Association between the Irrigation-Agitation Techniques and Periapical Healing of Large Periapical Lesions: A Randomized Controlled Trial

Clinical Trial Number: NCT06204887

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STUDY PROTOCOL

Local ethics committee approval was obtained from the Ethical Review Committee of the Research Foundation at the Medical Faculty of Recep Tayyip Erdogan University (No: 2023/35) and the study protocol was registered at ClinicalTrials.gov (NCT06204887).

Sample size calculation

The G Power 3.0.10 (University Kiel, Germany) program was used to calculate the effect size. The effect size was calculated based on chi-square analysis data between the control group and the laser group in the Verma, Yadav study [26]. An effect size of 0.51 Cohen d value was found to be sufficient for significance. With a type 1 error of 0.05, it was determined that at least 56 subjects were required for a total of 4 groups, 14 in each study group, with 95% power.

Patient Recruitment and Randomization

Patients were informed about the procedure, and written informed consent was obtained before the commencement of treatment. The study included mandibular single-rooted teeth that were diagnosed with asymptomatic apical periodontitis and had a periapical index (PAI) score of 3 or higher. A total of 97 patients aged 18-65 were evaluated radiographically and clinically for conformity with the inclusion and exclusion criteria. Patients with systemic diseases (diabetes, hypertension, chronic liver disease, coagulation disorders), bone metabolism disease and/or patients using drugs that affect bone metabolism (such as steroids and bisphosphonates) were excluded from the study. Immunosuppressed patients, patients with a history of radiotherapy, pregnant patients, patients with teeth with a mobility of 2 or more (Miller's mobility index), patients with teeth with a periodontal pocket depth of 5 mm or more, patients with generalized asymptomatic apical periodontitis, patients with teeth with internal and external resorption, and patients with teeth with vertical and horizontal root fractures were not included.

After applying the eligibility criteria, 70 patients were randomly divided into four groups using software (www.random.org) by a blinded researcher who was not otherwise involved in the study according to a standardized procedure. The numbers were placed in dark envelopes and concealed. The envelopes were only opened when the irrigation solution was to be activated. The patients were informed about the study without specifying the group to which they were assigned. All procedures were performed by a single operator with five years of experience (U.D.).

CBCT imaging (Planmeca Romexis, Helsinki, Finland) was requested for patients who met the study criteria before the procedure to obtain information about periapical lesion size, proximity to anatomical landmarks, and anatomical variations of the tooth. CBCT images were acquired with a field of view (FOV) of 5×5 cm using ENDO mode, an 85 µm voxel size, 6.3 mA, 90 kV, and 8.7 s.

Clinical procedures

A CONSORT flow diagram outlining the treatment methodology is presented in Figure 1. After the administration of local anesthesia and the placement of a rubber dam, the access cavity was opened with a sterile diamond round bur under water cooling. Each canal was rinsed with 2 mL of sodium hypochlorite and explored with a size 08 K-file (FKG Dentaire, La Chaux-de-Fonds, Switzerland). The working length was determined using an electronic apex locator, Root ZX mini (J. Morita Co., Tokyo, Japan), to be 0.5 mm shorter than a 0.0 reading. The length was confirmed radiographically. After that, progressively larger K-files were passively introduced into the canal until the operator felt the first one to bind at the WL and the next larger one not to reach that position [27]. The first instrument used to bind the canal was recorded for each canal. The crown-down technique was applied with ProTaper Next rotary files (Dentsply Maillefer, Ballaigues, Switzerland) using a torque-controlled endodontic motor (SybronEndo, Glendora, CA, USA) at 300 rpm/2-5.2 Ncm rotation mode according to the manufacturer's instructions. The final instrumentation file was set to 3 sizes larger than the first file used[28]. Between each instrument change, the root canal was irrigated with 5 mL of 2.5% NaOCl (Microvem AF, Istanbul, Turkey) for 1 min. After canal preparation was completed, the final irrigation procedure was carried out with the corresponding irrigation method in each group.

