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Evaluation of postoperative pain in patients using 8.25 % sodium hypochlorite compared with 5.25 % sodium hypochlorite using sonic and ultrasonic activation methods after single visit root canal treatment: an in-vivo study

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ABSTRACT

Introduction: The aim of this study was to evaluate the postoperative pain in patients using 8.25 % sodium hypochlorite compared to 5.25 % Sodium Hypochlorite concentration without activation and using sonic and ultrasonic activation methods after single visit root canal treatment.

Methods: In this double blind randomized trial, a total of 120 participants mandibular premolar with symptomatic irreversible pulpitis were included and randomly divided into 6 groups based on the different concentration of sodium hypochlorite and activation methods (sonic & ultrasonic activation) i.e. Group 1: 5.25 % NaOCl with no activation method, Group 2: 8.25 % NaOCl with no activation method, Group 3: 5.25 % NaOCl with sonic activation, Group 4: 5.25 % NaOCl with Ultrasonic activation, Group 5: 8.25 % NaOCl with sonic activation, Group 6: 8.25 % NaOCl with ultrasonic activation. The presence of postoperative pain was assessed 24, 48, and 72 h after treatment and recorded using the visual analogue scale (VAS).

Results: Intragroup postoperative pain in all six groups reduced after 24 h, 48 h and 72 h, showing statistically significant differences. At all-time intervals, postoperative pain was higher in the groups that used ultrasonic stimulation.

Conclusion: At all-time intervals, there was no significant difference in the presence of postoperative pain between the 8.25 % NaOCl and 5.25 % NaOCl irrigation solutions with no activation method and sonic activation compared to ultrasonic activation.

1. Introduction

Endodontic postoperative pain is an acute inflammation in the periradicular tissue caused by microbiological, chemical or mechanical injuries.[1] It is not uncommon and can occur between 3 % and 58 % of patients depending on the variables such as age, sex, preoperative pain and the presence of periapical lesions.[2,3] Postoperative pain may also be associated with the irrigation solutions used in the biomechanical preparation.[4] Thus, any procedure in the vicinity of periapical tissues has a potential to cause pain 5,6.

The action of endodontic instruments is generally limited to the main canal, which makes cleaning the root canal system inefficient.[7] Thus, the chemical action of irrigating solutions promotes the reduction of biofilm which is fundamental for the success of endodontic therapy.[8,9]

Sodium hypochlorite solution (NaOCl) is the most frequently used for the cleaning and disinfection of the root canals because of its antimicrobial action and capacity of dissolving organic material.[10,11] Previously, 5.25 % and 6 % NaOCl concentrations were available. In 2012, a concentrated 8.25 % NaOCl became available however, many dentists are not aware of this change. These solutions are frequently used ‘‘full strength’’ or they may be diluted with water to a concentration as low as 0.5 %.[12,13]

Higher concentration of NaOCl such as 8.25 % has a superior capacity for dissolving pulp tissue and capable of both rendering bacteria nonviable and physically removing the biofilm.[14]

Activation in root canal irrigation is the process of employing

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mechanical, physical or another form of energy to agitate and improve the flow of irrigant into the intricacies of the root canal system. Therefore, it is an essential step during the chemo-mechanical preparation of the root canal system. Among different activation methods, manual dynamic activation (MDA), passive ultrasonic irrigation (PUI), and sonic irrigation (SI) are some of the most widely used methods. However, due to the heterogeneity in the techniques it is still not possible to recommend any particular technique.[15]

Sonic irrigation operates at a lower frequency (1–10 kHz) and generates significantly greater amplitude (horizontal tip displacement).[16] Ultrasonically activated irrigation (UAI) implies the ultrasonic activation of irrigant in the centre of the instrumented root canal by a non-cutting, oscillating instrument.[17] Passive ultrasonic irrigation (PUI) is one of the most widely employed method of irrigation following root canal preparation and enlargement. The ultrasonic oscillation frequency of 25–40 kHz is achieved with either magnetostrictive (elliptical vibrations) or piezoelectric motion (linear vibrations).[18,19]

Thus, aim of the present study is to evaluate the postoperative pain in patients using 8.25 % sodium hypochlorite compared to 5.25 % Sodium Hypochlorite concentration without activation, sonic activation and ultrasonic activation method after single visit root canal treatment.

