EFFECT OF IRRIGATION WITH PRE-HEATED AND ULTRASONICALLY ACTIVATED SODIUM HYPOCHLORITE AT DIFFERENT CONCENTRATIONS ON POSTOPERATIVE PAIN LEVEL: A RANDOMIZED CONTROLLED CLINICAL STUDY

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Abstract

Introduction: Pain relief and complete disinfection is the primary goal of root canal treatment in any tooth. Post Operative pain is multifactorial and one of the factors affecting it is sodium hypochlorite used as an irrigant. Aim: The aim of the present study is to evaluate the effect of pre-heated and ultrasonically activated sodium hypochlorite on post operative pain when used at different concentrations.

Materials and Methods: In this randomized control trial, 80 patients were evaluated and divided into 4 groups. Two concentrations of NaOCl were used at 3% and 5.25%. For each concentration, preheated solution and ultrasonic activation is used. All treatments were done in single session on mandibular molars. Presence of post-operative pain was calculated at 6h, 24h, 48h, 72h on VAS scale. Pre-operative pain was also considered. Data regarding the intensity of postoperative pain was analysed for normality using one-way Anova.

Results: Overall, mean postoperative pain intensity was low, with the majority of patients having no or minimal pain 72 hours postoperatively. Comparison of pain postoperatively after 6 hours shows that the amean value of Group 2(5.25% pre-heated NaOCl) (2.9) is highest followed by Group 4(2.2), Group 1(2.05) least in Group 3(1.5) (3% UAI-NaOCl).

Conclusion: Pre-heated and ultrasonically activated irrigation resulted in low and comparable levels of postoperative pain. Pre-heated 5.25% NaOCl was associated with higher amount of pain comparatively. Though Post-operative pain overall from all the groups yielded similar results, using low concentration NAOCL and UAI is a more suitable option.

Keywords: Sodium hypochlorite, postoperative pain, ultrasonic activated irrigation, randomized controlled trial.

Introduction

Postoperative pain is a significant short-term consequence of root canal therapy (RCT). Endodontic postoperative pain is an inflammatory condition of the peri-radicular tissue resulting from microbiological, chemical, or mechanical injuries.[1] Depending on factors including age, sex, preoperative discomfort, and the existence of periapical lesions, it is not rare and can happen in between 3% and 58% of patients.[2]

Disinfection of the root canal remains incredibly difficult, possibly because there are isthmuses, lateral canals, curvatures, apical deltas, and dentinal tubules. [3] Thus, the chemical activity of irrigation solutions has vital role in the removal of biofilm, which is essential for the effectiveness of endodontic therapy.[4 5] However, the irrigation solutions employed during the biomechanical preparation may cause postoperative pain.[6]

Sodium hypochlorite (NaOCl) is the most often administered irrigant during root canal therapy due to its many benefits, including its antibacterial activity, antibiofilm activity, and organic-tissue-dissolution efficacy.[7] Dental professionals employ a range of NaOCl concentrations, from 0.5% to 8%, with a preference for greater concentrations (American Association of Endodontists (AAE) 2018).[9] Higher concentrations of NaOCl may improve the solution's efficacy, particularly its tissue-dissolving characteristic, but they compromise its safety.[8] On the other hand, it can cause an inflammatory response even at concentrations as low as 0.5%, which may indicate a higher likelihood of postoperative pain occurrence, especially in cases of teeth with patent apices and non-vital pulps. [8]

Sirtes, et al. (2005) previously stated that NaOCl has greater antibacterial effectiveness at 45 °C than at 20 °C. [10] A clinical study reported that the temperature of preheated NaOCl (60 °C) starts to decrease as soon as the solution touches the root canal wall and reaches body temperature (35.7 °C) within a few minutes.[11] Since the temperature of the irrigation solution is known to have an impact on postoperative pain, it is important to find out if preheated NaOCl exerts an additional antibacterial effect and affects the postoperative pain level clinically.[12]

