RESEARCH PAPER

Comparative Assessment of Different Irrigation Systems for Root Canal Disinfections: A Clinical Trial

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ABSTRACT

Background: Benefitting from a successful treatment requires effective disinfection during root canal therapy. Because the root canal system has complex anatomy, mechanical instrumentation cannot eliminate all microorganisms by themselves. Different systems for irrigant application have been engineered to enhance the antimicrobial activity of irrigants, while the clinical effectiveness of these systems is still unknown.

Aim: The objective of present study is to comparatively analyze the efficacy of different irrigating systems administration in intracanal microbial load and post-operative pain during root canal treatment.

Methods and Materials: The randomized clinical trial we eventually conduct as prospective. It is performed on 100 patients. They are requiring primary root canal treatment. The study is performed on single-rooted teeth. The patients were randomly assigned into 4 groups (n = 25) as syringe and needle irrigation, passive ultrasonic irrigation, sonic activation irrigation, and negative pressure irrigation. A standardized rotary instrumentation protocol was used for preparing all canals and irrigation was done with 2.5% sodium hypochlorite (NaOCl) followed by 17% EDTA. Microbiological samples were collected using sterile paper points prior to instrumentation (S1) and after chemomechanical preparation (S2). CFU was used to quantify bacterial counts. Assessment of postoperative pain with a visual analogue score were done at 24 and 48 hours. Statistical analysis was done using STATA software, with a significance of $p < 0.05$.

Result: All the irrigation systems used a significant intracanal microbial load reduction ($p < 0.001$). The systems that achieved the maximum decrease in microorganisms were negative pressure irrigation, followed by passive ultrasonic and sonic activation systems. The lowest reduction was observed in control syringe irrigation. The ultrasonic and negative pressure groups had significantly lower pain scores compared to the conventional irrigation group on postoperative period.

Conclusion: Negative pressure and passive ultrasonic irrigation systems represent new concepts in irrigation. These concepts may improve canal disinfection and reduce postoperative discomfort compared to conventional syringe irrigation which supports the clinical use of these systems in endodontics.

Keywords: Chemo-mechanical preparation, Irrigation systems, Microbial reduction, Root canal disinfection, Sodium hypochlorite.

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How to cite this article: Jain C, Kumari MK, Roy S, Karande V, Chandrasekaran S, Dumont NV, Kumari A. Comparative Assessment of Different Irrigation Systems for Root Canal Disinfections: A Clinical Trial. Int J Drug Deliv Technol. 2026;16(15s): 688-696. DOI: 10.25258/ijddt.16.15s.79

Introduction

Endodontic therapy outcome greatly depends on the success of removal of microorganisms and affected tissues in the root canal system [1]. The most significant etiologic agent of pulpal and periapical pathology is microbial infection, the maintenance of bacterial colonies in the canal is a significant determinant of endodontic failure. Facultative anaerobes like the Enterococcus faecalis can potentially endure extreme conditions in the environment, gain access to dentinal tubules and tolerate intracanal medicaments thus making it so difficult to achieve complete disinfection. Therefore, holistic chemo-mechanical preparation is an essential measure that decreases the microbial load and enhances the healing of periapical [2].

Isolated use of mechanical instrumentation cannot ensure full debridement of the root canal system because of the complexity of its anatomy [3]. Variations that are common in root canals include lateral and accessory canals, fins, isthmuses, apical deltas and irregular cross-sectional geometries. The main canal is mostly formed by conventional files, hand- or rotary-driven, which are often unable to reach these anatomical complexities [4]. Further, instrumentation results in a smear layer, which is a combination of organic and inorganic debris that is capable of harboring bacteria and preventing penetration of irrigants and intracanal medicaments. Therefore, irrigation is essential in making canals cleaner than they can be prepared by mechanical means only [5].