2. Materials and methods

This randomized controlled trial was approved by the Institutional Research Ethics Committee (RUHS-CDS/EC/2023/PG-The/09). A single operator performed all the examinations throughout the study. The operator was trained and calibrated in the Department of Conservative Dentistry and Endodontics to minimize diagnostic variability.

Sample size was 120 individuals with Symptomatic Irreversible Pulpitis in mandibular single rooted premolars with single canal (Type I Vertucci Classification with no periapical radiolucency), subdivided into 6 groups containing 20 each - Group 1: 5.25 % NaOCl with no activation method, Group 2: 8.25 % NaOCl with No activation method, Group 3: 5.25 % NaOCl with Sonic Activation, Group 4: 5.25 % NaOCl with Ultrasonic Activation, Group 5: 8.25 % NaOCl with Sonic Activation, Group 6: 8.25 % NaOCl with Ultrasonic Activation (Fig. 1).

The study included patients age above 18 years (18–50 years) with no medical condition or systemic diseases diagnosed with with symptomatic irreversible pulpitis in single rooted premolar teeth with single canal (Type I Vertucci Classification) and not taking analgesics 12 h before treatment. Grossly decayed teeth, root canal treated tooth, pathologic tooth mobility, patients with immature apices, root resorption or periapical pathology were excluded.

Randomization*:* Simple Block randomization was followed for dividing the individuals between the groups.

Blinding: Double-blinding technique (participants and operator unaware of material) was used in the study. The bottles containing the Sodium Hypochlorite solution were covered and labelled Bottle A and Bottle B by an assistant who was not involved in the study.

2.1. Standardized endodontic treatment protocol

The study included the teeth that met the inclusion criteria i.e. mandibular premolars with symptomatic irreversible pulpitis without apical periodontitis were chosen following appropriate history taking, clinical examination and radiographic examination. Patients were informed about the treatment protocol and consent was taken from those who accepted to participate in study. Also pain score before starting of treatment was recorded.

Pulp vitality test (PARKELL, USA) was performed. Then after the administration of local anaesthesia (2 % Lignocaine with Epinephrine

