Original Article

Evaluation Of Postoperative Pain After Using Two Different Irrigation Systems During Endodontic Treatment- A Randomized Clinical Trial

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Contributions:
FA[1] BQ FA[4] ZK- Conception, Design
FA[1] SA KI - Acquisition, Analysis, Interpretation
FA[1] FA[4] KI ZK- Drafting
FA[1] BQ SA - Critical Review

All authors approved the final version to be published & agreed to be accountable for all aspects of the work.

Conflicts of Interest: None
Financial Support: None to report
Potential Competing Interests: None to report

Disclaimer: This study has not been published or submitted elsewhere for publication.

AI Disclosure: Artificial intelligence tools were used solely for language refinement and formatting. No AI tools were used for data analysis, interpretation, or result generation. All scientific content, analyses, and conclusions were developed and verified by the authors, who took full responsibility for the integrity and accuracy of the work.

Data Availability Statement: The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Institutional Review Board Approval
Dental/HITEC/IRB/56
21-11-2023
Dental College HITEC-IMS Taxila

Review began 10/12/2025
Review ended 20/06/2026
Published 30/06/2026

How to cite this article: Altaf F, Qureshi B, Ahmed S, Arshad F, Iftikhar K, Khan Z. Evaluation of postoperative pain after using two different irrigation systems during endodontic treatment- A randomized clinical trial. JRMC. 2026 Jun. 30;30(2).

https://doi.org/10.37939/jrmc.v30i2.3122

Abstract

Objective: To compare the effects of conventional and sonic irrigation on postoperative pain during root canal treatment.

Methodology: A randomised clinical trial was conducted at the Department of Operative Dentistry and Endodontics at HITEC-IMS Taxila. Eighty-two patients were randomly selected and assigned equally to two groups (n = 41 each) using a lottery method. Postoperative pain was assessed using the visual analogue scale, and analgesic intake was recorded at 6, 12, 24, and 48 h. Mean VAS scores and mean analgesic intake between groups were compared using the independent-samples t-test, with significance set at $P < 0.05$.

Results: Patients treated with sonic irrigation reported lower postoperative pain than those treated with needle irrigation at all evaluated time points. At 6 h, 65.9% of patients in the sonic irrigation group had mild pain, and 17.1% were pain-free, whereas 61% of patients in the needle irrigation group had moderate pain and 17.1% had severe pain. At 12 to 24 h, 85.4% of patients in the sonic irrigation group were pain-free, whereas 41.5% in the needle irrigation group still had moderate pain. By 48 hours, 90.2% of the patients in the sonic irrigation group were pain-free.

Conclusion: Sonic irrigation significantly reduced postoperative pain and analgesic intake compared to conventional needle irrigation.

Keywords: Analgesics, Endodontics, Postoperative Pain, Root Canal Irrigation, Dental Pulp Disease, Pain Measurement, Sodium Hypochlorite.

Introduction

Dentistry has progressed from a manual craft to a specialized, technology-driven field. Endodontics plays a key role in preserving natural teeth, relying on the clinician's precision and skill. The introduction of motor-driven instruments has enhanced the efficiency and effectiveness of endodontic procedures.[1]

Despite these advancements, the primary goal of endodontic treatment remains the elimination of microorganisms from the root canal system and the prevention of reinfection.[2] Achieving this requires a combination of biomechanical preparation, intracanal medication, and effective irrigation. Due to the complex canal anatomy, especially apically, chemo-mechanical debridement is crucial for effective disinfection. This phase aims to remove pulpal tissues, microorganisms, and their byproducts, and debris using endodontic instruments and irrigants.[3]

Although the type of irrigant is important for eliminating microorganisms from infected canals, the activation method plays a major role in enhancing its effectiveness.[4] Different activation techniques have been used, including manual methods with needles, files, or gutta-percha points, as well as machine-assisted approaches involving rotary brushes, continuous irrigation, sonic activation, ultrasonic activation, and negative pressure systems.[5] These advanced methods improve the cleaning of complex canal anatomy and are more effective than traditional syringe needle irrigation, because they allow deeper irrigant penetration and better removal of debris and microorganisms.[6]

The endo-activator, which is part of the sonic subgroup of machine-assisted irrigation, uses smooth plastic tips of various sizes to activate irrigants at sonic frequencies of up to

6000 Hz. It enhances cleaning efficiency by promoting cavitation and acoustic streaming while reducing irrigant extrusion compared to conventional irrigation methods, especially in lateral canals.[7,8]

Despite the availability of different irrigation activation techniques, it remains unclear whether sonic irrigation provides better postoperative pain control than conventional needle irrigation during root canal treatment. Therefore, the research question of the present study was whether sonic irrigation using the endo-activator reduces postoperative pain and analgesic intake more effectively than conventional needle irrigation. Assuming that sonically activated irrigation offers better access to complex anatomy and reduces apical extrusion, leading to less postoperative pain in endodontically treated teeth than needle irrigation. The objective of this study was to evaluate the effects of traditional needle irrigation and sonic irrigation on postoperative pain during root canal treatment.

