Original Article

Comparison of ultrasonic versus side-vented needle irrigation for reductions in bacterial growth and postoperative pain: A randomized controlled trial

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Abstract

Background: Postoperative pain affects 16%–25% of root canal therapy patients. The irrigating system and irrigants used should reduce bacterial load without irrigant extrusion beyond the root canal apex, potentially reducing postoperative pain and discomfort.

Aim: This study aims to compare the effects of passive ultrasonic irrigation and side-vented needle irrigation on postoperative pain and bacterial load in single-rooted teeth with pulp necrosis.

Materials and Methods: Eighty patients with pulpal necrosis in single-rooted teeth were randomly categorized into two groups (n = 40 each): Group A (side-vented needle irrigation) and Group B (passive ultrasonic irrigation). Bacterial samples were collected using sterile paper points after initial access cavity preparation (S1) and standard endodontic instrumentation + irrigation (S2). Bacterial growth was assessed on MacConkey and blood agar. Pain was recorded 30 min preoperatively and 6, 12, 24, and 48 h postoperatively.

Statistical Analysis Used: Chi-square test, independent t-test and paired t-test.

Results: Irrigation with Irrisafe tips showed increased number of bacteria-free samples and a significant reduction in postoperative pain (at the 6 and 12 h time-points) when compared to side-vented needle.

Conclusions: Passive ultrasonic irrigation with Irrisafe tips may be more effective than side-vented needle irrigation in reducing postoperative pain and intracanal bacterial load in patients undergoing endodontic treatment.

Keywords: Bacterial load; irrigation; passive ultrasonic activation; postoperative pain

INTRODUCTION

Endodontic therapy success is determined not only by the cleaning and disinfection of the root canal but also by the patient's reduction in pain.[1] Because 35% of root canal surfaces remain untouched during preparation, mechanical instrumentation alone is not enough to completely remove cultivable bacteria from a complex root canal system.[2,3] As a result, the primary determinant of a successful endodontic treatment is disinfection of the root canal system with antimicrobial irrigating solutions. To be effective, the irrigant must come into direct contact with the canal walls, particularly in the apical third. To increase the distribution and flow of the irrigant to the apical third of the root canal system, various activation techniques and delivery systems have been proposed.[4]

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IrriSafe (Satelec Aceton group), a passive ultrasonic irrigation activator, enhances micro-streaming and micro-cavitation by transmitting ultrasonic energy.[5] The active streaming of irrigants, with a parallel-shaped noncutting tip, improves acoustic streaming and cavitation, effectively removing dentine debris, microorganisms, and organic tissues from root canals. This active streaming also increases contact with canal walls, resulting in more efficient and effective irrigation.[6,7]

Moderate-to-severe postoperative endodontic pain affects 16%–25% of patients, due to inflammation from bacterial toxins, debris, and chemicals extruding into the periapical tissue. Any delivery system that reduces the risk of extrusion minimizes postoperative pain and discomfort significantly.[8]

This study aimed to assess and compare the incidence of postoperative pain and decrease in bacterial load in patients following root canal therapy using passive ultrasonic irrigation with Irrisafe tips and conventional needle irrigation.

MATERIALS AND METHODS

This randomized clinical trial was written according to the Consolidated Standards of Reporting Trials guidelines.[9] The study protocol was registered at www.clinicaltrials.in. (CTRI/2019/11/022089) after obtaining Institutional Ethical Committee approval. After providing explanations about the procedures and potential risks, all patients signed informed consent forms.

The research question according to the PICO format was as follows: In patients with pulp necrosis (P: Population), how effective is passive ultrasonic irrigation with Irrisafe tips (I: Intervention) compared to conventional syringe needle irrigation using side-vented needles (C: Comparison) in reducing postoperative pain and bacterial growth in the root canals (O: Outcome)?

This study's inclusion criteria were healthy patients between the ages of 18 and 55 years; single-rooted teeth with pulpal necrosis with or without symptomatic apical periodontitis; teeth that required primary root canal treatment; and teeth with an adequate crown structure for isolation. Patients who had recently received analgesics or antibiotics; the presence of periapical radiolucency and severe periodontal disease; patients undergoing orthodontic treatment; pregnant or lactating patients; teeth with complex root canal morphology or calcified canals; and patients with chronic systemic disease were excluded from the study.

Randomization and blinding

The randomised, parallel, double-blind clinical trial had a 2-day follow-up period. The permuted block method was used to randomly divide 80 patients into two groups of four patients each. The randomization scheme was created using tools from http://www.randomization.com; the card containing information about group allocation was placed in a closed envelope to be opened by the clinician during the final irrigation of the root canal. Pulp sensibility tests and clinical examinations were performed, and a diagnosis of pulp necrosis with or without symptomatic apical periodontitis was confirmed. Teeth that had a likelihood one of bacterial infection were selected.

Treatment procedure

Before anesthesia, patients were asked to quantify their pain on a Visual Analog Pain Intensity Scale. The tooth, rubber dam retainer, and surrounding area were disinfected following Moller's protocol,[10] with 30% hydrogen peroxide and 5% iodine tincture. A primary bacteriologic sample was taken to ensure that all cultivable bacteria had been eradicated from the tooth's surface after any leftover iodine was inactivated with 5% sodium thiosulphate. Samples showing bacterial growth were not included in the study.

After access opening with endo access burs (Mani EA 10, EA 13) and minimal instrumentation with 15-size K-file (Mani Inc., Japan), sterile saline was introduced the canal to take a second bacterial culture (S1) and confirm microbial infection. Pre flaring the canals with Gates glidden drill size 2 (Mani Inc., Japan) and obtaining a working length that was 1 mm below the radiographic apex, confirmed with an apex locator (Canal pro, Coltene), were part of the standardized instrumentation protocol. Canal instrumentation was accomplished using rotary and hand files, as well as 5.25% sodium hypochlorite irrigation (Septodont, India). All teeth were prepared with ProTaper rotary instruments (S1-F2; Dentsply, Tulsa, OK); At this point, the clinician removed a card from the envelope to reveal the final irrigation protocol.

