Assessment of the Antibacterial Effect and Post-operative Pain Following Various Techniques of Intracanal Heating of Sodium Hypochlorite: A Randomized Clinical Trial

تقييم التأثير المضاد للبكتيريا وألم ما بعد الجراحة للتقنيات المختلفة لتسخين هيبوكلوريت الصوديوم داخل قناة الجذر: تجربة سريرية عشوائية

A Thesis Protocol

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Submitted By

Alaa Eldin Yasser Mohamed Salah Eldin

Teaching assistant, Endodontics division, Conservative Surgery Department, College of Oral and Dental Surgery, Misr University for Science and Technology

Bachelor's Degree of Dentistry (2019)

Main Supervisor:

Prof. Dr. Mahmoud Hassan Mohamed

Professor of Endodontics, College of Oral and Dental Surgery, Misr University for Science and Technology and Al-Azhar University

CO-supervisors:

Dr. Rehab Ali Farag

Lecturer of Endodontics, College of Oral and Dental Surgery, Misr University for Science and Technology

Dr. Shaimaa Mohamed Seleim

Lecturer of Micribiology, Microbiology and Immunology Department, Faculty of Medicine, Cairo University

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1- Research Question:

Is the antibacterial effect of sodium hypochlorite irrigation and the postoperative pain affected by heating using either Ultrasonic or System-B activation or a combination of both?

2- Rationale for conducting the study:

Intracanal heating of sodium hypochlorite has been suggested as a method of activation of root canal irrigation in in-vitro studies. This clinical trial aims to evaluate the antibacterial effect of sodium hypochlorite heated inside the root canal using various activation techniques.

3- Introduction & background:

Root canal treatment success depends on removal of necrotic and vital pulp tissues and bacteria and bacterial byproducts from root canal system (Dioguardi et al., 2018).

Mechanical cleansing and removal of necrotic or vital pulp tissue lead to formation of a layer of debris called " Smear layer" which is made of organic and inorganic substances that should be removed from root canal system with the help of irrigants (Vaz Braga Pintor et al., 2016).

The presence of complex anatomy like isthmi and anastomoses makes chemical cleansing of root canal system difficult because they are filled with the smear layer (Torabinejad et al., 2002).

The ideal features of root canal irrigants include cleansing, lubrication of endodontic instruments and root canal system, dissolution of inorganic and organic tissues, antimicrobial properties, absence of cytotoxicity without alteration of dental microstructure. Sodium hypochlorite (NaOCl) has been the most used irrigant in endodontics due to its antimicrobial and tissue dissolving action (Zehnder, 2006).

Due to presence of complex anatomy inside root canal system, activation of irrigation is essential to improve cleaning such complex system. Ultrasonic activation is presently the most popular method for activation of irrigation. It delivers the irrigant farther into areas of the root canal system untouched by instruments and it improves the mechanical cleaning by increasing the wall shear stress (Boutsioukis and Arias-Moliz, 2022).

NaOCl is used in concentrations between 0.5% - 6%. In high concentrations, it may have a faster dissolution capacity, but it is associated with toxicity in cases of extrusion, thus, methods to improve the action of less concentrated solutions become relevant, such as agitation of the irrigant, constant refreshment and volume, and heating of the solution. Using NaOCl solution in high temperature is related to an increase in reactivity and, therefore, a reduction in bacterial counts, and bacterial biofilm dissolution. Although the dentin acts as a thermal insulator, the excessive increase in temperature could dissipate to the periapical tissues, causing damage to the bone tissue (Borges et al., 2023).

Initially, it was suggested to heat NaOCl before inserting it into the canals, but this was of little effectiveness (De Hemptinne et al., 2015).

Woodmansey demonstrated that NaOCl solution can dissolve pulp tissue 210 times faster at boiling temperature (90-120°C) than at room temperature. However, this method remained limited due to the lack of studies confirming its safety until Simeone et al. confirmed that when NaOCl solution is heated inside the canals at a temperature of 150°C for 10 seconds, the temperature of the periodontal tissues does not rise above 42.5°C, which is within the acceptable limits for the periodontal tissue (Ahmad Ali et al., 2023) (Woodmansey, 2005) (Simeone et al., 2015).