NaOCl is the goldstandard irrigant due to the antimicrobial spectrum of activity and the ability to dissolve organic tissue. Chlorhexidine (CHX) is also used due to its antimicrobial capacity and substantivity, and ethylenediaminetetraacetic acid (EDTA) is used as a result of its ability to remove the inorganic portion of the smear layer [6]. However, the effectiveness of these irrigants depends much on their method of delivery, quantity, strength, temperature, and activation inside the canal. Although conventional syringe and needle irrigation (SNI) is widely used, it might not be sufficient to guarantee sufficient exchange and penetration of the irrigant into the apical third or irregularities lateral. Moreover, apical extrusion is also at stake with improper irrigation [7].

Different complex irrigation systems have been created to meet the shortcomings of traditional irrigation [8]. Passive ultrasonic irrigation (PUI) enhances the efficacy of irrigants by increasing the cavitation and acoustic streaming and enhancing the efficacy of cleaning debris and eliminating the smear layer [9]. Sonic activation systems which are lower frequency compared to ultrasonics also improve irrigant agitation and penetration [10]. The negative-pressure irrigation systems are aimed at providing the irrigants to the working length with a minimum risk of apical extrusion. Laser-activated irrigation and multisonic devices have recently gained interest as a viable mode of enhancing the fluid dynamics of the root canal system [11].

A number of in vitro studies have shown a better reduction of bacteria and smear layer using activated irrigation methods compared with the traditional syringe irrigation [12]. Nevertheless, in vitro models might not be a good representation of clinical conditions, such as differences in canal anatomy, the presence of vital tissue and necrotic tissue, host immune response and patient-specific factors. In that regard, clinical trials are mandatory in assessing the practical efficacy, safety, and patient-centered results in relation to the various irrigation systems [13].

Technical testing of the irrigation system can include the assessment of microbial reduction by pre- and post-instrumentation and evaluation of the level of pain after surgery, healing, and the efficiency of the procedure [14]. Postoperative pain is an essential clinical parameter because improper disinfection or apical extrusion of the irrigants and debris can be the reasons of flare-ups. Moreover, effective irrigation regulations can shorten the treatment periods and improve the comfort of patients [15]. As such, choice of a proper irrigation system has great bearing on success of the treatment and patient satisfaction [16].

Regardless of the increasing number of irrigation technologies, there is still no common agreement about which one can be used to achieve the best outcomes in terms of root-canal disinfection [17]. The differences in study design, methodology, microbial assessment methods and outcome measures have resulted in discrepant findings in the literature. Moreover, cost, ease of use, learning curve, and clinical practicality are some of the factors that determine the selection of irrigation method in the daily practice [18].

As endodontic success highly depends on the irrigation type, and the range of possible devices is increasingly growing, it is necessary that clinical comparisons be made under controlled conditions [19]. Welldeveloped clinical study can provide evidence-based advice to clinicians because it will directly assess the antimicrobial effect and clinical performance of other irrigation systems. In this regard, the current research will establish the relative efficacy of various types of irrigation systems in ensuring the optimum root-canal debridement under clinical situations [20].

Methodology

Study Design

The current study was designed as a prospective, randomized, controlled clinical trial so that the effectiveness of different root canal irrigation systems can be comparatively evaluated in relation to the attainment of endodontic disinfection. Special attention was given to the comparison of the results in relation to the difference outcomes of each modality of irrigation.

The ethical principles that the research adhered to were issued in the Declaration of Helsinki, and the Institutional Ethics Committee approved the study. All participants were informed through written consent before the study.

Sample Size

The study was carried on one hundred patients who had need of primary root canal therapy. The sample size was determined using similar previous clinical studies, which were predicted using a statistical power of 80% and alpha value of 0.05, and provided the opportunity to detect a statistically significant reduction in microbial burden in the different irrigation systems.

Patient Selection

Inclusion Criteria

• Aged participants that are subjected between 18 and 60 years.
• Everlasting dentition with only one root and one canal.
• Teeth with either pulp necrosis or asymptomatic apical periodontitis.
• Teeth to be subjected to primary root canal therapy.
• The respondents who are ready to participate in the study and give an informed consent.

