will reduce the potential for unwanted side effects. The requirements for obtaining adequate anesthesia must be determined on an individual basis, keeping in mind the desirability of the minimal effective concentration of the local anesthetic.

Conclusions

When used in young pediatric dental patients for selective anesthesia of primary molars:

1. One and 2% lidocaine were equally effective in achieving local anesthesia for minor procedures involving tooth preparation.
2. Although decreased anesthetic effectiveness of 1% lidocaine was revealed for major procedures that included pulpotomies and extractions, no significant statistical difference between the two solutions was demonstrated.
3. An anesthetic solution of 1% lidocaine may be considered when multiple minor restorative procedures are anticipated, and potential toxicity in the young dental patient is a concern.

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Why patients stay with a dentist

A survey reported in the *Journal of Dental Practice Adminstration* identified reasons why patients remain with a practitioner. The majority of patients indicated that honesty of their dentist was the primary reason they continued in a dental practice.

Patients also cited cleanliness, professional appearance, knowledge of dentistry, gentleness, concern and quality of work as factors that influenced their decision to stay in a dental practice.

The top responses in each category are listed below:

- Importance of general treatment skills: knows latest techniques; gentle.
- Importance of dentist's character and patient rapport: honest; clean and professional.
- Importance of appointment availability: available for emergencies; easy to schedule appointments.
- Importance of office facilities: clean and neat facilities; modern facilities.
- Importance of finances: no payment needed at time of appointment; fees are very low.

Dental practitioners can use results from this survey to improve patients' perceptions of their practices.