Maintaining Apical Patency Does Not Increase Postoperative Pain in Molars with Necrotic Pulp and Apical Periodontitis: A Randomized Controlled Trial

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Abstract

Introduction: This prospective, single-center, single-blind, randomized controlled trial aimed to evaluate whether maintaining apical patency (AP) during endodontic treatment increases postoperative pain in molar teeth with necrotic pulp and apical periodontitis. **Methods:** Three hundred twenty qualified patients between 21 and 45 years of age were randomized into 1 of 2 groups (the AP group and the nonapical patency [NAP] group) using a series of random numbers in a 1:1 ratio. Qualified patients were selected from patients who had necrotic pulp and apical periodontitis in the maxillary or mandibular molar teeth. The primary outcome was to assess postoperative pain severity, and the secondary outcome was to evaluate analgesic consumption during the 7-day follow-up period using the visual analog scale (VAS). The VAS consisted of a 100-mm line. Pain severity was evaluated as no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm). The Student *t* test was used to identify statistically significant differences between the study groups ($P < .05$). **Results:** The mean VAS scores were significantly lower in the AP group in the first 5 postoperative days ($P < .05$); after which, it was nonsignificant. In the NAP group, the postoperative pain increased between 12 and 24 hours, whereas the postoperative pain decreased in the AP group during that period. At 12 and 24 hours, the mean VAS scores for the AP group were 42.90 and 37.78 mm, respectively. The mean VAS scores for the NAP group were 64.46 and 65.74 mm, respectively. None of the patients had severe postoperative pain during the follow-up period. No significant difference was found in analgesic consumption ($P > .05$) between the groups. **Conclusions:** The maintenance of AP in molar teeth with necrotic pulp and apical periodontitis was associated with less postoperative pain when compared with NAP. *(J Endod 2017;■:1–6)*

Key Words

Apical patency, endodontics, postoperative pain, reciprocation

Significance

This randomized controlled trial indicated that maintaining apical patency did not increase the level of postoperative pain. There was significantly less postoperative pain in the first 5 days when apical patency was maintained.

The apical portion of the root canal system is very challenging. During mechanical preparation, dentinal and pulpal debris can block access to the apical third and cause procedural errors such as apical transportations, perforations, and ledge formations (1). It has been shown that apical canal blockage can be avoided by using a patency file (2). In teeth with necrotic pulp and apical periodontitis, bacterial biofilms may be present not only within the apical part of the root canal system but also within the apical lesion itself (3–5). In such cases, maintaining patency in the apical region may help remove the bacterial biofilms that are present around the apical foramen (6).

Apical patency (AP) is a technique in which the apical portion of the canal is maintained free of debris by recapitulation with a small flexible file through the apical foramen (7). In this technique, the patency file (eg, #10 K-file) is set at a length 1 mm longer than the final working length (WL), and the file passively moves through the apical constriction, a width of 0.5–1 mm, without widening it (2, 8).

Maintaining AP is taught in only 50% of the dental schools in the United States. In the other half of the dental schools, AP is not taught, claiming that AP might increase the displacement of debris and irritate the periodontal ligament (9). Some authors suggest maintaining AP, whereas others suggest avoiding it. Vera et al (10) indicated maintaining AP improves the delivery of irrigants into the apical third. Siqueira (11) reported AP may help remove bacteria present around the apical foramen in teeth with necrotic pulp. Buchanan (8) published that maintaining AP minimizes the risk of loss of the WL. On the other hand, Siqueira (12) suggested that apical extrusion of infected debris, resulting from mechanical instrumentation, is a reason for postoperative pain. It has also been reported that the repeated passing of small patency files through the apex can cause an acute apical inflammatory response (9). Based on the results of previous research, the debates for maintaining or avoiding AP seem equivocal.

To date, several randomized controlled trials (RCTs) have investigated the influence of maintaining AP on postoperative pain. Arias et al (13) reported that there was

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significantly less postoperative pain when AP was maintained in nonvital pulp; however, the authors did not detail the periapical status. In another RCT, Arora et al (14) indicated that maintaining AP had no significant influence on postoperative pain in mandibular first molars with necrotic pulp and apical periodontitis; however, the study was conducted on a sample size of 68 participants. Furthermore, the root canals in these studies were prepared with either hand files (13) or a continuous rotary system (14).

Given the limitations of the previous studies, the present RCT was performed with a larger sample size (N = 320). In addition, the root canals were prepared using a reciprocating file system.

Materials and Methods

This single-center, single-blind, prospective RCT was performed between January 2016 and October 2017 at the State Hospital in Isparta, Turkey. The ethical approval for this study was provided by the University of Near East Ethics Committee (reference number: 2016/36-273). All participants provided written informed consent. The study protocol is registered in www.ClinicalTrials.gov databases, with the identifier number NCT02768285. A Consolidated Standards of Reporting Trials (2010) flow diagram is presented in Figure 1.