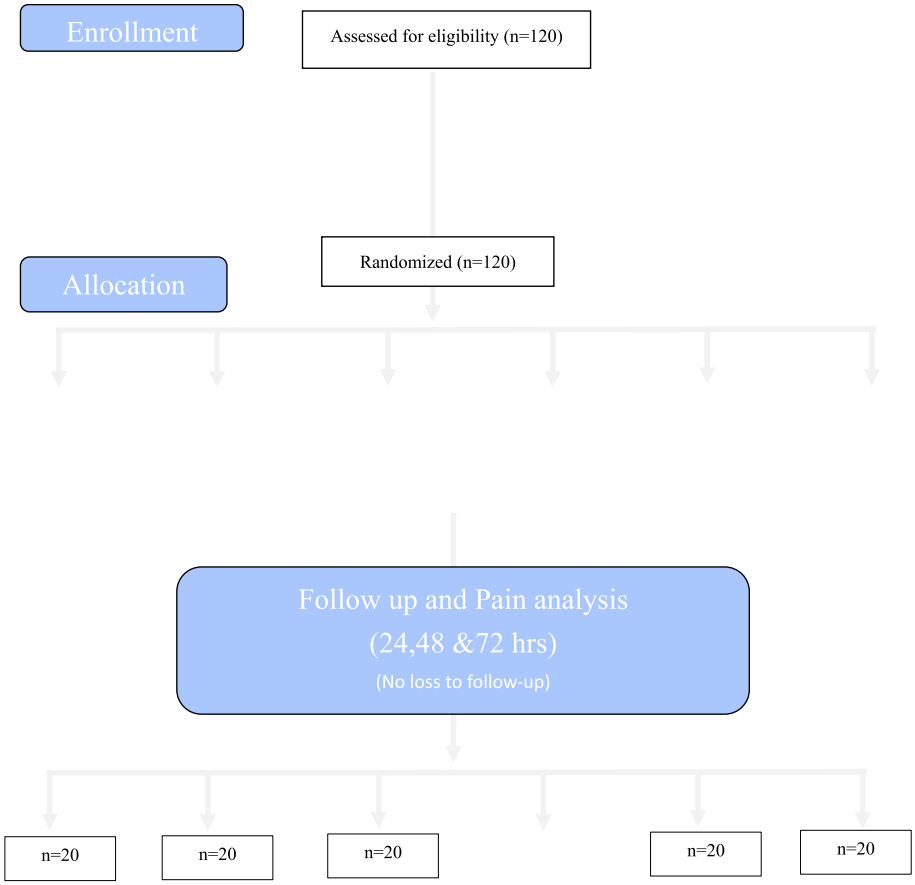


Fig. 1. The Consolidated Standards of Reporting Trials (CONSORT) flowchart of participants throughout the trial.

1:100000; Martin & Brown Bio-Sciences Pvt. Ltd.), an access cavity was prepared under rubber dam isolation (Coltene Whalent, USA). The working length was determined with the help of an electronic apex locator- Root ZX mini (J Morita, Tokyo, Japan) during the procedure with size 10 and 15 K-files (MANI, INC, Japan). Working length was then confirmed with parallel and angled radiographs to verify that the file tip lay within 0.5 of the radiographic apex.

The crown down preparation with apical preparation up to size 30 0.06 taper using Hyflex CM rotary files (Coltene) was performed. In between sequential filing, irrigation was performed using one of the concentrations of Sodium hypochlorite i.e. 5.25 % or 8.25 % according to the assigned group using 30G needle (Master Clean 1- Ident, Ahmedabad, Gujarat) placed 2 mm from working length (3 mL volume per canal per instrumentation). After the instrumentation was completed, final irrigation was performed with sodium hypochlorite and activation of irrigant was done either using Sonic activator - SuperEndo for 20 s at 6000 Hz or Ultrasonic Activator (Ultra X, Eighteeth) for 20 s at 40 kHz using #20/02 metal activator tip according to the group respectively. The smear layer was removed using a 17 % EDTA solution followed by final flush with 0.9 % saline (OTSUKA Pharmaceutical India Pvt. Ltd.). After drying with sterile absorbent points (Meta Biomed, Korea), the canals were obturated with single cone technique (Meta Biomed ISO GP points, Korea) and AH Plus Sealer (Dentsply DeTrey, Germany). The tooth was then restored using composite restoration - Te-Econom Plus (Ivoclar Vivadent, AG Liechtenstein) after which the occlusion was checked.

Patients were informed that they might experience pain in the days after treatment and were instructed to record their pain at 24 h, 48hrs and 72hrs after the treatment, to be submitted at the next follow up appointment, scheduled after three days. They were instructed to use analgesics (Tab. Ibuprofen 400 mg every 6–8 h), if needed for pain relief. They were also told to note down the details of analgesic intake on the pain form (VAS).

2.2. Statistical analysis

The data for the present study was analyzed using the SPSS statistical software 23.0 version. The inter group comparison of mean pain scores and mean number of medicines taken was done using One Way ANOVA test followed post hoc analysis using Fisher's LSD (Least Significant Difference) method to find the difference between groups. The intra-group comparison between the time intervals was done using the Paired *t*-test. The ordinal variables like intensity of pain were compared using the Chi Square test The level of the significance for the present study was fixed at 5 %. The Shapiro–Wilk test was used to investigate the distribution of the data and Levene's test to explore the homogeneity of the variables.

3. Results

At the 24-h time point, significant differences in pain scores were observed among the various groups. Group 1 reported the lowest mean pain score (3.75 ± 3.14), with no significant difference compared to Group 2 (3.70 ± 3.31) and Group 3 (4.80 ± 2.69). Also, Group 1 showed significantly lower pain scores compared to Group 4 (7.90 ± 2.17) and Group 6 (8.35 ± 1.27), both of which involved ultrasonic activation, indicating that ultrasonic activation may be associated with higher pain perception. These results suggest that the type of activation method (particularly ultrasonic activation) and the higher concentration of NaOCl (8.25 %) may had contributed to higher pain levels at 24 h (Tables 1 and 2).

