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A Clinical Trial of Long-Acting Local Anesthetics for Periodontal Surgery

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The efficacy of long-acting local anesthetics for anesthesia during periodontal surgery and for analgesia during the immediate postoperative period was evaluated. The rationale for using long-acting local anesthetics such as etidocaine and bupivacaine is that they can provide surgical anesthesia and, because of their long duration, prevent discomfort that may occur for 4–6 hours postoperatively. Two clinical trials were performed. The first enrolled patients requiring bilateral periodontal surgery. Using a matched pair design and double-blind randomized study conditions, 2% lidocaine 1/100,000 epinephrine was compared with 1.5% etidocaine 1/200,000 epinephrine for periodontal surgery. The time until complete recovery and the time until pain onset were found to be longer for the etidocaine surgeries. Postoperative pain appeared more severe, and the need for oral analgesics was greater for the lidocaine surgeries. Surgeons' rating of surgical bleeding was significantly greater for the etidocaine procedures. When matched bilateral surgeries were not available, a second double-blind randomized parallel trial was performed that compared 1.5% etidocaine 1/200,000 epinephrine to 0.5% bupivacaine 1/200,000 epinephrine. No significant differences were seen in the quality of anesthesia, degree of bleeding, or postoperative pain between these two long-acting anesthetics.

Local anesthetics possessing extended durations have been shown to be effective for controlling pain during dental surgery and minimizing pain in the immediate postoperative period.[1–3] Two long-acting local anesthetics, bupivacaine (Marcaine, Cook Waite Laboratories, NY) and etidocaine (Duranest, Astra Pharmaceutic Products Inc., MA), are available in dental cartridges in the United States. Introduced in 1963, bupivacaine is a water-soluble amide anesthetic structurally similar to mepivacaine (Carbocaine). In 1972, etidocaine, a water-soluble amide anesthetic structurally similar to lidocaine (Xylocaine) was introduced. The long duration of these two agents is primarily related to their lipid solubility and protein-binding characteristics.[4]

A number of clinical trials evaluating the use of etidocaine and bupivacaine in oral surgery for third molar extraction have confirmed their safety and efficacy.[5–11] In general, these studies have found bupivacaine and etidocaine to provide reasonably rapid onsets, profound anesthesia, and prolonged duration following mandibular block anesthesia. Clinical trials involving surgical endodontics have found these long-acting agents to be effective for both maxillary and mandibular anesthesia.[12,13] The most commonly used concentrations (0.5% bupivacaine and 1.5% etidocaine) appear to obtund postoperative pain for 6–12 hours.

Epinephrine (1/200,000) is included in long-acting dental anesthetic solutions to improve profundity of anesthesia. There is little evidence that they significantly prolong the duration of anesthesia.[6] In certain circumstances, the lower concentrations of vasoconstrictor used with etidocaine and bupivacaine may not provide adequate hemostasis. Sisk et al[14,15] found increased intraoperative bleeding with 1.5% etidocaine 1:200,000 epinephrine when removing impacted third molars. Concern that hemostasis may be inadequate has also been noted during periodontal flap surgery.[16,17]

The purpose of the present two-part study was to evaluate the efficacy of both etidocaine and bupivacaine anesthesia for periodontal surgery. These clinical trials use a previously established methodology that permits the

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characterization of both maxillary infiltration and mandibular block anesthesia, hemostasis, and postoperative pain.[12]

METHODS

Healthy adults (21–70 yr) scheduled for periodontal surgery at either West Virginia School of Dentistry or University of Pittsburgh School of Dental Medicine were recruited into the study. The study was approved by the respective Human Studies Committees and all patients provided written informed consent. Exclusion criteria included: pregnancy; a history of allergic reactions to any of the study medications; serious cardiovascular, hepatic, or renal disease; and maxillofacial deformities that might interfere with the injections and evaluations.