The development of various irrigant activation tools or techniques to enhance irrigant distribution and boost disinfection have been made to reduce post operative pain and increase the action of sodium hypochlorite at lesser concentration. [8] Ultrasonically activated irrigation (UAI) indicates the use of an oscillating, non-cutting device to apply ultrasound waves to an irrigant in the middle of a root canal that has been instrumented.[7] The primary mechanism of action is the creation of acoustic microstreaming, or the continuous, unidirectional circulation of fluid around the vibrating instrument. Regarding the removal of pulp tissue and hard tissue debris, UAI has been shown in multiple laboratory experiments to be more effective than traditional syringe irrigation. [13, 14]

Even with such advances, postoperative pain is a major complication after root canal treatment. The incidence of postoperative pain stated in cases is 39% after endodontic treatment and in the first 24 hours, this rate can even be up to 65% and above.[15] Our randomized controlled clinical study aimed to evaluate the effect of final irrigation of root canals with NaOCl solution at different temperatures and techniques on postoperative pain level in single sitting root canal treatment of lower mandibular molars.

Materials and method

Study design and setting

This double-blind, single-centre, superiority with a parallel design randomized controlled trial was designed and reported in accordance with the ethical committee guidelines. The University's Institutional Review Board and Ethics Committee granted its approval for the study's ethical conduct. Participation in the study was voluntary. All patients signed an informed consent form after aims, procedures, benefits and potential risks of the study were explained. The study was conducted by single postgraduate student, trained in endodontic procedures (using rotary instruments, irrigation, and canal filling).

Eligibility criteria

The inclusion criteria were as follows:

- Healthy individuals aged 20-50 years without any systemic disease,
- Mandibular molar teeth that were diagnosed with symptomatic or asymptomatic irreversible pulpitis or that showed prolonged response in the tooth even after the removal of the thermal and electric pulp test.
- Using the Schneider [7] (1971) approach, teeth with all root canals angled up to 25 degrees, two canals in the mesial root, and one canal in the distal root.
- No previous history of endodontic treatment, and
- A pocket depth of <3 mm

The exclusion criteria were the following:

- Patients who have taken analgesics or anti-inflammatory medications during the previous 12 hours.
- Patients who are expecting or nursing.
- Teeth with too much damage for rubber dams.
- Teeth having radiographic signs of calcification, resorption, or open apices.
- Patients lacking occlusal contact; patients with traumatic malocclusion.

A computer algorithm was used to randomly divide 80 patients into four groups based on the type of irrigation used during root canal preparation (available at www.randomizer.org). Patients were blinded and were not informed regarding the groups. However, due to the nature of the trial, the clinician could not have been blinded regarding the technique of groups, though blinding was done regarding the concentration of sodium hypochlorite.

Division of Groups

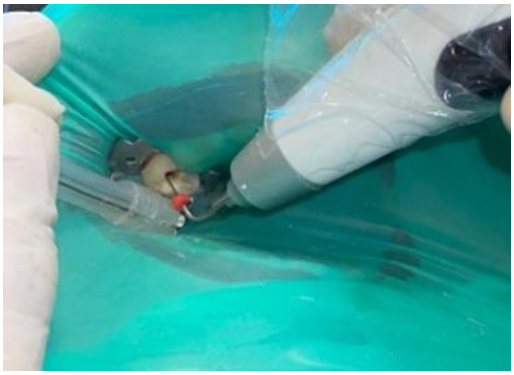
- Group 1 Preheated 3% Sodium hypochlorite
- Group 2 Preheated 5.25% Sodium hypochlorite
- Group 3 Ultrasonically activated 3% Sodium hypochlorite
- Group 4 Ultrasonically activated 5.25% Sodium hypochlorite

Figure 1: Sodium Hypochlorite syringe

Figure 2: Ultrasonic activator

Figure 3: Treatment procedure

Figure 4: UAI in rubber dam isolation



Treatment procedure

Each person's medical and dental histories were logged, along with a clinical and radiographic examination. The clinical examination comprised percussion tests, periodontal probing, palpation, inspection of the tooth and surrounding tissues, and evaluation of restorability. Pre-Operative pain were considered. Before treatment, an oral rinse was performed with 0.12% chlorhexidine and the teeth were isolated with the rubber dam. Teeth were anaesthetized with a local anaesthetic solution containing 4% lidocaine with 1:100.000 epinephrine.