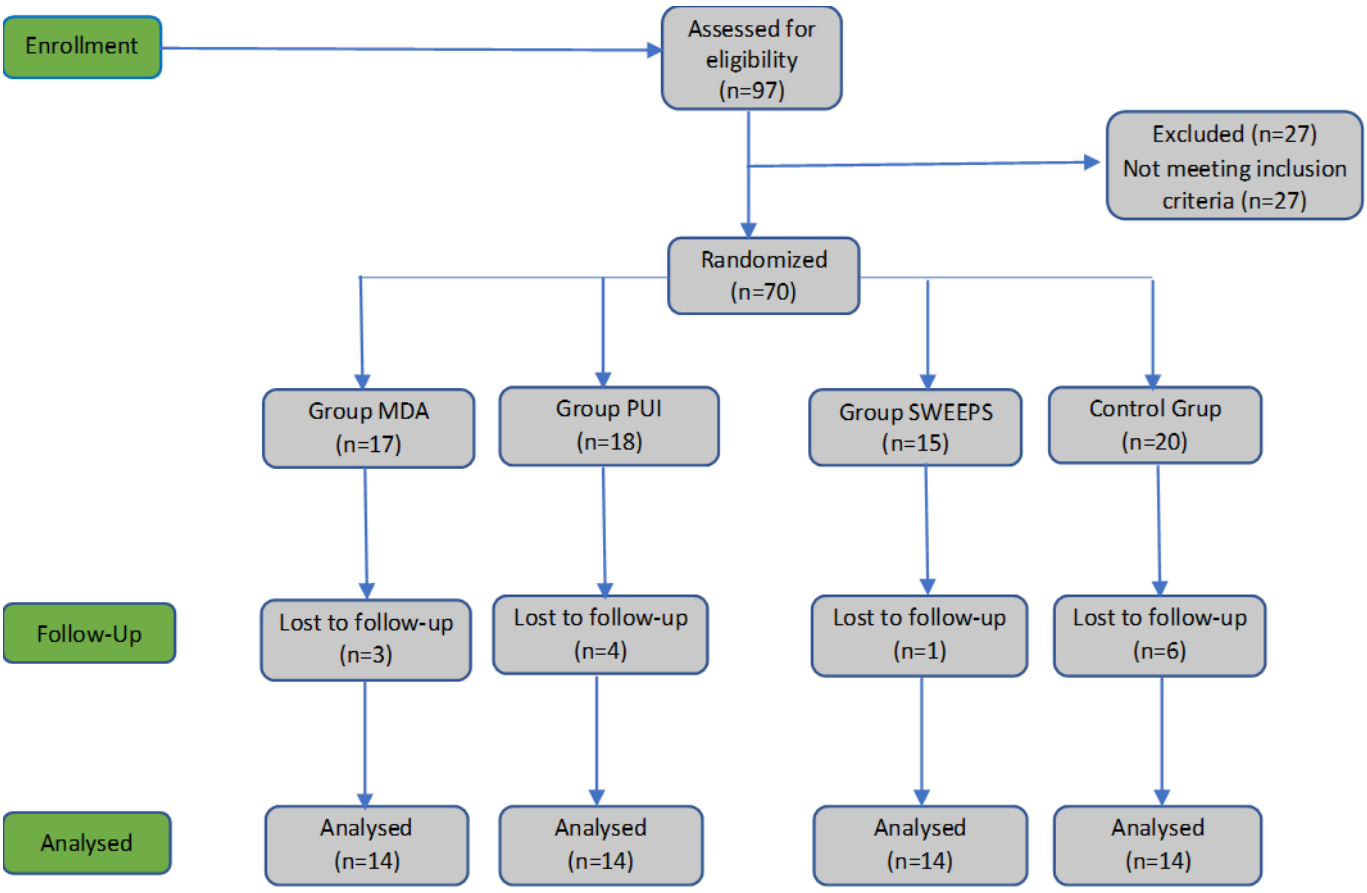

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram for patients included in this study.

Control Group: Conventional Syringe Irrigation

A 30-gauge side-vented irrigation needle (Kerr Hawe Sa, Bioggio, Switzerland) was used. The needle was inserted into the canal 1 mm shorter than the working length, and the canal was irrigated with up-and-down movements of 1-2 mm amplitude using the same and constant average pressure. The irrigation protocol was performed with 6 ml of 17% EDTA followed by 6 ml of 2.5% NaOCl for 1 min. Between each cycle, 5 ml of distilled water was used to prevent chemical interactions.

Group 1: Manual Dynamic Activation (MDA)

After the root canal preparation was completed, the final irrigation was started, the main gutta percha cone was positioned 1 mm shorter than the working length, and a 2 mm coronal-apical movement was performed at a speed of 100 strokes/minute for 60 seconds. The irrigation protocol was performed with 6 ml of 17% EDTA followed by 6 ml of 2.5% NaOCl for 1 min. Between each cycle, 5 ml of distilled water was used to prevent chemical interactions.