Rathore et al. in 2020 has stated that intracanal heating to 180°C using System-B Heat Source shows better antibacterial efficacy than preheated sodium hypochlorite at 60°C. Also it has been suggested to use low concentration NaOCl at elevated temperature to report the evidence for better antimicrobial and tissue dissolution properties (Govindaraju et al., 2024) (Rathore et al., 2020).

Combination of these two activation methods by ultrasonic agitation of sodium hypochlorite followed by intracanal heating may have promising results with regards to removal of bacteria (Yared and Al Asmar Ramli, 2020).

Patients frequently encounter postoperative pain after root canal treatment and one of the causes is that NaOCl at higher concentration is irritant to surrounding tissue particularly in case of extrusion. Irrigation using lower concentration NaOCl was effective in reducing postoperative pain (Rahim et al., 2024).

Based on the previous studies, studying the effect of irrigation using low concentration NaOCl (2.6%) which can be activated to increase its reactivity could give predectible antibacterial effect while reducing postoperative pain and toxicity associated with extrusion.

Aim of the study: is to evaluate the antibacterial effect of sodium hypochlorite heated inside root canals using various activation techniques.

4- PICO Elements:

Participants: Patients with asymptomatic single rooted restorable necrotic teeth.

Intervention 1: Intracanal heating for activation of sodium hypochlorite using System-B.

Intervention 2: Combination of Ultrasonic and System-B for activation of sodium hypochlorite.

Comparator: Ultrasonic for activation of sodium hypochlorite.

Outcome: primary: Antibacterial effect

secondary: Postoperative pain

Outcomes:

Prioritization of Outcome	Outcome	Measuring device	Measuring unit
Primary outcome	Antibacterial effect	Colony counting	CFU/ml
Secondary outcome	Postoperative pain	Visual Analog Scale	Scoring Scale (0-10)

Primary Outcome

Antibacterial effect is evaluated by counting number of bacterial colonies, samples are collected and placed in brain–heart infusion (BHI) broth and subjected to microbiological analysis to determine the colony-forming unit (CFU)/ml (Shroff et al., 2024).

Secondary Outcome

Postoperative pain is assessed for each patient using Visual Analog Scale (VAS) with a score ranging from 0 (no pain) to 10 (unbearable pain) (Rahim et al., 2024).

5- Time Frame:

3 days for postoperative pain follow-up.

6- Study design & Methods:

The study design is a parallel randomized controlled clinical trial with allocation ratio 1:1:1

This study is conducted at Soad Kafafi University Hospital, Clinics of Faculty of Dentistry

Sample size: 36 patients divided into 3 groups (12 patients/ group)

Participants' inclusion criteria:

For patients: adult male and female patients and medically free.

For selected teeth: asymptomatic necrotic single rooted teeth, teeth with mature root and restorable teeth.

Exclusion criteria:

For patients: Patients with dental related symptoms ,patients with chronic or systemic diseases and pregnant females.

For selected teeth: multirooted teeth, vital teeth, teeth with incompletely formed roots, teeth with internal or external resorption and previously root canal treated teeth

Intervention Assignment:

Randomization:

Randomization will be done according to a check list including the number of participants divided into 3 groups according to interventions/Control assessment methods.

The allocation sequence will be generated using (www.random.org).

Allocation concealment mechanism:

Allocation concealment is done using sequentially numbered opaque sealed envelopes method.

Blinding:

The participants will be blinded to interventions/control assessment methods. Assign numerical codes to samples, ensuring that the experimenters do not know which treatment corresponds to which code until the study is completed.

Materials and methods:

Preoperative radiograph will be taken for each targeted tooth and vitality test will be performed, informed consent will be obtained from patients, preoperative pain score will be recorded using VAS, local anasthesia will be administered, rubber dam isolation and local disinfection measures applied, then access cavity preparation will be performed. Small K #15 file will be used to check canal patency, then working length will be determined using electronic apex locater and confirmed by a radiograph.

