Influence of Hemostatic Agents in the Prognosis of Periapical Surgery: A Randomized Study of Epinephrine versus Aluminum Chloride

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Abstract

Introduction: Several variables have been associated with a better prognosis of periapical surgery. The aim of this study was to evaluate the influence of 2 hemostatic agents on the prognosis of periapical surgery at 12 months. **Methods:** A prospective study was designed with 2 randomized parallel groups established depending on the hemostatic agent used: epinephrine or aluminum chloride. The analysis of the hemorrhage control was recorded as 0 (no hemorrhage control), 1 (slight but apparent intermittent bleeding persisted after application of the material), or 2 (complete hemorrhage control). At 12 months, periapical lesion healing was determined clinically and radiologically as success, improvement, or failure. **Results:** Ninety-five patients (67 women and 28 men) with periapical lesions involving a single tooth were enrolled in this study; in 45 teeth, epinephrine was used and in 50 teeth aluminum chloride. In the epinephrine group, 28 teeth were classified as successes, 10 as improvements, and 7 as failures. In the aluminum chloride group, 34 teeth were classified as successes, 11 as improvements, and 5 as failures. No statistically significant difference was found. **Conclusions:** The present study found no association between the use of epinephrine or aluminum chloride as hemostatic agents on the prognosis of periapical surgery. The efficacy of hemostatic agents at the time of surgery showed no relationship with the healing outcome. *(J Endod 2018;44:1205–1209)*

Key Words

Aluminum chloride, endodontic surgery, epinephrine, hemostatic agents, periapical surgery, prognosis

Significance

The outcome of periapical surgery can be influenced by adequate bleeding control because it improves vision, minimizes operating time, and is a requirement for setting retrograde filling; however, the influence between the hemostatic agent used and the prognosis of the lesion has not been determined.

Several variables have been associated with a better prognosis of periapical surgery including the absence of preoperative signs and symptoms (1–3), reduced radiographic lesion size (3–6), cases with first-time surgery (7, 8), technique of root-end cavity with microtip preparation (9–11), use of an endoscope (12), and mineral trioxide aggregate as the root-end filling material (13, 14). Adequate bleeding control is essential because it reduces the operating time, improves vision in the surgical site, and is a requirement for placement and setting of retrograde filling; however, the influence between the hemostatic agent used and the prognosis of the lesion has not been determined.

Only 2 studies (4, 15) have related the outcome of periapical surgery to the use of hemostatic agents. Wang et al (4) used 1:50,000 epinephrine-saturated pellets or ferric sulfate as hemostatic agents. The authors did not find statistically significant differences between using or not using a hemostatic agent in the prognosis of periapical surgery. Peñarrocha-Diago et al (15) compared dressings impregnated with anesthetic solution containing a vasoconstrictor with aluminum chloride (Expasyl; Produits Dentaires Pierre Rolland, Merignac, France), and there were no statistically significant differences. No study has determined the relationship between the hemostatic agent efficacy at the time of surgery with the prognosis of the lesion.

The aim of this study was to evaluate the influence of epinephrine and aluminum chloride on the prognosis of periapical surgery at 12 months. The second objective was to relate the efficacy of hemostatic agents at the time of surgery with the healing outcome. The null hypothesis was that the influence on periapical surgery prognosis of epinephrine is equal to that produced by aluminum chloride. The null hypothesis for the second objective was that the healing outcome is not related to hemostasis efficacy.

Materials and Methods

Study Design

A prospective study was performed following the Consolidated Standards of Reporting Trials statement (16) in the Oral Surgery Department, Faculty of Medicine

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and Dentistry, University of Valencia, Valencia, Spain, from October 2010 to February 2016.

All patients were provided with full information about the study and were asked to sign a written informed consent form before taking part. The study design was approbated by the Ethical Committee of the University of Valencia (H1275980266460).

The inclusion criteria were periapical lesions involving a single tooth with a diameter of the periapical lesion lower than 10 mm and patients with at least 12 months of follow-up. The exclusion criteria were apicomarginal defects or probing greater than 6 mm, teeth with periapical pathology associated with a vertical fracture, teeth in which the hemostatic agent did not allow the placement and setting of the retrograde filling (no hemorrhage control), patients with anticoagulant therapy, or incomplete study protocols.

The study design was based on a previous study (17). Two parallel groups were established depending on the hemostatic agent used (ie, epinephrine or aluminum chloride). A block randomization scheme was generated using the Randomization.com website (http://www.randomization.com) (seed: 13053). Assignment was concealed from the investigator until the moment of hemostatic agent application by an opaque envelope. Patient-dependent variables (sex, age, smoking habits, and plaque index [18]) and variables dependent on the tooth (arch and position) were collected.