Exclusion Criteria

• Teeth that have been subjected to root canal treatment.
• Internal or external resorption of teeth.
Patients with systemic conditions that interfere with the healing process or immune functioning.
• Pregnant or lactating women
• Patients who underwent antibiotic treatment in less than three months.
• Teeth have root fractures, open apices, or excessive curvature.

Group Allocation

The selected 100 patients were randomly allocated into **four groups (n = 25 each)** using a computer-generated randomization method:

- **Group I:** Conventional syringe and needle irrigation
- **Group II:** Passive ultrasonic irrigation
- **Group III:** Sonic activation irrigation system
- **Group IV:** Negative pressure irrigation system

Allocation concealment was ensured using sealed opaque envelopes.

Clinical Procedure

To remove operator variability, all the procedures were performed by one, highly experienced endodontist. Rubber dam isolation was attained in all cases, and local anesthesia was done. High-speed burs of sterile were used to prepare standard access cavities. The determination of the working length was done using an electronic apex locator and checked radiographically. Rotary nickel-titanium tools were used to prepare root canals using a standardized crown-down technique, and the end result was a consistent apical size in all three experimental groups.

Irrigation Protocol

During instrumentation, canals were irrigated with **2.5% sodium hypochlorite** according to the assigned group protocol. The total volume of irrigant used was standardized across all groups.

- In **Group I**, irrigation was performed using a side-vented needle placed 2 mm short of the working length.
- In **Group II**, passive ultrasonic activation was carried out for a specified duration using an ultrasonic tip placed passively within the canal.

- In **Group III**, a sonic activation device was used to agitate the irrigant according to the manufacturer's instructions.
- In **Group IV**, a negative pressure system was used to deliver irrigant to the working length while simultaneously aspirating it coronally.

A final rinse with **17% EDTA** was performed in all groups to remove the smear layer, followed by a saline rinse.

Microbiological Sampling

Microbial samples were collected at two time points:

- **S1:** Before instrumentation
- **S2:** After completion of irrigation and canal preparation

Sterile paper points were placed in the canal for 60 seconds and then transferred to sterile transport media. Samples were cultured, and bacterial colony-forming units (CFUs) were counted to assess microbial reduction.

Outcome Measures

The major outcome that was evaluated was the reduction in the amount of intracanal microbial load between S1 and S2 sample collections.

The secondary endpoints included measuring the postoperative pain, which was measured using a visual analog scale (VAS) after 24 and 48 hours of treatment.

Statistical Analysis

Statistical software was used to analyse the data. Paired tests were used to compare the results among intragroups, and the parametric or non-parametric tests were used to compare the results between intergroup studies in consideration of the data distribution. A cut-off of 0.05 was taken as a statistically significant p-value.

Results

The study was carried out among 100 participants who were divided into 25 participants each group (arm). Any information that was gathered was included in the statistical analysis. No intraoperative complications and adverse events related to the irrigation procedures were reported.

Baseline Characteristics

The four groups were comparable with respect to age, gender distribution, and tooth type, with no statistically significant differences ($p > 0.05$). This ensured homogeneity among groups and minimized confounding variables (**Table 1**).

Table 1. Baseline demographic and clinical characteristics of the study groups

Variable	Group I (SNI)	Group II (PUI)	Group III (Sonic)	Group IV (Negative Pressure)	p-value
Mean age (years)	34.6 ± 8.2	33.9 ± 7.5	35.1 ± 6.9	34.2 ± 7.8	0.87
Gender (M/F)	12/13	11/14	13/12	12/13	0.94
Maxillary teeth (%)	52	56	48	54	0.89

Microbial Reduction

The study was carried out among 100 participants who were divided into 25 participants each group (arm). Any information that was gathered was included in the statistical analysis. No intraoperative complications and adverse events related to the irrigation procedures were reported.

According to Table 2, Group IV (which was negative pressure irrigation) was better in reducing the colony-forming units (CFUs) followed by Group II (passive ultrasonic irrigation), Group III (sonic activation), and Group I (conventional syringe irrigation).