Materials And Methods

Data collection commenced after the approval of the research proposal by the Institutional Review Board (IRB) at the Dental College, HITEC Taxila Cantt. This randomised clinical trial was registered with clinicaltrials.gov PRS under registration number NCT07108842 and conducted from 21 November 2023 to 21 November 2024. The trial was registered before patient enrolment. Ethical approval was obtained from the Institutional Ethics Committee of the Dental College, HITEC IMS, Taxila Cantt, under reference number Dental/HITEC/IRB/56.

The total sample size of 82 patients (41 in each group) was calculated using the WHO sample size calculation formula, with a level of significance of 5%, test power of 90%, and population proportions of 80.8% and 100 % %for Groups 1 (needle irrigation group) and 2 (Endo-Activator group) 100%.[7] The inclusion criteria were as follows: single-rooted teeth (anterior or posterior) with symptomatic irreversible pulpitis and acute apical periodontitis in patients aged 18–65 years. Patients with non-restorable teeth, acute or chronic apical abscesses, internal or external root resorption, anatomical difficulties such as open apices, calcified canals, and dilacerations, serious medical illnesses or systemic disorders, previously root canal–treated teeth, periodontally compromised teeth, and sinus tracts were excluded from the study.

Patients attending the outpatient department of the Operative Dentistry Department were recruited for the study based on the inclusion criteria, following the acquisition of informed consent and assessment of their presenting problems. The data collection technique, including the steps and time required, was clearly explained to the patients. The diagnosis of single-rooted teeth exhibiting symptomatic irreversible pulpitis and acute apical periodontitis was clinically validated using the patient's history, intraoral and extraoral examinations, cold testing, electric pulp testing, and periapical radiography. Teeth diagnosed with symptomatic irreversible pulpitis demonstrate exaggerated and lingering pain lasting several minutes after the removal of the stimulus**.** An electric pulp tester was used to assess the pulpal response. A positive but heightened response compared to that of the adjacent teeth supported the diagnosis of irreversible pulpitis. Radiographic findings typically include deep carious lesions approaching the pulp chamber and, in some cases, slight widening of the periodontal ligament space, which is suggestive of early periapical inflammation. Teeth with radiographic signs of periapical abscesses, extensive periapical radiolucency, or other pathological changes were excluded. During the initial visit, all patients were randomly assigned to two groups using the lottery method while maintaining single blinding. A total of 82 identical slips of paper were prepared before the study commenced. Each slip was labelled with the group allocation: Group 1 (needle irrigation group) or Group 2 (endo activator group). All slips were folded in an identical manner to conceal the group identity and placed into an opaque container. For every eligible patient who consented to participate in the study, a slip was randomly drawn from the container by a dental assistant who was not involved in the treatment procedure. The allocation written on the slip determined the irrigation protocol used for that patient. Participants were blinded to the assigned irrigation activation technique. Because local anesthesia was administered before treatment and both procedures were performed under rubber dam isolation, patients were unable to directly observe or reliably distinguish whether conventional needle irrigation or sonic activation was used. One endodontist diagnosed the condition and treated all. Figure 1 shows the study flowchart. Upon verifying eligibility, the affected tooth was anaesthetised with 1.8 ml of 2% lignocaine HCl containing 1:100,000 epinephrine (medicaine injectable solution comprising 36 mg lignocaine and 0.0324 mg epinephrine), utilising local infiltration for mandibular anterior/maxillary teeth or an inferior alveolar block for mandibular premolars. After rubber dam isolation, access cavities were created using a long-shank Endo-Z bur (Mani, Japan) connected to a high-speed handpiece (Appledental A1). A glide path was created using size 10 and 15 K-files (Mani Japan), with the operating length ascertained using an electronic apex locator (J Morita) and verified radiographically (Eighteenth hyperlight-G). Pulp extirpation was performed using a barbed broach (Nernadeln). Canal preparation was conducted using shaping and finishing files (SX–F3) from the ProTaper Universal rotary system (DENTSPLY, Switzerland) in the prescribed order. The final apical preparation for all included teeth was standardised to F3 (size 30, 0.09 taper)

irrespective of the initial apical file to standardise canal enlargement across all samples, thereby minimising variability that could influence irrigation effectiveness and postoperative pain.