The canals will be enlarged to size 25 K-type file with no irrigation. Then each canal will be filled with sterile distilled water using a sterile plastic syringe to obtain the first bacteriological sample (S1) before any irrigation. Then a 3 sterile paper points size 25 will be placed in the canal for 1 minute. The paper points will be immediately transferred into brain–heart infusion (BHI) broth and subjected to microbiological analysis.

Patients are randomly divided using computer generated randomization (www.random.org) into three groups (n=12/group) according to the irrigant activation method :

Group A (Control group): Activation is done using ultrasonic.

Group B : Activation is done using System-B.

Group C: Activation is done using ultrasonic followed by intracanal heating using System-B.

The assistant supervisor generates the random sequence and assignes the participants to the interventions or control groups.

Then mechanical instrumentation is performed and canals are irrigated with 2.6% NaOCl after each file and the final irrigation protocol is done with activation using either ultrasonic or System-B or combination of ultrasonic and System-B according to the assigned group.

The ultrasonic activation will be done using ultrasonic tip that reaches 2 mm shorter than the working length without touching dentin walls then moved 2-3 mm in coronal-apical direction for 30 seconds then cycle is repeated 3 times with NaOCl refreshment between cycles.

The intracanal heating will be achieved using System-B with temperature set at 180°C and a suitable tip that reaches 3 mm shorter than working length while not touching dentin walls, irrigation is done using 6 ml NaOCl delivered in a syringe with side vented needle that reaches 2 mm shorter than working length and System-B tip is inserted and activated for 8 seconds then left nonactivated for 10 seconds, this activation is repeated 10 times and sodium hypochlorite solution is refreshed with new solution at each cycle.

Combination of these two activation techniques can be achieved by ultrasonic activation followed by intracanal heating using System-B in same manner as mentioned in each activation method.

Then the second beacteriologic sample (S2) will be obtained in same manner as S1. Then bacteriologic samples will be transferred to microbiology laboratory to detect change in bacterial count {Log (CFU/ml)} (Mukundan et al., 2024),(Nashaat, 2020),(Iandolo et al., 2018),(Ahmad Ali et al., 2023) (Shroff et al., 2024) (Yared and Al Asmar Ramli, 2020).

Pain score is recorded for each patient in all groups using Visual Analog Scale (VAS) at 6h, 12h, 24h, 48h and 72h postoperative. (Rahim et al., 2024)

7- Statistical plan

Sample size calculation based on bacterial count

According to a previous study by Mukundan et al (2024) The mean of The mean colony count post irrigation for 3 % NaOCl was 258.05 ± 28.61, and for 1 % NaOCl it was 267.60 ± 30.56. Using G power statistical power Analysis program (version 3.1.9.4) for sample size determination (Uttley, 2019), A total sample size (n=36; subdivided to 12 in each group) will be sufficient to detect a large effect size (f) = 0.54, with an actual power (1-β error) of 0.8 (80%) and a significance level (α error) 0.05 (5%) for two-sided hypothesis test.

Statistical analysis

Statistical analysis will be performed using a commercially available software program (SPSS Chicago, IL, USA).

Numerical data will be described as mean and standard deviation or as median and range as appropriate according to the normality of the data. Data will be compared using Kruskal Wallis test or ANOVA test depending on normality. The level of significance will be set at P≤0.05. All tests will be two tailed.

8- Ethics consideration:

The present research will be conducted after the approval of the Research Ethics Committee (REC) of the Faculty of Dentistry & Ethics Committee of Misr University For Science and Technology. It will be conducted on healthy patients with asymptomatic single rooted restorable necrotic teeth.

Ethical considerations regarding patients well-being and confidentiality will be undertaken by the researcher and an informed written consent will be signed by the patients before commencing the study explaining all clinical examinations , procedures and follow up. (Attached appendix)

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