The surgical field was photographed before and after application of the hemostatic agent (EOS 70D, Macro Ring Lite MR-14EX, and EF 100 mm f/2.8 Macro USM; Canon, Tokyo, Japan). The bleeding was assessed by the surgeon (M.P.D.) at the time of surgery and by 2 independent examiners (J.C.B. and I.M.N.) through the photographs. For hemostasis evaluation, we proposed an alternative classification based on previous articles (19, 20) as follows:

- 0: no hemorrhage control, continuous or intermittent bleeding that compromised root-end filling procedures
- 1: slight but apparent intermittent bleeding that allowed root-end filling procedures
- 2: complete hemorrhage control that allowed root-end filling procedures

At 12 months, periapical lesion healing was determined clinically and radiologically according to the scale of von Arx and Kurt (21) as follows:

1. Success, osseous regeneration >90% and pain and clinical scores = 0;
2. Improvement, osseous regeneration 50%–90% and pain and clinical scores = 0; and
3. Failure, osseous regeneration <50% or pain or clinical score ≥1.

Periapical radiographs (VistaScan; Dürr Dental AG, Bietigheim-Bissingen, Germany) were taken immediately after periapical surgery and at the 1-year postsurgical control.

Surgical Technique

All operations were performed by the same surgeon (M.P.D.). The surgical procedures were performed under locoregional anesthesia with 4% articaine and 1:100.000 epinephrine (Inibsa; Lliça de Vall, Barcelona, Spain). A mucoperiosteal flap was raised with a submarginal incision design, and an ostectomy was performed using round 0.27-mm tungsten carbide burs (Jota AG, Rüthi SG, Switzerland) mounted in a handpiece and abundant irrigation with sterile physiological serum. Affected roots were resected at approximately 3 mm from the apex with minimal or no bevel, and the pathologic soft tissue was debrided. Retrograde cavities were prepared using ultrasonic retrotips (Piezon Master 400 EMS; Electro Medical Systems SA, Switzerland) to a 3-mm depth. The root ends were inspected using a rigid endoscope (Möller-Wedel, Munich, Germany).

Hemostasis of the bony crypt in the epinephrine group was performed using gauzes with epinephrine (1 mg/mL; B-Braun, Rubí, Barcelona, Spain) compressed against the bony crypt for 2 minutes. In the aluminum chloride group, Expasyl was applied on the bony crypt for 2 minutes. The root-end cavities were filled with mineral trioxide aggregate (Dentsply Tulsa Dental, Tulsa, OK), and the quality of the retrograde fillings was evaluated with an endoscope. In the aluminum chloride group, the superficial bone layer was removed with rotary instruments; in both groups, the cavity was irrigated with sterile saline solution to remove the remaining hemostatic agent. Flap tensionless soft tissue closure was performed with a 6/0 suture (Polinyl; Sweden & Martina, Carrare, Italy).

Antibiotics (2 g amoxicillin/clavulanic acid or 600 mg clindamycin) were given 1 hour before surgery, anti-inflammatory medication (600 mg ibuprofen) was given on demand, and 0.12% chlorhexidine rinses were used 2 times a day for 7 days. The sutures were removed after 1 week.

Statistical Analysis

Blinding of the patients and a biostatistician with expertise in dentistry was performed. Masking was carried out as follows: patients were not informed of the assignment, and the statistician received a database divided into group "I" and "II" without specifying the allocation groups. Statistical analysis was performed using the chi-square test and the Mann-Whitney test according to SPSS software (Version 8.0 for Windows; SPSS Inc, Chicago, IL). A P value < .05 was considered significant.

The sample size was calculated using G*power version 3.1 (University of Düsseldorf, Düsseldorf, Germany) (22). For an alpha value of 0.05, a beta value of 0.05 (95% power), and an effect size of 0.4 (16), a sample size of 42 patients (21 in each group) was estimated.

Results

The initial study sample consisted of 120 patients allocated to 2 groups (60 in each group). In the epinephrine group (Fig. 1), 5 were excluded for involving other teeth at the time of surgery, 2 presented vertical fractures diagnosed with the endoscope, on 2 occasions the control of bleeding failed (no hemorrhage control) and aluminum chloride was needed, 3 patients were excluded because of incomplete study protocols, and 3 were lost to follow-up at 12 months. In the aluminum chloride group (Fig. 2), 7 were excluded for involving multiple teeth at the time of surgery, 1 presented vertical fractures diagnosed with the endoscope, 1 was excluded because of incomplete study protocols, and 1 was lost to follow-up at 12 months (Fig. 3).

Ninety-five patients (67 women and 28 men) with a mean age of 47.5 years (standard deviation = 15 years) were enrolled in this study and divided into 2 groups according to the hemostatic agent used. In 45 teeth (34 mandibular teeth and 11 maxillary teeth), epinephrine was used and in 50 teeth (45 mandibular teeth and 5 maxillary teeth) aluminum chloride (Table 1).

Taking into account the healing definitions, in the epinephrine group, 28 teeth (62.2%) were classified as successes, 10 teeth (22.2%) as improvements, and 7 teeth (15.6%) as failures; in the aluminum chloride group, 34 teeth (68%) were classified as successes, 11 teeth (22%) as improvements, and 5 teeth (10%) as failures (Table 2). No statistically significant difference was found in the influence of epinephrine and aluminum chloride on the prognosis of