Access cavities were prepared using sterile burs (Mani, Tochigi, Japan) under cooling with sterile saline solution. Working length determination was done with an electronic apex locator (J.Morita Root ZX mini, Munich, Germany) with 10 K-file (Mani, Tochigi, Japan). Root canals were prepared using Rotary files Hyflex CM (Coltene, Switzerland) (25.04 and 25.06) according to the manufacturer recommendations. During preparation, root canal irrigation was performed using 2 mL of NaOCl (According to the various groups) and saline between three pecking motions of the file and final irrigation was performed with 5 mL of NaOCl (at different temperatures according to the specific groups):

Group 1 and Group 2: Preheated Sodium hypochlorite

NaOCl 45ºC: A double boiler system was used to heat a syringe filled with 5 mL of NaOCl. The syringe was left in the device for 30 seconds to reach an average temperature of 45±0.2ºC, because the device cannot be set to a specific temperature. Then the syringe was removed from the device and, root canal irrigation was performed for 1 minute (the room temperature was 24.2ºC).

Group 3 and group 4: UAI group

Ultrasonically activated NaOCl was used. 5ml NaOCl was introduced in the canal with needle and then activated with Ultrasonic Activator (Ultra -X, Eighteeth, China) for 30 secs.

Next, paper points were used to dry the root canals and the warm lateral compaction technique was used to obturate the root canals with gutta-percha cones and sealer (Sealapex, Kerr Corporation, Orange, CA). Permanent restorations were performed using flowable and nanohybrid composite resins Tetric-n-Ceram (Ivoclar Vivadent, Liechtenstein, Germany).

Postoperative pain evaluation

Every patient was given a pain journal to keep track of their pain at the following intervals: 6, 24, 48, and 72 hours following the intervention. The pain level was indicated using a visual analogue scale (0–100 mm). The patients were given a full explanation of the VAS before being given the task of marking the horizontal VAS line with a

mark matching to the postoperative intensity at each of the different times. Patients were instructed to take the prescribed medicine only if they thought the pain was interfering with their daily activities, and mention in the pain dairy. Patients were instructed to return the reports either via email, or phone message or at their next visit at the dental school.

Statistical analysis

The statistical analyses for postoperative pain values were performed using IBM® SPSS® Statistics 20 software (IBM SPSS Inc., Chicago, IL, USA) at 5% significance level (p=0.05). Data regarding the intensity of postoperative pain were analysed for normality using One-way Anova. Posthoc tukey test was used to compare the postoperative pain between groups for each time interval. Paired t test to compare the before and after VAS score in each group separately. Categorical variables were analysed using Pearson's chi-square test. A binomial logistic regression for each time interval was used to assess the association between postoperative pain (No/Yes), Post operative pain after 7 days (No/Yes) and the independent variables (gender, age, radiolucency). McNemar Chi square test to compare the before and after of the categories.

Results

A total of 83 subjects were initially screened for inclusion, of which 80 were enrolled in final groups (20 per group) and 56 patients were finally in the study. The age group of the patients is from 20-50 years. Demographic data (gender and age) of the groups are shown in Table 1 and Table 2. No statistically significant difference was found between the groups according to gender distribution (p>0.05). There was also no significant difference between two groups regarding the presence of an apical radiolucency (Table 3).

Table 4 shows the mean and Standard Deviation of pain intensity in the four groups at the different time intervals. Overall, mean postoperative pain intensity was low, with most patients having no or minimal pain 72 hours postoperatively. Comparison of Postoperative 6 hours using one way ANOVA test shows that the mean value of Group 2 (2.9) is highest followed by Group 4(2.2), Group 1(2.05) least in Group 3(1.5). The distributions of pain levels evaluated at various periods in each group showed a statistically significant difference.

Comparison of Pain difference from 6 hours to 72 hours shows a significant difference in reduction of pain overall. A comparison of patients with pre-operative pain to post operative pain after 7 days is shown in Table 5. 52 people had pain in the beginning before treatment but 50 of them became painless after 7 days of treatment. That is significant improvement.