Two protocols were used. When matched bilateral surgical sites of equal difficulty were available, a double-blinded matched-pair design was used that randomly assigned 2% lidocaine 1/100,000 epinephrine or 1.5% etidocaine 1/200,000 epinephrine. The criteria for matching of sites was the need for identical surgical procedures and the presence of similar maximum pocket depth ±2 mm. When a quadrant of surgery could not be matched to the contralateral side, a parallel design was used that randomly assigned 1.5% etidocaine 1/200,000 epinephrine or 0.5% bupivacaine 1/200,000 epinephrine. Double-blind conditions were maintained by coding identical appearing unlabeled cartridges of the agents. The code for each protocol was available in a sealed envelope if needed.

Patients were asked to fill out and return a questionnaire that requests the following data: the time when the local anesthetic began to wear off (a "pins and needles" feeling); the time that feeling completely returned to normal; the presence or absence of pain following therapy; whether the pain was mild, moderate, or severe; the need for oral pain medication (325 mg acetaminophen with codeine 30 mg provided), the time when this medication was first taken, the total number of tablets taken in the first 24 hours, and any comments regarding the local anesthetic experience. These questions were developed in a previous evaluation of long-acting local aesthetics in endodontics.[12,13]

The periodontist collected the following demographic data at the time of surgery: name, address, date, telephone number, age, sex, weight, medical history, and current medications. Additionally the study information was recorded: teeth numbers, diagnosis, treatment, estimated surgical trauma (mild, moderate or severe), time of injection, time for anesthesia onset, estimate of bleeding during surgery (more than expected, equal to expected and less than expected), and profundity of anesthesia. The last category is rated excellent, satisfactory, or inadequate based respectively on whether two cartridges were sufficient, whether supplemental injections were necessary, or whether complete anesthesia was not possible.

There was no remuneration for participation in this study. Patients received the usual postoperative analgesic at no charge.

Statistical analyses of the two studies were done separately. Continuous data (age, weight, time) was compared using a Student's *t*-test and nonparametric categorical data (pain ratings, etc.) were compared using contingency tables (χ^2) and sign tests.

Table 1. Demographics

	Lidocaine vs Etidocaine
Age (mean ± SD)	40.6 ± 7.2 yr
Gender	
Male	6
Female	5
Weight (mean ± SD)	169 ± 44 lb

RESULTS

The average age and weight of the six males and five females enrolled in the crossover designed comparison of 2% lidocaine 1/100,000 epinephrine and 1.5% etidocaine 1/2000,000 epinephrine are listed in Table 1. Although there were no significant differences in onset of anesthesia, quality of anesthesia, or surgical trauma, the surgeries using etidocaine were associated with greater bleeding ($\chi^2 = 10.5$, df = 2) (Table 2). Table 3 lists the differences between lidocaine and etidocaine seen during

Table 2. Assessments of Surgery and Anesthesia: Lidocaine vs Etidocaine

	Lidocaine	*Etidocaine*
Onset times (mean ± SE) (min)	3.3 ± .4	4.5 ± .9
Quality of anesthesia		
Excellent	7	5
Satisfactory	4	6
Inadequate	0	0
Surgical trauma		
Severe	0	1
Moderate	8	7
Minimal	3	3
Bleeding estimates*		
More than expected	1	7
Equal to expected	4	4
Less than expected	6	0

* $P < 0.01$.

Table 3. Postoperative Recovery: Lidocaine vs Etidocaine

	Lidocaine	*Etidocaine*
Initial recovery (mean ± SE) (min)	196 ± 15	275 ± 35
Complete Recovery* (Mean ± SE) (min)	274 ± 21	516 ± 80
Pain onset* (mean ± SE) (min)	299 ± 28	420 ± 57
Severity of postoperative pain		
Severe	5	1
Moderate	4	4
Mild	2	6
None	0	0
Analgesic medication* (mean ± SE) (tablets)	4.5 ± .5	2.5 ± .7

* Paired t test, $P < 0.05$.

the postoperative period: the surgeries using etidocaine had prolonged recovery ($t = 2.86$, $df = 10$) and extended periods until pain onset ($t = 3.23$, $df = 10$). The use of etidocaine was associated with a trend towards less severe postoperative pain (NS) and the use of fewer analgesics ($t = 3.83$, $df = 10$).