Each canal was irrigated with 2 ml of 2.5% sodium hypochlorite (Haq Chem) between file applications, while apical patency was preserved with a size 10 K-file throughout the operation. The final irrigation comprised 2.5% sodium hypochlorite (NaOCl) and 17% ethylenediaminetetraacetic acid(EDTA), interspersed with 5 ml of distilled water. A total irrigant volume of approximately 10–14 ml of 2.5% sodium hypochlorite per canal during the entire preparation phase, 5 ml of EDTA as a final irrigant, and 5 ml of distilled water were used during the entire procedure with a flow rate of 0.1 ml/sec**.** The irrigation protocol was the same in both groups, differing only in the activation method. In Group 1 (needle irrigation group), a 23-G needle was positioned 3 mm short of the working length, and the syringe was oscillated vertically while delivering 4 ml NaOCl of 2.5% into each canal for 40 seconds with an approximate flow rate of 0.1 ml/sec. In Group 2 (endo activator group EA group), 4 ml of 2.5% NaOCl was delivered into pulp chamber with conventional needle and activated utilising an endo activator (UDG United Dental Group Sonic Irrigator Pro) tip (size#15 0.2) positioned 1 mm short of the working length, for 60 seconds at 10,000 rpm with vertical strokes of 3–4 mm. Following irrigation, canals were dried using F3 paper points (Gavin Dento), and the teeth were temporarily sealed with Cavit. Postoperative pain assessment was conducted through telephone follow-up by a trained dental assistant who was blinded to the treatment group allocation.

