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The Effects of Sonic Activation of Irrigant on Post-Operative Pain after Root Canal Treatment on Permanent Dentition: A Randomized Controlled Trial

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ABSTRACT

Objective: To compare postoperative pain levels following root canal therapy using EndoActivator sonic irrigation versus conventional syringe irrigation in posterior molars.

Study Design: Randomized controlled trial (ClinicalTrials.gov (NCT07062419).

Place and Duration of Study: Department of Operative Dentistry, 28-Military Dental Centre, Combined Military Hospital, Lahore Pakistan, from Aug 2024 to Jan 2025.

Methodology: Fifty-eight patients aged 18–60 years, diagnosed with symptomatic or asymptomatic apical periodontitis, were randomly allocated into two groups: Group-A (Conventional syringe irrigation, Control) and Group-B (EndoActivator sonic irrigation, Experimental). Post-operative pain was measured using the Numerical Rating Scale (NRS) at 24, 36, and 48 hours.

Results: There was no statistically significant difference in post-operative pain levels between the groups at any time point. At 24 hours, 34% of patients in the EndoActivator Group-And 27% in the control group reported no pain (p=0.321). By 48 hours, 86.67% of patients in both groups were pain-free (p=1.000).

Conclusion: Both EndoActivator and conventional syringe irrigation techniques yielded comparable post-operative pain outcomes. Selection of irrigation technique should be based on factors such as procedural efficiency and patient comfort rather than pain reduction alone.

Keywords: EndoActivator, Irrigation Techniques, Post-operative Pain, Root Canal Therapy, Sonic Irrigation.

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INTRODUCTION

Root canal treatment (RCT) is an indispensable therapeutic intervention in endodontics aimed at eradicating intracanal infection and preserving natural dentition. Despite its well-documented clinical efficacy, post-operative pain remains a prevalent and significant clinical concern, affecting approximately 25–40% of patients within 48 hours post-procedure.[1] The success of RCT fundamentally depends on effective chemo-mechanical debridement, where irrigation plays a pivotal role in removing necrotic tissue, microbial biofilms, and smear layer, thereby enhancing disinfection and overall treatment prognosis.[2]

Globally, persistent apical periodontitis is predominantly associated with inadequate root canal fillings and compromised coronal restorations. Epidemiological data indicate that over 60% of root-filled teeth with suboptimal technical quality exhibit periapical pathology.[3] In the South Asian context, approximately 31.7% of previously treated teeth manifest apical periodontitis, with fewer than half conforming to acceptable technical standards.[4] In Pakistan, high rates of periapical radiolucencies, particularly in posterior teeth, further underscore the prevalence of substandard endodontic treatment outcomes.[5]

Recent advancements propose irrigation activation techniques, such as ultrasonic and sonic agitation, which aim to enhance irrigant penetration into complex root canal anatomies.[6] Nevertheless, these methods carry risks, including irrigant extrusion and consequent tissue irritation or damage.[7,8] The EndoActivator sonic system has gained recognition as a safer alternative, facilitating effective irrigant distribution with minimal extrusion risk.[9] While some evidence suggests sonic activation may reduce post-operative pain compared to conventional methods, findings remain inconclusive and underexplored in regional populations.[10]

Despite global evidence on the effectiveness of sonic irrigation systems, there is a paucity of research evaluating their impact on post-operative pain in the Pakistani population. Thus, we aimed to compare postoperative pain levels following root canal therapy

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using EndoActivator sonic irrigation versus conventional syringe irrigation in posterior molars.

METHODOLOGY

This Randomized Controlled Trial study conducted at the Department of Operative Dentistry, 28-Military Dental Center, Combined Military Hospital (CMH), Lahore, from August 2024 to January 2025. Ethical approval was obtained from the Institutional Review Board (Ref. No. 107/Civ/Trg/Op/15/24), and the trial was registered at ClinicalTrials.gov (NCT07062419). All participants provided written informed consent prior to enrolment.

Inclusion Criteria: Adult patients of either gender aged 18–60 years diagnosed with symptomatic or asymptomatic irreversible pulpitis and/or apical periodontitis in posterior molars of the maxilla or mandible were included.

Exclusion Criteria: Patients with apical abscesses, those classified as ASA physical status III or IV, and cases with teeth deemed to have a poor prognosis for successful endodontic therapy were excluded.

Sample size was calculated using OpenEpi for comparison of mean postoperative pain scores on the Numerical Rating Scale (NRS, 0–10). Keeping the Cohen's d≈0.74, the required sample size was approximately 29 participants per group (58 total).[11] The study therefore enrolled 32 patients in Group-A and 26 patients in Group-B.