Table 1: Chi square test to compare the categorical variables Sex M/F * Group

Crosstab							
			Group				Total
			Group 1	Group 2	Group 3	Group 4	
Sex M/F	F	Count	11	12	11	13	47
		% within Group	55.0%	60.0%	55.0%	65.0%	58.8%
	M	Count	9	8	9	7	33
		% within Group	45.0%	40.0%	45.0%	35.0%	41.2%
Total		Count	20	20	20	20	80

	% within Group	100.0%	100.0%	100.0%	100.0%	100.0%

Chi-Square Test – Value = .567, df =3, P value (<0.05 is significant) = 0.904

Table 2: Chi square test to compare the categorical variables Age * Group

Crosstab							
			Group				Total
			Group 1	Group 2	Group 3	Group 4	
Age	<30	Count	5	3	5	6	19
		% within Group	25.0%	15.0%	25.0%	30.0%	23.8%
	31-40	Count	9	7	9	10	35
		% within Group	45.0%	35.0%	45.0%	50.0%	43.8%
	41-50	Count	6	10	6	4	26
		% within Group	30.0%	50.0%	30.0%	20.0%	32.5%
Total		Count	20	20	20	20	80
		% within Group	100.0%	100.0%	100.0%	100.0%	100.0%

Chi-Square Test - Value = 4.466, df = 6, P value (<0.05 is significant) = 0.614

Table 3 Chi square test to compare the categorical variables Periapical Radiolucency * Group

Crosstab							
			Group				Total
			Group 1	Group 2	Group 3	Group 4	
Periapical Radiolucency	NO	Count	13	14	12	15	54
		% within Group	65.0%	70.0%	60.0%	75.0%	67.5%
	YES	Count	7	6	8	5	26
		% within Group	35.0%	30.0%	40.0%	25.0%	32.5%
Total		Count	20	20	20	20	80
		% within Group	100.0%	100.0%	100.0%	100.0%	100.0%

Chi-Square Test – Value = 1.140, df = 3, P value (<0.05 is significant) = 0.768

Table 4 One-way anova and posthoc tukey test for comparing the 4 groups

		N	Mean	Std. Deviation	Statistics/ mean squares	df2(welch) / F(Anova)	p value
Postoperative 6 hours	Group 1	20	2.05	2.259	6.646	1.266	0.292
	Group 2	20	2.9	2.614			
	Group 3	20	1.5	1.933			
	Group 4	20	2.2	2.308			
	Total	80	2.16	2.303			
Postoperative 24 hours	Group 1	20	0.8	1.105	1.881	40.689	0.148
	Group 2	20	1.25	1.446			
	Group 3	20	0.45	0.759			
	Group 4	20	0.95	1.432			
	Total	80	0.86	1.23			
Postoperative 48 hours	Group 1	20	0.25	0.444	1.154	40.052	0.339
	Group 2	20	0.5	0.889			
	Group 3	20	0.15	0.366			
	Group 4	20	0.4	0.883			
	Total	80	0.33	0.689			
Postoperative 72 hours	Group 1	20	0.1	0.308	0.715	39.801	0.549
	Group 2	20	0.25	0.639			
	Group 3	20	0.05	0.224			
	Group 4	20	0.15	0.489			
	Total	80	0.14	0.443			
Pain Difference 24 to 6 hours	Group 1	20	1.25	1.372	1.267	0.746	0.528
	Group 2	20	1.65	1.387			
	Group 3	20	1.05	1.276			
	Group 4	20	1.25	1.164			
	Total	80	1.3	1.297			
Pain difference 48-6 hours	Group 1	20	1.8	1.908	3.712	1.078	0.364
	Group 2	20	2.4	2.137			
	Group 3	20	1.35	1.631			
	Group 4	20	1.8	1.704			

	Total	80	1.84	1.859			
Pain difference 72 to 6 hours	Group 1	20	1.95	2.139	4.85	1.073	0.366
	Group 2	20	2.65	2.455			
	Group 3	20	1.45	1.791			
	Group 4	20	2.05	2.064			
	Total	80	2.03	2.129			

Table 5: McNemar Chi square test to compare the before and after of the categories

Pre- operative pain * Postoperative 7 days Crosstabulation				
Count				
		Postoperative 7 days		Total
		N	Y	
Pre- Operative Pain	N	26	2	28
	Y	50	2	52
Total		76	4	80

One patient from the group 3 group reported severe pain up to 78 mm on the VAS till 48h postoperatively. This case was associated with swelling, and an emergency visit. No other untoward effects were reported. Post operative medication was taken by 16 patients of which 7 were from group 2 and 4 from group 1, 3 from group 4 and only one from group 3.