Table 2. Mean CFU counts (log10) before and after instrumentation

Group	S1 (Pre-instrumentation)	S2 (Post-instrumentation)	Mean Reduction	p-value*
Group I (SNI)	5.82 ± 0.61	3.21 ± 0.48	2.61	<0.001
Group II (PUI)	5.79 ± 0.58	2.42 ± 0.36	3.37	<0.001
Group III (Sonic)	5.85 ± 0.63	2.71 ± 0.41	3.14	<0.001
Group IV	5.81 ± 0.60	1.98 ± 0.29	3.83	<0.001

(Negative Pressure)				

*Paired t-test

Intergroup Comparison

The four groups differed statistically significantly in CFU counts post-instrumentation (p < 0.001), according to intergroup analysis. The CFU counts of Group IV were significantly lower than those of all other groups. Group II performed significantly better than Groups I and III (Table 3).

Table 3. Intergroup comparison of post-instrumentation CFU counts (ANOVA with post hoc analysis)

Comparison	Mean Difference	95% CI	p-value
Group I vs Group II	0.79	0.51–1.07	<0.001
Group I vs Group III	0.50	0.23–0.77	0.002
Group I vs Group IV	1.23	0.95–1.51	<0.001
Group II vs Group IV	0.44	0.19–0.69	0.001

Postoperative Pain Assessment

All groups showed a significant progressive drop in postoperative pain scores from 24-48 hours. At both time points, the lowest pain scores were recorded in Group IV while the highest scores were recorded in Group I. The groups were statistically significantly different at both 24 hours (p = 0.003) and 48 hours (p = 0.01). (**Table 4**).

Table 4. Mean postoperative pain scores (VAS)

Group	24 hours	48 hours	p-value†
Group I (SNI)	3.8 ± 1.2	2.4 ± 0.9	0.01
Group II (PUI)	2.9 ± 1.0	1.8 ± 0.7	0.02
Group III (Sonic)	3.2 ± 1.1	2.0 ± 0.8	0.01
Group IV (Negative Pressure)	2.1 ± 0.8	1.3 ± 0.6	0.03

†Repeated-measures ANOVA

STATA Statistical Findings

Statistical analysis was performed using **STATA software (version XX)**. Normality testing using the Shapiro–Wilk test confirmed normal distribution of CFU data (p > 0.05). One-way ANOVA showed a significant difference among groups for post-instrumentation CFU counts (F = 18.62, p < 0.001). Tukey's post hoc test identified Group IV as significantly superior in microbial reduction.

Regression analysis revealed that the type of irrigation system was a significant predictor of microbial reduction (β = –0.64, p < 0.001), even after adjusting for age and tooth location (**Table 5**).

Table 5. STATA multivariate linear regression analysis for microbial reduction

Variable	β Coefficient	Standard Error	z-value	p-value
Irrigation system	–0.64	0.09	–7.11	<0.001
Age	0.03	0.02	1.21	0.23
Tooth location	0.07	0.05	1.38	0.17

Overall, advanced irrigation systems particularly negative pressure and passive ultrasonic irrigation demonstrated significantly superior microbial reduction and lower postoperative pain compared to conventional syringe irrigation.

Discussion

The aim of the randomized clinical trial was to compare the effectiveness of different irrigation systems to disinfect the root canal system. Negative pressure irrigation along with passive ultrasonic irrigation was found to reduce the intracanal microbial load to a greater extent and had lesser postoperative pain when compared to syringe irrigation. Similar conclusions have been made by many clinical and experimental studies, which have assessed different irrigation delivery and activation techniques in endodontics. A recent clinical study by **Orozco et al. (2019) [21]** compared the effectiveness of passive ultrasonic activation (PUA) and conventional needle irrigation in primary endodontic infections using microbiological culture and DNA–DNA hybridization.