At the 48-h time point, Group 1 reported the lowest mean pain score (1.40 ± 1.98), significantly lower than Group 4 (5.25 ± 2.57) and Group 6 (5.60 ± 2.54). Group 2 (1.15 ± 1.63) and Group 3 (1.80 ± 1.47) also exhibited significantly lower pain scores than Group 4 and Group 6, highlighting the higher pain associated with ultrasonic activation and higher NaOCl concentration while no activation or sonic activation groups are associated with lower pain levels (Tables 1 and 2).

Table 1
Intergroup comparison of mean pain scores between time intervals.

	24h Mean ± SD	48h Mean ± SD	72h Mean ± SD
Group 1	3.75 ± 3.144	1.40 ± 1.984	0.50 ± 1.147
Group 2	3.70 ± 3.310	1.15 ± 1.631	0.10 ± 0.308
Group 3	4.80 ± 2.687	1.80 ± 1.473	0.40 ± 1.142
Group 4	7.90 ± 2.174	5.25 ± 2.573	2.00 ± 2.471
Group 5	5.10 ± 2.174	2.75 ± 2.023	0.90 ± 1.252
Group 6	8.35 ± 1.268	5.60 ± 2.542	2.15 ± 2.368
P-value	0.001*	0.001*	0.001*

* Statistically significant.

Group 4 and Group 6 reported higher pain scores at 72 h compared to other groups suggesting that the combination of higher NaOCl concentration (8.25 %) and ultrasonic activation leads to higher pain scores while lower concentrations of NaOCl and no activation or sonic activation methods are associated with reduced pain (Tables 1 and 2). Graph 1 depicts intergroup comparison of mean pain scores at 24 hr, 48 hr and 72 hr.

4. Discussion

The goal of endodontic therapy is to eliminate all microorganisms from root canal by means of cleaning, shaping, disinfecting and filling the root canal system. The reduction of the microbial load and the disruption of biofilms are achieved by a combination of mechanical instrumentation, irrigation with tissue-dissolving and antimicrobial medicaments.

Comparing to other irrigants available, Sodium Hypochlorite is the "gold standard" solution. Its main advantages are pulpal dissolution and antimicrobial effect. Higher concentrations of NaOCl exhibit more cytotoxicity, while providing more tissue dissolving properties.[10]

Activation techniques such as passive ultrasonic irrigation (PUI) and sonic irrigation, may help the irrigating solution reach the apical third by activating the NaOCl, after the cleaning and shaping procedure, thus improving the cleaning efficiency of the irrigating solution by reaching irregularities in the root canal system.[20]

The present study took into the consideration of 8.25 % NaOCl to be used as irrigant to evaluate that if pain scores are same or different in comparison to other concentration of NaOCl i.e. 5.25 %. If the higher concentration is more cytotoxic then pain score values will be higher with 8.25 % hypochlorite. Sonic and ultrasonic activation methods are the commonly used activation system in endodontics. Thus, these activation methods are employed in this study.

The Visual Analogue Scale (VAS) is widely recognized and frequently used. Scores are recorded by making a mark on a 10-cm line that represents a continuum between no pain and worst pain 21.

Since pain after endodontic treatment is often felt in first 72 h after treatment[22] therefore three-time intervals of 24, 48 and 72 h were selected to assess the severity of pain in patients.

Mandibular premolars with single canal (Type I Vertucci Classification) were selected as this consistency reduces variability in the root canal morphology, making it easier to compare pain experience.