Discussion

One of the crucial phases in root canal therapy is cleaning and extensive debridement of the root canal, with an aim to provide painless treatment to the patient. In order to determine the most effective root canal irrigating method, root canal irrigants have frequently been explored for novel approaches. [7]

Clinical research investigating into postoperative pain encounter a variety of challenges since post-endodontic pain might be caused by several variables rather than just one. [16] The ability of the intra-treatment factors (mechanical irritation caused by excessive instrumentation, debris extrusion and canal overfilling, chemical trauma by irrigants, and residual intracanal bacteria) to cause postoperative pain on their own or whether they should be paired with one of the pre-treatment circumstances is still unknown.[17] Because they balance these known and unknown aspects, randomised controlled trials are an excellent tool for dealing with these types of challenges. [16]

Our study compared the effect of NaOCl with different temperatures and techniques in final irrigation on postoperative pain level. It was found that the lowest post-operative pain was recorded for 3% NaOCl used with ultrasonic activation. When comparing the different concentrations, it can be said that the lower concentration causes lesser amount of pain. This is in accordance with various studies. In their investigations, Farzaneh, et al.[18] (2018) assessed the impact of 5.25% NaOCl and 2.5% NaOCl solution on postoperative pain and found that 2.5% NaOCl solution showed reduced pain levels. Additionally, Mostafa, et al.[19] (2020) observed that the 1.3% NaOCl solution demonstrated decreased pain levels compared to 5.25% NaOCl.

Utilizing a technique to agitate and enhance the flow of irrigants to the intricate root canal system via mechanical or other energy forms is known as activated irrigation. [20] in various studies done UAI technique is found to be effective in reducing post operative pain. [20,21] Our study also assessed how NaOCl at various temperatures affected the severity of postoperative pain, and it revealed that root canal irrigation with NaOCl at 45°C led to a considerably higher postoperative pain score.[22] Thus a better technique for irrigation when keeping in mind post operative pain will be UAI. The preheated NaOCl's ability to induce postoperative pain can be explained by the fact that heat raises tissue temperature, which causes vasodilation. Vasodilatation improves blood flow while allowing leukocytes and plasma proteins to leave the body. This may lead to a rise in inflammatory reactions, which would heighten postoperative discomfort.[23] Higher concentrations may be compensated for by frequent exchange, higher volumes, and agitation. [24]

By considering elements pertaining to the patient and the damaged tooth, Arias et al.[23] looked into the likelihood of the incidence, intensity, duration, and triggering of endodontic postoperative pain. Pamboo et al.[25] reported that while there was no statistically significant difference for age in relation to postoperative pain, there was a significant difference for sex, with a higher prevalence in women. Different tooth types in different regions have an impact on postoperative pain, according to studies in the literature. Ali, et al.[26] reported more pain in the mandibular region than in the maxillary region. This variation in pain may be brought on by the different tooth canal configurations and apical third anatomy. In accordance with studies in the literature, mandibular molar teeth were utilised in this study.

A 100 mm scale was utilised instead of a lesser scale (50 mm) by VAS to measure the intensity of the pain.[27] Studies examining pain during or during root canal therapy typically employed VAS.[28] It is simple to use, methodologically sound, and accurate for measuring pain.

The fact that the root canal solution's temperature varied during the irrigation process is one of the study's limitations. When the solution was employed for root canal irrigation in vivo, De Hemptinne et al.12 (2015)[11] demonstrated that the solution temperature (45°C) dropped to body temperature (37°C) after 60 seconds. The warmed NaOCl solution's antibacterial effectiveness can be determined after 60 seconds because NaOCl exerts its antibacterial efficacy in seconds13. Furthermore, it can be asserted that a drop in solution temperature had no appreciable impact because the warmed NaOCl group displayed greater postoperative pain scores than the normal temperature NaOCl group. This indicates that the heat's effects were evident in our study.

Conclusion

Within the limitations of the study, using preheated NaOCl during chemo-mechanical preparation of root canals, resulted in higher postoperative pain. For both techniques, lower concentration showed less pain level. Though overall all groups resulted in reduced pain level at the end of 7 days post operative.

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