Participants were randomly assigned to one of two groups using a computer-generated randomization sequence in a 1:1 ratio. Allocation concealment was achieved using sealed, opaque envelopes opened at the time of treatment. The study followed a single-blind design, wherein participants were unaware of their Group assignment. Operators were not blinded. Group-A (Control) received conventional syringe irrigation, and Group-B (Experimental) received EndoActivator sonic irrigation (Figure).

Each participant was assigned a unique identifier to maintain confidentiality. Baseline demographic data including age, gender, and tooth treated were recorded. All procedures were standardized to ensure consistency. Local anesthesia was administered followed by rubber dam isolation. Access cavities were prepared, and working length was determined using an electronic apex locator and confirmed radio-graphically. Cleaning and shaping of the root canals were performed using a standardized rotary system.

In the control group, conventional syringe irrigation with 5.25% sodium hypochlorite was employed throughout the procedure. In the experimental group, the same irrigant was activated using the EndoActivator system following manufacturer instructions. Final irrigation was completed with 17% EDTA in both groups. All canals were obturated using the lateral condensation technique with gutta-percha and AH Plus sealer. Post-operative pain was evaluated using the Numerical Rating Scale (NRS), ranging from 0 (no pain) to 10 (worst imaginable pain). Patients were instructed to self-report their pain at 24-, 36-, and 48-hours post-treatment. Analgesics were provided if required, and usage was documented.

Statistical Package for Social Sciences (SPSS) version 20 was used for analyzing descriptive statistics. Association between categorical variables, such as tooth type, pain levels, and irrigation method, were analyzed using Chi-square tests to identify significant associations. A *p*-value of less than 0.05 was considered statistically significant.

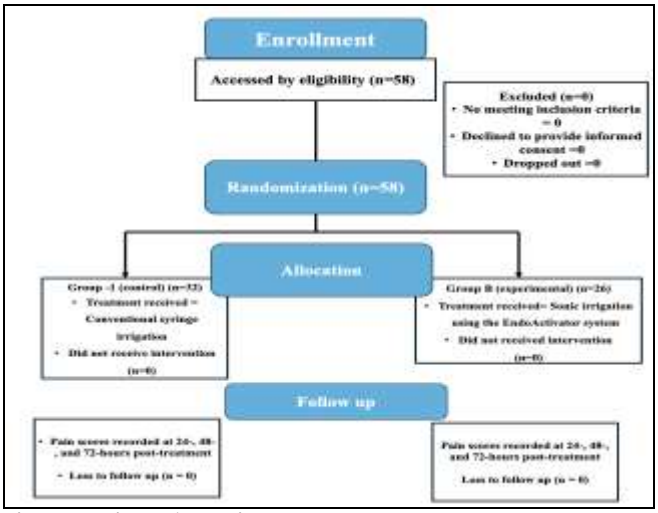

Figure: Patient Flow Diagram

RESULTS

A total of 58 patients were included in the study, with 32(55%) assigned to Group-A (Conventional syringe irrigation, Control) and 26(45%) to Group-B (EndoActivator, Experimental). The mean age of participants was 34.8±8.6 years (range: 20–59 years). The largest proportion of patients were in the 20–29-year age group 21(35%), while the smallest proportion were in the 50–59-year age group 3(5%). Males constituted 39(65%) of the sample, whereas there were 21(35%) females, as seen in Table-I.

Table-I: Demographic and Treatment Distribution of Participants (n=58)

Variable	Category	n(%)
Age	20–29	20(34.5%)
	30–39	17(29.3%)
	40–49	17(29.3%)
	50–59	4(6.9%)
Gender	Male	38(65.5%)
	Female	20(34.5%)
Treatment Type	Non-Sonic Activation (Group-A)	32(55.0%)
	Sonic Activation (Group-B)	26(45.0%)

At 24 hours post-treatment, the most frequent pain level was mild pain, reported by 14 patients (48%) in Group-A and 16 patients (55%) in Group-B. Severe pain was least common, recorded in 3 patients (10%) in Group-A and none in Group-B. A greater proportion of patients in Group-B reported no pain compared with Group-A (34% vs. 27%), but the difference was not statistically significant (χ^2=3.50, p=0.321, Table-II).

Table-II: Pain Distribution across Groups 24 hours Post-Procedure (n=58)

Pain level	Group-A Non-sonic activation	Group-B Sonic activation	*p*-value
No pain	8(27%)	10(34%)	0.321
Mild	14(48%)	16(55%)	
Moderate	4(13%)	3(10%)	
Severe	3(10%)	0(0%)	

At 36 hours, no pain became the predominant finding, reported by 14 patients (47%) in Group-A and 18 patients (60%) in Group-B. Moderate pain was infrequent, with 3 patients (10%) in each group, and no cases of severe pain were observed. The difference between groups was not statistically significant (χ^2=1.3, p=0.522), which can be seen in Table-III.