Though both interventions significantly reduced microbial counts, the PUA group demonstrated a greater median reduction of culturable bacteria than conventional irrigation group. Therefore, ultrasonic activation may have in vivo implications for enhancing microbial elimination. The clinical healing benefits of ultrasonic irrigation activation were not as hoped for. The results have been a mix of outcomes. As mentioned in a systematic review by **Silva et al. (2019) [22],** clinical trials comparing passive ultrasonic irrigation (PUI) with non-activated irrigation have shown that current evidence for superior periapical healing or superior microbial disinfection is inconclusive. This is due to methodological heterogeneity and insufficient statistical power of clinical studies. It can be inferred that the presence of PUI is useful in enhancing the distribution of the irrigants along with reducing the infective agents but may not translate into better long term healing unless large sample sizes and proper protocols are followed.In clinical and experimental settings, negative pressure irrigation systems like EndoVac are also assessed on their performance. **Ruksakiet et al. (2012) [23]** conducted a prospective in vivo study (often cited in endodontic literature) to compare antimicrobial efficacy of EndoVac irrigation versus syringe irrigation. According to the results, the frequency of canals negative for culture was similar in both groups. Thus, apical negative pressure can achieve effective microbial reduction similar to conventional delivery while posing lesser risk of irrigant extrusion. Other comparative studies beyond clinical trials have confirmed the mechanistic benefits of activated irrigation. In an ex vivo study, an investigation using simulated lateral canals by **Tanomaru-Filho et al. (2016) [24]** aimed to evaluate the effects of negative pressure irrigation, PUI and manual irrigation, revealing that both EndoVac and PUI had significantly better irrigant penetration into lateral canal anatomies as compared to manual syringing. Taking everything together, our findings advance this growing area of evidence by showi In contrast to field studies, several laboratory studies suggest that differences between irrigation techniques may not always be significant. The effectiveness of sonic and ultrasonic activation in removing Enterococcus faecalis using an in-vitro root canal model has been assessed **by Rödig et al. in (2010) [25]**. They noted that although activated irrigation resulted in greater penetration of the irrigant and more debris removal, the bacterial reduction was not significantly different from conventional syringe irrigation. While this study was performed under laboratory conditions, it demonstrates that the effectiveness of irrigation is influenced by many factors, including the anatomy of the canal, concentration of irrigant, duration of activation, and experimental model used.ng in a clinical setting that activated irrigation especially NPI and ultrasonic systems can achieve more significant reductions in microbes and better early clinical outcomes (e.g., postoperative pain) than syringe irrigation. The finding that agrees with clinical observation from Orozco et al. confirms the possible clinical benefits of irrigant activation in primary endodontic infections. In the interim, findings of systematic reviews and individual reports have been varied, thereby highlighting the need for well powered studies that follows the same standard protocol for definition of comparative benefits of irrigation systems. To conclude, the present randomized clinical trial study of one hundred patients adds support to the previous clinical evidence, which suggests that the disinfection of the root canal system may be improved with advanced irrigation techniques. According to clinical or ex vivo studies, thereon, further studies on the optimal irrigation should be performed focusing on long-term healing outcome, standardized methods of microbiological assessment and broad range of patients.

Limitations

The present study comes with certain limitations that must be kept in view. Having a sample size of 100 patients is a fair statistic, but the limitation of the study was that it focused on only single rooted teeth which have a relatively simpler canal anatomy. Not the same can be said for multi-rooted ones. Instead of showing the total diversity of microbial species in the root canal system, the measurement of microbiological assessment using colony-forming unit counts of culturable bacteria underestimates the presence of unculturable species with molecular detection. The assessment was restricted to short-term eradication of microbes and early postoperative pain. There was no long-term follow-up to check periapical healing or treatment success. Moreover, a unique concentration of irrigant was delivered with a standard activation time which might not represent the full potential of each irrigation system. Since just one operator was performing all procedures, operator bias was minimized, but it cannot be completely excluded.

Conclusion

Advanced irrigation systems exhibited better disinfection efficacy than syringe irrigation methods in disinfecting root canals in this clinical trial. The use of negative pressure and passive ultrasonic irrigation resulted in a larger microbial reduction and marked reduction in postoperative pain. Irrigation methods that were activated helped the irrigant to penetrate better into the root canal system. The efficiency of conventional syringe irrigation is less as compared to other systems. Hence, the use of advanced irrigating solutions can enhance the clinical outcomes of endodontic treatment.

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