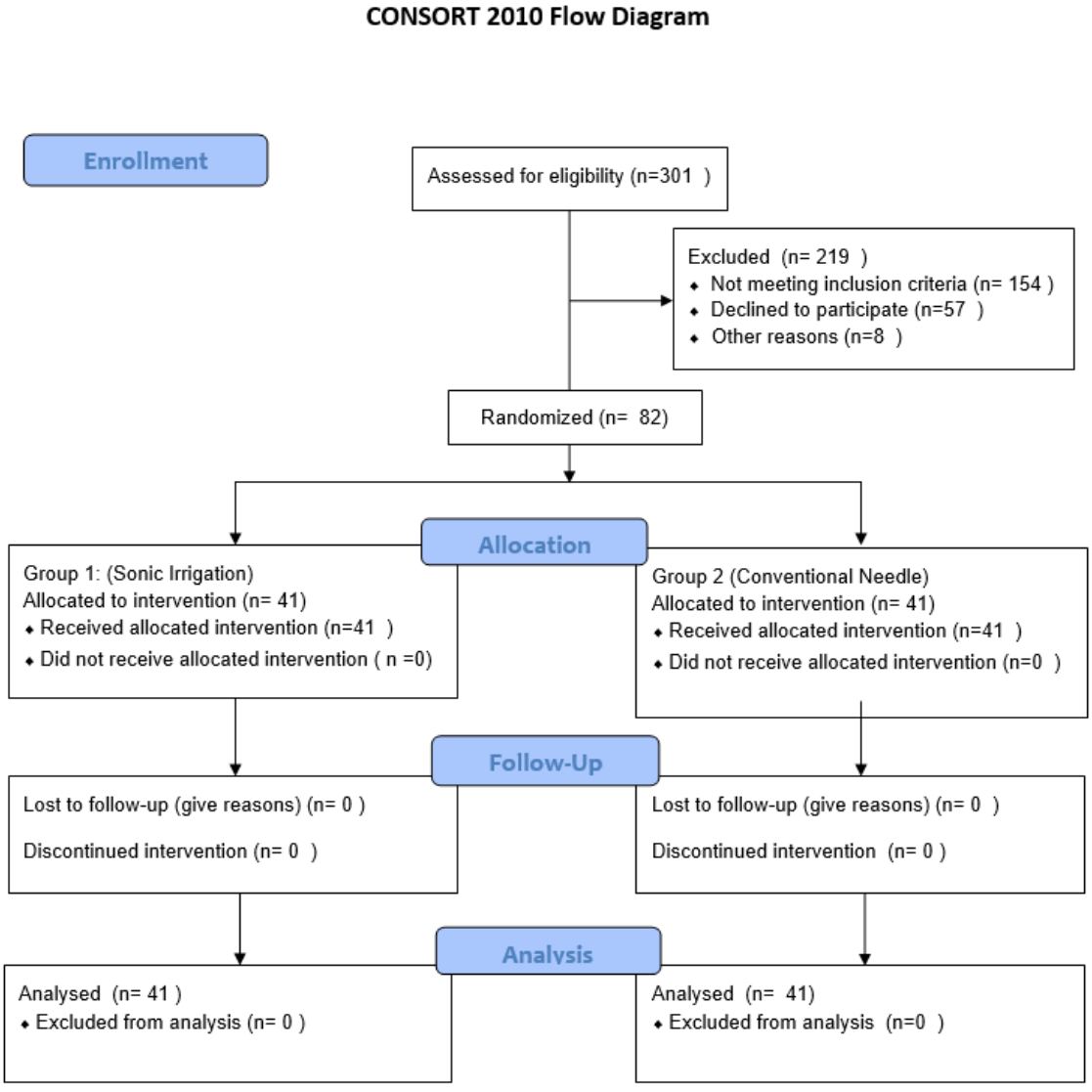

Figure 1: Consort Diagram of Study Design

Each participant was contacted four times after the procedure, specifically at 6 hours, 12 hours, 24 hours, and 48 hours following completion of the root canal treatment utilising a visual analogue scale (VAS) score which is a 10-point numerical scale ranging from 0 to 10, where: 0 is No pain, 1–3 is mild pain, 4–6 is moderate pain and 7–10 is severe pain and by documenting the quantity of analgesics (ibuprofen 400 mg) administered. Mean VAS scores were calculated for statistical analysis, while categorical pain levels were used to describe the distribution of pain intensity in the results. Patients were recalled for a second visit after one week. The canals were re-irrigated, dried with F3 paper points, and obturated using the lateral condensation technique with F3 gutta-percha cones (Bio GP Points) using sealapex root canal sealer (Kerr Endodontics). The teeth were subsequently repaired permanently using composite resin (Ivoclar).

Data was entered into an Excel sheet and later exported to SPSS v 21. All analyses were carried out using SPSS version 21.0. For quantitative variables, such as age, duration of symptoms, and pain score, the mean ± SD was calculated for normal data. Shapiro-Wilk's test was used to assess normality. Qualitative variables such as gender, tooth type, and presence of pain were presented as frequency and percentage. We used an independent samples t-test to compare the mean VAS scores and the mean number of analgesics taken between the groups. All effect modifiers, such as age, duration of symptoms, gender, and tooth type, were controlled through stratification. A p-value of <0.001 was taken as significant.

During the preparation of this manuscript, the authors used ChatGPT (OpenAI) for language editing and drafting assistance. The generated text was reviewed, revised, and verified by the authors, who took full responsibility for the accuracy, originality, and integrity of the final manuscript. No generative AI tool was used for data collection, analysis, or independent interpretation.

Results

A total of 301 patients were assessed for eligibility to be included in this study, of which 154 patients did not meet the inclusion criteria, 57 declined to participate, and 8 failed to give consent; thus, a total of 82 patients were enrolled. Of the 82 participants, the majority were women(n=43), while the rest were men (n=39). The mean age of the participants included in the study was 36.5 ± 9.63 years.

The primary outcome of the study was postoperative pain assessed at 6, 12, 24, and 48 h. At all evaluated time points, patients in the endo activator group experienced lower postoperative pain than those in the Needle Irrigation group. At 6 hours, most patients in the Needle Irrigation group reported moderate pain (61%, n= 25/41) and severe pain (17.1%, n= 7/41), whereas most patients in the Endo-Activator group reported mild pain (65.9%, n = 27/41), with a higher percentage being pain-free (17.1%, n=7/41),14.6% (n=6/41) reported moderate pain, and very few experienced severe pain (2.4%, n= 1/41). At 12 h, moderate pain remained predominant in the Needle Irrigation group (65.9%, n=27/41), while pain levels in the EndoActivator group shifted further towards mild pain (53.7%, n= 23/41) or no pain (41.5%, n=17/41). By 24 hours, nearly half of the Needle Irrigation group still reported mild pain (48.8%, n= 20/41) and 41.5%, n=17/41 moderate pain, whereas 85.4% of patients (n=35/41) in the Endo Activator group were completely pain-free. At 48 hours, only 17.1% of patients (n=7/41) in the Needle Irrigation group had no pain, with 68.3%(n=28/41) still experiencing mild pain, whereas 90.2%(n=37/41) of patients in the EndoActivator group were completely pain-free. These findings answer the research question by showing that sonic irrigation using an endo-activator was more effective than conventional needle irrigation in reducing postoperative pain after root canal treatment. In addition, patients in the sonic irrigation group required fewer analgesics at all assessed time points, indicating better overall postoperative pain control.