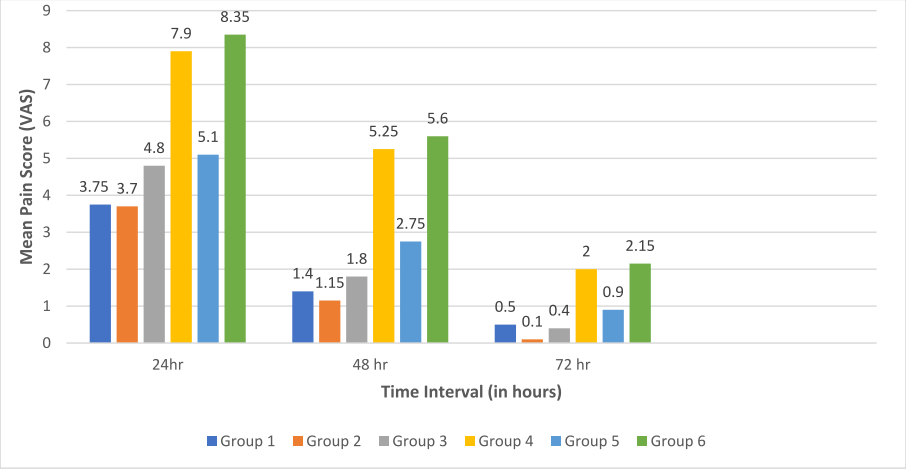
Another aspect related to the method must be discussed is the single visit root canal treatment, the technique of choice in this study. Sevekar and Gowda demonstrated that there was no significant difference in this outcome between patients treated in single or multiple sessions.[23]

At the 24-h time point, Group 1, which used 5.25 % NaOCl with no activation, reported the lowest mean pain score with no significant difference compared to other groups. Group 4 and Group 6 had the highest pain scores, with Group 6 showing the most intense pain at attributing to combine effect of higher concentration of hypochlorite (8.25 %) and ultrasonic activation.

Table 2
Post hoc intergroup comparison of mean pain scores between time intervals.

Comparison	24 h		48 h		72 h	
	Mean Difference	P value	Mean Difference	P value	Mean Difference	P value
G1 vs G2	0.050	0.951	0.250	0.704	0.400	0.440
G1 vs G3	−1.050	0.196	−0.400	0.544	0.100	0.847
G1 vs G4	−4.150	0.001*	−3.850	0.001*	−1.500	0.004*
G1 vs G5	−1.350	0.097	−1.350	0.072	−0.400	0.440
G1 vs G6	−4.600	0.001*	−4.200	0.001*	−1.650	0.002*
G2 vs G3	−1.100	0.176	−0.650	0.325	−0.300	0.562
G2 vs G4	−4.200	0.001*	−4.100	0.001*	−1.900	0.001*
G2 vs G5	−1.400	0.086	−1.600	0.017	−0.800	0.124
G2 vs G6	−4.650	0.001*	−4.450	0.001*	−2.050	0.001*
G3 vs G4	−3.100	0.001*	−3.450	0.001*	−1.600	0.002*
G3 vs G5	−0.300	0.711	−0.950	0.151	−0.500	0.335
G3 vs G6	−3.550	0.001*	−3.800	0.001*	−1.750	0.001*
G4 vs G5	2.800	0.001*	2.500	0.001*	1.100	0.035*
G4 vs G6	−0.450	0.578	−0.350	0.596	−0.150	0.772
G5 vs G6	−3.250	0.001*	−2.850	0.001*	−1.250	0.017*

* Statistically significant.



Graph 1. Intergroup comparison of mean pain scores between time intervals.

Similarly, at 48-hr time point, Group 4 and Group 6 reporting higher pain level compared to other groups. At 72-hr time point, Group 6 recorded highest pain level followed by Group 4 as compared to other groups. This suggest that the combination of higher NaOCl concentration (8.25 %) and ultrasonic activation leads to higher pain scores even at 72 h, while lower concentrations (5.25 %) with no activation or sonic activation are associated with reduced pain. Overall, pain levels decreased across all groups at all time interval, but the groups without activation or with sonic activation had significantly better outcomes than those using ultrasonic activation.