Group 2: Passive Ultrasonic Irrigation (PUI)

In this group, a noncutting ultrasonic tip (IRRI S 21/25; VDW, Munich, Germany) coupled to an ultrasonic device (DTE S6 Led, Guilin Woodpecker Co., Guilin, Guangxi, China) (mode: E, setting: 6) was used according to the manufacturer's recommendations.

The tip was positioned 2 mm short of the working length without contacting the walls. Continuous irrigation was performed using 2 ml of 17% EDTA followed by 2 ml of 2.5% NaOCl with activation 3 times for 20 seconds. To prevent chemical interactions between NaOCl and EDTA, 5 ml of distilled water was used between each irrigant. In total, 1 min of irrigation activation was carried out.

Group 3: Laser-Activated Irrigation (SWEEPS)

In this group, a 2940 nm Er:YAG laser device (Lightwalker, Fotona, Ljubljana, Slovenia) equipped with a handpiece (H14, Fotona) holding an 8.5 mm long and 600 µm diameter tapered fiber tip (SWEEPS 600, Fotona) was used for irrigation activation. The device was set to AutoSWEEPS mode with two ultrashort micropulses (25 µs) continuously varying at 0.3 W, 20 mJ, and 15 Hz. The air and water sprays were turned off.

A 30-gauge side-perforated irrigation needle (Kerr Hawe Sa, Bioggio, Switzerland) was inserted 1 mm shorter than the working length, and the fiber tip was positioned in the center of the access cavity and fixed in this position. Then, 2 ml of 17% EDTA was activated 3 times for 20 s. The same procedure was repeated with 2 ml of 2.5% NaOCl solution by flushing distilled water between each irrigant as described before.

After the final irrigation procedures, the root canals were dried with 25/.06 paper cones (DiaDent, Heungdeok-gu, Korea), and the cold lateral compaction obturation technique with a root canal sealer (Meta Biomed, Cheongju, Güney, Korea) was used to fill all the canals. Permanent restoration was performed directly with composite resin material (Palfique Estelite, Tokuyama Dental Co., Tokyo, Japan).

Follow-up procedures

For routine follow-up, 2D radiographs were taken at 3, 6, and 9 months, as well as via intraoral examinations. Radiographic healing in both 2D and 3D at baseline and at a follow-up of 1 year was assessed by a calibrated evaluator who was blinded to the allocation group. The teeth were assessed for reported symptoms, sensitivity to palpation and percussion, mobility and probing depth. The presence of failure (intraoral swelling or sinus tract) was recorded.

Healing evaluation: lesion area and volume calculation

Twelve months after the root canal treatment, new CBCT images were taken with the same device (Planmeca Promax 3D Classic device (Planmeca Romexis, Helsinki, Finland)) and the same parameters (85 µm voxel size, 6.3 mA, 90 kV, 8.7 with FOV area 5x5 cm).

3D lesion volume calculation was performed using ITK SNAP (free software under the GNU General Public License developed by the National Institutes of Health, the US National Institute of Biomedical Imaging and Bioenergy needs, the US National Library of Medicine, the Universities of Pennsylvania and North Carolina, and an independent group of developers) by an oral maxillofacial radiologist with 12+ years of experience.

The preoperative and 1-year postoperative CBCT images of the patients were measured following the same steps in the ITK-SNAP program. We used the same techniques used by Schloss et al[15]. First, the captured CBCT images were exported in DICOM file format from the Planmeca Romexis software. The exported images were then opened with ITK-SNAP software. Using the highest resolution allowed by the captured CBCT images (0.09 mm), the slice thickness and slice interval were set to 0.09 mm. The ITK-SNAP program includes a semiautomatic segmentation feature, which was utilized. In this feature, automated spherical fillers, or bubbles, as referred to in the program, were placed according to the grayscale of the lesion. Repeated runs were performed until the entire area of the lesion was filled, with the bubbles placed in the lesion area. After the internal area of the lesion was completely filled, the images were evaluated from axial, sagittal, and coronal sections to correct any possible overfilling or underfilling situations due to artifacts from canal filling materials using a manual marker. The volume of the painted area obtained was calculated in mm3 using the program's feature. The evaluation of the tomography images obtained before and after treatment was conducted at one-month intervals. The images were provided to the evaluators in a randomized manner.

The volume data were compared with the preoperative CBCT measurements for each patient. The volume changes were measured, and the long-term outcomes of the procedures were compared.