The comparison of post-operative pain and analgesic intake at different time intervals is listed in Tables I and II. The results demonstrated that the endo-activator group consistently exhibited significantly lower mean VAS pain scores than the needle irrigation group at all evaluated time intervals. At 6 hours**,** the mean VAS score was 4.68 ± 0.309 in the needle irrigation group, whereas it was 2.15 ± 0.256 in the endo-activator group ($p < 0.001$, 95% confidence interval)**.** At 12 h, the mean VAS score decreased to 3.66 ± 0.251 in the needle irrigation group and 1.12 ± 0.232 in the endo-activator group. A similar trend was observed at 24 h, where the mean pain score was 2.88 ± 0.230 for the needle irrigation group and 0.41 ± 0.171 for the endo-activator group. By 48 hours, the mean VAS score further reduced to 2.05 ± 0.215 in the needle irrigation group, while patients in the endo-activator group reported minimal pain with a mean score of 0.15 ± 0.075**.**

The secondary outcome of this study was to evaluate the number of analgesic intakes, and the mean number of analgesic tablets consumed was significantly higher in the needle irrigation group than in the endo-activator group at all assessed time intervals.

Throughout the trial period, neither group experienced any adverse events, complications, flare-ups, oedema, or treatment-related safety issues. Tolerability was indirectly reflected by analgesic consumption and pain experience, both of which favoured the EndoActivator group across all follow-up intervals and were indirect indicators of tolerability.

Table 1: Comparison of VAS Pain Scores Between Groups

Post- Operative Pain Score (VAS)	Groups	N	Mean	Std Deviation	Mean difference (Needle – Endo-Activator)	95% Confidence interval	P-Value
At 6 Hours	Needle Irrigator	41	4.68	0.309			
	Endo-activator	41	2.15	0.256	2.53	2.41-2.65	
At 12hrs	Needle Irrigator	41	3.66	0.251			
	Endo-activator	41	1.12	0.232	2.54	2.43-2.65	
At 24hrs	Needle Irrigator	41	2.88	0.230	2.47	2.38-2.56	<0.001
	Endo-activator	41	0.41	0.171			
At 48hrs	Needle Irrigator	41	2.05	0.215			
	Endo-activator	41	0.15	0.075	1.90	1.83-1.97	

Table 2: Comparison of Number of Analgesic Intake Between Groups

Analgesic intake	Groups	N	Mean	Std. Deviation	Mean difference (Needle – Endo-Activator)	95% CI	P-Value
At 6hrs	Needle Irrigator	41	2.59	1.048			
	Endo-activator	41	0.83	0.771	1.76	1.36-2.16	
At 12 hrs	Needle Irrigator	41	2.15	1.038			
	Endo-activator	41	0.32	0.789	1.83	1.42-2.24	
At 24hrs	Needle Irrigator	41	1.66	1.063			<0.01
	Endo-activator	41	0.12	0.400	1.54	1.19-1.89	
At 48 hrs	Needle Irrigator	41	1.17	1.116			
	Endo-activator	41	0.05	0.218	1.12	0.77-1.47	

Discussion

Chemical disinfection of the root canal system is an essential component of endodontic therapy, as mechanical instrumentation alone cannot eliminate microorganisms from the complex root canal anatomy.[12] The contact of the disinfectant with the canal is more important than the type of disinfectant used in reducing post-endodontic symptoms. The contact time of an irrigant can be improved by activating the irrigant within the root canal space.

This study was conducted to compare the effectiveness of the conventional method of activating an irrigant via mechanical agitation with a needle with that of the sonic endo-activator.

Our study included patients aged 18-60 years, to focus on the healthy adult population, avoid ethical issues with minors, and minimise age-related confounding factors.[10] In the present study, women constituted 52.43% of the study population. However, postoperative pain was not analysed separately according to sex. Therefore, although Sadaf et al. 2014,[11] reported a higher frequency of postoperative pain among females, a direct comparison with the present study cannot be made.