The age, gender, and weight of the 14 patients enrolled in the parallel designed comparison of 0.5% bupivacaine 1/200,000 epinephrine and 1.5% etidocaine 1/200,000 epinephrine are not significantly different (Table 4). No significant differences were seen for anesthesia parameters, bleeding estimates, recovery from anesthesia, or onset and severity of postoperative pain (Tables 5 and 6).

DISCUSSION

The purpose of this study was to evaluate the efficacy of long-acting local anesthetics when used for periodontal surgery and for managing immediate postoperative discomfort. Though the onset of anesthesia, quality of anesthesia, and surgical trauma were not significantly different among the agents tested, the duration of soft tissue anesthesia, level of hemostasis, and degree of postoperative pain were significantly different for 1.5% etidocaine 1/200,000 epinephrine and 2% lidocaine 1/100,000 epinephrine only. Recovery time of soft tissue anesthesia for etidocaine was twice that of lidocaine. This prolonged recovery time may account for the decreased report of postoperative pain and the consumption of fewer analgesics during etidocaine administration.

The findings of the present study are in agreement with previous reports.[11,13,15] Although pulpal anesthesia may not a be a significant concern in periodontal surgery, an extended duration of soft tissue anesthesia with long-acting agents may not be seen when pulpal anesthesia is evaluated.[18] Since narcotic analgesics are not without side effects,[19] etidocaine may provide an alternative management strategy to postoperative pain medication. This may be an important advantage (as it was at one of the study sites) when patients must travel long distances after surgery.

Significantly more bleeding was associated with 1.5% etidocaine 1/200,000 epinephrine than 2% lidocaine 1/100,000 epinephrine. This finding has been reported in

Table 4. Demographics: Bupivacaine vs Etidocaine

	Bupivacaine	*Etidocaine*
Age (mean ± SD)	58 ± 17 yr	46 ± 15 yr
Gender		
Male	4	5
Female	3	2
Weight (mean ± SD)	164 ± 31 lb	174 ± 50 lb

Table 5. Assessment of Surgery and Anesthesia: Bupivacaine vs Etidocaine

	Bupivacaine	*Etidocaine*
Onset time (min)	4.3 ± 1.0	3.8 ± 1.0
Quality of anesthesia		
Excellent	4	1
Satisfactory	3	6
Inadequate	0	0
Surgical trauma		
Severe	0	0
Moderate	4	4
Minimal	3	3
Bleeding estimates		
More than expected	2	2
Equal to expected	2	4
Less than expected	3	1

Table 6. Postoperative Recovery: Bupivacaine vs Etidocaine

	Bupivacaine	*Etidocaine*
Initial recovery (mean ± SE) (min)	270 ± 27	281 ± 34
Complete recovery (mean ± SE) (min)	409 ± 36	435 ± 40
Pain onset (mean ± SE) (min)	323 ± 47	393 ± 54
Severity of postoperative pain		
Severe	0	0
Moderate	0	2
Mild	3	2
None	4	3
Analgesic medications (mean ± SE) (tablets)	1.4 ± 1.0	0.9 ± .6

conjunction with oral surgery[14] and periodontal surgery.[16] It has been suggested that the difference in blood loss may be due to the vasodilatory characteristics of the anesthetic agent, the concentration of vasoconstrictor, or a combination of both.[14] Etidocaine, therefore, may not be the best local anesthetic if used as the sole agent for periodontal surgery considering increased blood loss and lack of an adequate level of hemostasis for visibility of the surgical field. However, an anesthetic regimen that combined lidocaine with etidocaine, when the latter is used near the end of the periodontal surgical procedure, might avoid excessive bleeding while maximizing the potential for lessened postoperative pain.

It has been suggested that the use of higher concentrations of vasoconstrictor (1/100,000) may provide better hemostasis during surgery while increasing the incidence of postoperative bleeding.[20] The possibility of increased bleeding postoperatively following periodontal surgery, although not evaluated in the present study, is of some concern. Future studies will evaluate the significance of vasoconstrictors on healing and recovery from periodontal surgery.

In conclusion long-acting local anesthetics appear to be effective in managing pain following periodontal surgery. If hemostasis is an important element of the surgical anesthesia, a standard agent such as 2% lidocaine 1 : 100,000 epinephrine is recommended.

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