At all-time interval pain score of Group 1 and Group 2 showed no significant difference. The result was similar to the study done by Luciana et al. which concluded that there was no significant difference in the presence of postoperative pain between the 8.25 % NaOCl and 5.25 % NaOCl.[24] The exact reason for less pain when a higher concentration (8.25 %) of NaOCl used is unclear. No periapical radiolucency and the presence of normal periapical structures may prevent extrusion of the irrigant as well as debris despite the higher dissolution capacity of 8.25 % NaOCl. Also, the higher dissolution capacity of NaOCl may dissolve the remaining apical pulp tissues more effectively and therefore not let them release signaling molecules that may up-regulate inflammation in the periapical tissues.

The current study's findings were in conflict with those of a study conducted by FC Vitali et al., which found that postoperative pain was higher with 8.25 % NaOCl than with 2.5 % NaOCl, with pain scores rising by 3.48 times.[25] This is because teeth with necrotic pulps associated with apical periodontitis and periapical lesions have foraminal resorption and periapical extrusion is more common when the apical constriction is disrupted. Intact periapical tissues can act as a barrier against irrigant and material extrusion.[26]

Study by Farazaneh S et al. revealed 5.25 % NaOCl was associated with significantly lower postoperative pain compared to 2.5 % NaOCl during the first 72 h following one-visit root canal treatment of mandibular molars with irreversible pulpitis.[26]

Group 6 followed by Group 4 exhibited high pain score as compare to other groups at all times as both groups were treated with the ultrasonic activation of irrigant irrespective of the hypochlorite concentration. The reason may be due to apical extrusion of irrigant as well as generation of shear forces by ultrasonic activation which may be responsible for higher postoperative pain. Similarly, Mitchell et al. in-vitro study concluded that ultrasonically activated irrigation (UAI) shown a comparable amount of irrigant (6 % NaOCl) extrusion to conventional syringe irrigation and sonic irrigation system.[27]

Group 3 and Group 5 used 5.25 % & 8.25 % respectively and sonic activation showed no difference in pain score at all time intervals and pain gradually decreased from 24 h to 72 h time interval when compared with Group 4 and Group 6. This may be due to the fact that SuperEndo Sonic Activator (1–6 KHz) remove debris from the apex without forcing the irrigant into the periapical tissues, thus reducing the chances of periapical extrusion irrigant and thus reduced chances of postoperative

pain in these groups. These findings are in accordance with the study by Gümüs et al. and Yılmaz et al. who attributed this to the fact that the use of sonic activated method results in less apical extrusion compared to the conventional endodontic syringe and therefore less postoperative pain28,29.

Group 6 had significantly higher medication usage than Groups 1, 2, 3, 4 and 5 with all comparisons reaching statistical significance which suggest that ultrasonic activation especially in combination with 8.25 % NaOCl-was associated with higher post-operative pain necessitating more medication.

As the use of single file systems has increased which made the canal preparations faster and thus in less time it requires higher concentration of sodium hypochlorite with increased availability of hypochlorite ions in contact with root canal system to remove bacterial biofilm. Also, the pulpal dissolution capacity of 8.25 % sodium hypochlorite is much superior to other concentration available. Hence, 8.25 % sodium hypochlorite can therefore be used in clinical practice with caution.

The limitation of this trial is not including more subjects due to its limited time period and stricter inclusion criteria adopted. It is also important to point out that due to the specific nature of teeth included in the present study, the findings of this study cannot be generalized. Also, no bacteriologic sampling was performed to determine the microbial burden remaining in the canals after irrigation with 8.25 % and 5.25 % NaOCl and its activation. Thus, future studies are recommended to assess the effects of high concentrations of hypochlorite to assess the short- and long-term outcomes.

5. Conclusion

Within the limitation of this study, it can be concluded that at all-time intervals, ultrasonic activation of 8.25 % and 5.25 % NaOCl results in higher postoperative pain. There was no significant difference in the presence of postoperative pain between the 8.25 % NaOCl and 5.25 % NaOCl irrigation solutions with no activation method and sonic activation of irrigant.

Informed consent statement

Informed consent was obtained from all subjects involved in the study.

Institutional review board statement

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Research Ethics Committee (RUHS-CDS/EC/2023/PG-The/09).

Data availability statement

The datasets used and/or analyzed during the current study are available from the corresponding author.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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