Our studies used VAS Scores (mean and standard deviation) and the number of analgesics taken to record post-endodontic outcomes. Many other studies have used the same subjective testing.[6,12] While many studies have used other common pain assessment tools, including the numerical rating scale (NRS), verbal rating scale (VRS), faces pain scale-revised (FPS-R), and McGill pain questionnaire (MPQ).[13,14]

The answer to the research question our study implies that sonic irrigation with the endo-activator may improve the patient experience after root canal treatment by reducing postoperative pain and the need for analgesics. This matters clinically because postoperative pain is one of the most important patient-centred outcomes in endodontics and can influence patient satisfaction, confidence in treatment, and compliance with follow-up care. As shown and stated in the results of this study, the endo-activator group experienced less post-operative pain than the needle irrigation group at all assessed time intervals. At 6 hours, 65.9% had mild pain and 17.1% were pain-free, versus 61% moderate and 17.1% severe pain in the needle group. By 12 hours, 85.4% of endo activator patients were pain-free, while 48.8% of needle patients had mild and 41.5% had moderate pain. At 48 hours, 90.2% of endo activator patients were

pain-free, compared to 68.3% of needle patients with mild pain; similar findings were seen in other studies.[17,18] The present findings are consistent with previous studies that have reported lower postoperative pain with sonic or activated irrigation systems compared with conventional needle irrigation. Ramamoorthi et al. 2017,[17] stated that at 8, 24, and 48 hours post-treatment, 88.9%, 57%, and 13.9% of endo-activator patients reported mild or no pain, compared to 83.3%, 13.9%, and 55.6% in the needle group, showing consistently lower pain in the endo-activator group. A similar study conducted in the Department of Operative Dentistry and Endodontics, Sindh Institute of Oral Health Sciences, Karachi, Pakistan, showed that fewer patients reported pain at 6 hours (60%) in the endo-activator group when compared to pain at 6 hours (100%) in the conventional irrigation group.[9]

The mean VAS Score for the needle irrigation group decreased over time, but the decrease in VAS score for the endo-activator was significantly more (P = 0.01). Several studies have reported that mean visual analogue scale (VAS) scores for postoperative pain following root canal treatment with advanced irrigation activation systems, such as the Endo-Activator, showed significantly greater pain reduction compared to traditional needle irrigation 4-12. Supporting this, Alkahtani et al. found that sonic activation devices reduced postoperative pain intensity more than conventional methods.[6]

However, a few studies have found no significant differences between sonic activation and needle irrigation in pain outcomes, attributing pain variations more to individual patient factors and operator technique than to the irrigation method.[15,16,19] Erkan et al.,[19] examined the effects of manual dynamic activation and PUI on postoperative pain in the root canals of mandibular premolar teeth diagnosed with symptomatic irreversible pulpitis, and no significant differences were found between the groups at the 8th and 48th hours. Many studies believe that endo-activators may be better than needle irrigation in some situations, but not all. The clinical circumstances, device, and patient characteristics may affect outcomes; therefore, more research is needed to determine the best irrigation strategy for endodontic postoperative pain treatment.[19-21]

Additionally, concerns have been raised that differences in study design, sample size, and pain assessment timing may influence the results. Therefore, while evidence favours endo-activators for reducing postoperative pain, further large-scale randomised controlled trials are necessary to confirm these findings and clarify the clinical significance of irrigation activation methods.

Root canal treatment can sometimes cause pain after the procedure, which may affect the patient's comfort and recovery. One reason for this pain may be the manner in which the cleaning solution is delivered inside the root canal. This study compared two methods of irrigation during root canal treatment: conventional needle irrigation and sonic irrigation using the EndoActivator device.

A total of 82 patients were included and equally divided into two groups. Pain levels and use of pain medicine were recorded at 6, 12, 24, and 48 h after treatment. Patients treated with sonic irrigation reported less pain at all time points than those treated with conventional irrigation. They also required fewer pain tablets after treatment.

These findings suggest that sonic irrigation may improve patient comfort after root canal treatment by reducing postoperative pain and the need for analgesic use. This may help dentists choose techniques that provide a better treatment experience for their patients.

Conclusions

The results of our study indicate that irrigation with sonic irrigation devices (endo-activator system) provides significantly improved post-endodontic outcomes compared to conventional needle irrigation. Specifically, the endo-activator significantly reduced post-endodontic pain at all assessed time intervals and decreased the need for analgesic intake.

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