Objective

The aim of this study was to evaluate whether maintaining AP during endodontic treatment increases postoperative pain in molar teeth with necrotic pulp and apical periodontitis. The null hypothesis was that there would be no differences in the level of postoperative pain between the 2 treatment groups.

Sample Size

The power analysis of the study was performed based on the minimal clinically important differences in the visual analog scale (VAS) scores. The sample size calculation indicated that a minimum of 30 patients would be required in each group to identify any significant differences in pain level, with an alpha risk of 0.05, a power of 0.9, and an effect size of 0.8 (14).

Participants

The study recruited patients between January 2016 and October 2017. After clinical and radiologic examinations, 338 subjects, ages 21–45 years, were enrolled in the study. Only patients who had maxillary or mandibular molar teeth with pulp necrosis and radiographic evidence of apical periodontitis (minimum lesion size: 2 × 2 mm) were included. Only 1 tooth per patient was included in the study. Exclusion criteria were systemic disorders, pregnancy, preoperative pain, treatment with antibiotics in the past month, and analgesic treatment within the past 5 days. The baseline data of the participants were recorded before the randomization.

Sequence Generation and Blinding

A researcher who had not participated in the study generated the randomization sequence using a computer random table generator (www.random.org) with a 1:1 allocation ratio. The participants were randomized into the AP group or the NAP group. There were 160 patients in each intervention arm. The operator (I.E.Y.) was not blinded to the interventions because of the nature of the interventions. However, participants were blinded and not informed of the allocation. The success of blinding was verified by asking the participants to guess their intervention groups (15). All participants (N = 320 [100%]) reported that they were not able to guess their intervention group. To prevent fainting of the sequence, the names and dates of birth of the participants were noted on the envelopes. Just before treatment, the operator opened the sealed opaque envelopes in which the method of intervention was noted.

Interventions

All endodontic treatments were performed by the principal investigator (I.E.Y.) in a single-visit approach using a standardized treatment protocol. The vitality of pulp was determined using the hot and cold test and confirmed visually by the absence of bleeding when entering the pulp chamber. Rubber dam isolation was used in all cases. As needed, patients were given local anesthesia (2% lidocaine hydrochloride with epinephrine 1:100,000) for patient comfort. Both study groups underwent the same protocol, except for the WL used.

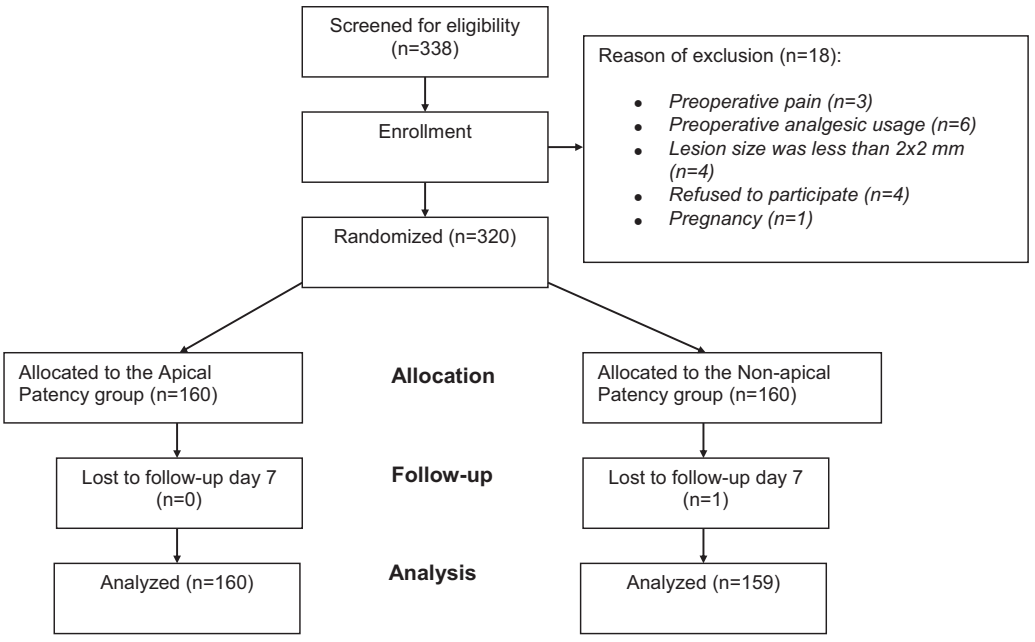

Figure 1. Consolidated Standards of Reporting Trials flow diagram showing the progress of subjects at each stage of the clinical trial.