Table-III: Pain distribution across Groups 36 hours Post-Procedure (n=58)

Pain level	Group-A Non-sonic activation	Group-B Sonic activation	*p*-value
No pain	14(46.67%)	18(60.00%)	0.522
Mild	12(40.00%)	8(26.67%)	
Moderate	3(10.00%)	3(10.00%)	
Severe	0	0	

By 48 hours, the vast majority of patients in both groups were pain-free 26(87%) each. Mild pain persisted in 3 patients (10%) per group, and no moderate or severe pain was reported. At this stage, no difference was observed between groups (χ^2=0.0, p=1.0), as shown in Table-IV.

Table-IV: Pain Distribution across Groups 48 hours Post-Procedure (n=58)

Pain level	Group-A Non-sonic activation	Group-B Sonic activation	*p*-value
No pain	26(86.67%)	26(86.67%)	1.000
Mild	3(10.00%)	3(10.00%)	
Moderate	0	0	
Severe	0	0	

DISCUSSION

The current randomized clinical trial assessed post-operative pain after root canal treatment with Group-B (EndoActivator, Experimental) compared to Group-A (Conventional syringe irrigation, Control). Group-B had a slightly higher proportion of patients reporting no pain at 24 and 36 hours, but differences between groups were not statistically significant (p=0.321, 0.522, and 1.0 at 24, 36, and 48 hours, respectively). Overall, literature indicates a modest benefit of sonic activation in certain subgroups, but no consistent effect on post-operative pain has been observed across general populations.

These results align with some studies and differ from others. A randomized clinical trial for primary molars reported significantly lower post-operative pain at 24 hours (p<0.05) in the sonic activation group, suggesting an advantage in children's cases.[12] Conversely, comparisons of different irrigant activation methods, including SWEEPS, PIPS, sonic, and ultrasonic systems, showed no significant differences in post-operative pain, consistent with the current findings.[13]

Another study reported reduced post-operative pain with high-power sonic activation in patients with acute irreversible pulpitis (p=0.02 at 12 and 24 hours). Differences from the current study may be due to variations in study populations, particularly underlying pulpal pathology.[14] Similarly, sonic activation in teeth with apical periodontitis demonstrated better periradicular healing but no significant differences in short-term post-operative pain (p=0.47).[15] In this study, at 48 hours, 86.67% of patients in both groups were pain-free (χ^2=0.0, p=1.0), supporting the conclusion that sonic activation does not significantly affect short-term post-operative pain under routine clinical conditions.

Previous in vitro and clinical studies have shown improved debris removal and canal cleanliness with sonic and ultrasonic irrigation, but patient-reported pain outcomes were not evaluated.[16,17] Furthermore, improved irrigant penetration from activation

techniques may be offset by multifactorial contributors to post-operative pain, such as apical extrusion, tissue hypersensitivity, and individual pain tolerance.[18]

The lack of a significant difference in this study may reflect similar final disinfection efficacy between sonic and conventional methods when standardized protocols are followed. Proper mechanical and chemical debridement can minimize apical tissue irritation, resulting in comparable patient experiences regardless of irrigation technique.[19]

Overall, while previous studies suggest that sonic activation may offer modest benefits in specific subgroups, evidence across general populations remains inconsistent. In the context of Pakistan, where cost, equipment availability, and clinician training vary, these findings suggest that the choice of irrigation technique should be guided by practical considerations rather than expectations of superior pain reduction. Clinicians may prioritize procedural efficiency, patient comfort, and canal cleanliness when selecting an irrigation method, recognizing that sonic activation does not confer a substantial advantage in short-term post-operative pain under routine clinical conditions.

LIMITATION OF STUDY

This study relied on the Numerical Rating Scale (NRS) for pain assessment, which is inherently subjective and may be influenced by individual patient factors. The follow-up period of 48 hours may have missed potential delayed or long-term post-operative pain responses. Operator blinding was not implemented, which could introduce bias in treatment administration or assessment. Additionally, the study did not stratify results by pulp status (irreversible pulpitis vs apical periodontitis), which may influence post-operative pain outcomes and limit subgroup analyses.

CONCLUSION

Both EndoActivator and conventional syringe irrigation techniques yielded comparable post-operative pain outcomes. Selection of irrigation technique should be based on factors such as procedural efficiency and patient comfort rather than pain reduction alone.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

SR & IK: Data acquisition, data analysis, critical review, approval of the final version to be published.

JAS & ZZ: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

JS & TS: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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