Final irrigation protocols

On the basis of the final irrigation protocol, the patients were allotted one of the two groups: Group A receiving side-vented needle irrigation, and Group B receiving passive ultrasonic irrigation using Irrisafe tips.

The final irrigation in Group A was done with 6 mL of 2.5% NaOCl and a 31G, 27 mm NaviTip (Ultradent, South Jordan UT), Sideport needle, 1 mm from the working length for 3 min (flow rate, 2 mL/min). This was followed by irrigation with 1 ml of 17% EDTA for 1 min and 1 ml of 2% chlorhexidine for 1 min. The flow rates were standardized using a countdown timer. To neutralise the antimicrobial effect of chlorhexidine, the canals were rinsed with a mixture of 0.3% L-lecithin and 3% Tween-80 before being flushed with sterile saline (to prevent interference with microbial sampling).

In Group B, the irrigant was introduced as in Group A and agitated with a 150-µm, noncutting, stainless steel wire (Irrisafe, Satelec, Bordeaux, France) attached to an ultrasonic device (P5 Newtron unit, Satelec) set to 10 (frequency, 30 kHz).[11] The irrigation protocol was similar to that used in Group A, but the irrigants were passively agitated using Irrisafe tips (#15 ultrasonic file) for 30 s before changing the solution.

Obtaining the bacterial samples from the root canals

At this point, a second sample (S2) from the canal was obtained for both groups and transported to a microbiology laboratory in a bacterial transport medium (Peptone water).[12] Calcium hydroxide paste (Henry Schein, Melville NY) was placed as an intracanal medicament and Cavit (3M ESPE, St. Paul MN) was placed as a temporary restoration.

Bacterial load and postoperative pain assessment

The bacteria were cultured on blood agar plates (5% sheep blood) and MacConkey (Lactose monohydrate) using the spread plate and streaking technique in a laminar airflow chamber and placed in an incubator for 24 h at 37°C. The bacterial cultures were observed after 24 h and colonies were counted using a colony counter. A colony count of at least 10^5 colony-forming units was considered as positive growth. The bacterial growth at each stage (before and after the intervention) was recorded and compared.

Following the intervention, patients were given postoperative forms to record pain levels. They received instructions to record Visual Analog Scale pain scores at 6, 12, 24, and 48 h postoperatively, with messages sent as reminders. They were asked to categorise their pain experience into five categories: 0 (no pain), 1–3 (mild pain), 3–5 (moderate pain), 5–9 (severe pain), and worst possible pain.[13]

Patients were recalled 48 h postoperatively for data collection and obturation. If pain was unmanageable, patients were informed to contact the principal investigator. Ibuprofen 400 mg (Abbott, India) was prescribed as a rescue drug. Data recorded after the time of taking rescue drug was excluded from the study.

Statistical analysis

The data were collected in Excel and analyzed using SPSS version 20 (IBM Corporation Armonk, NY, USA). Both descriptive and inferential statistics were applied. Data with binary or nominal data were summarized using count and percentage, while data following normal distribution were presented as mean and standard deviation to determine the percentage of positive and negative cultures within and between groups, the Chi-square test was used. The changes score was calculated from baseline, and pain scores were analysed at various time points using an independent *t*-test for comparison between groups and a paired *t*-test for comparison within groups. A $P = 0.05$ was regarded as statistically significant.

RESULTS

All the patients reported for follow-up. Out of the 40 patients in Group A that had single-rooted necrotic teeth, 24 were male and 16 were female. Group B consisted of 21 males and 19 females having single-rooted teeth with pulpal necrosis. Bacterial growth on blood agar and MacConkey's agar plates was observed in both groups [Figure 1]. Significant reductions in bacterial growth were observed in the S2 samples when compared to the S1 samples in both groups [Figure 2a]. Group B had a higher proportion of bacteria-free samples than Group A [Figure 2a].

Postoperative pain reduction was significant at all time points in both groups, with significant differences between Group A and B at 6 and 12 h postoperative time points. Group B showed a significant reduction in pain at 6 and 12 h compared to Group A ($P < 0.05$), but there were no significant differences observed at 24 and 48 h time-points [Figure 2b and c].

DISCUSSION

The study focused on the bacterial load within the root canal and postoperative pain incidence in single-rooted teeth requiring root canal therapy after using two irrigation techniques. Patients requiring root canal therapy for single-rooted teeth due to pulp necrosis, without the presence of any other endodontically affected teeth, were examined in this study.[14] Initial bacteriological samples showed no growth after disinfection and before access opening, confirming the operating field was aseptic. The common irrigant in both the experimental: conventional (30-gauge side-vented needle) and passive ultrasonic irrigation (Irrisafe) was sodium hypochlorite.

Previous studies on passive ultrasonic irrigation using Irrisafe tips have evaluated its effectiveness in removing

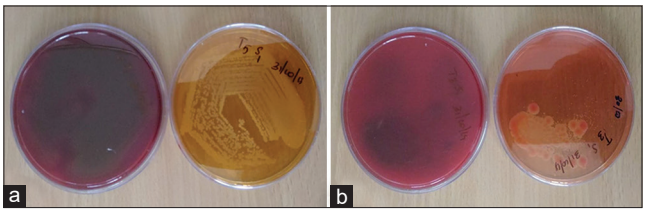

Figure 1: Representative samples with bacterial Growth on blood agar and MacConkey's agar plates in samples from Groups A and B. (a) Group A (side-vented needle irrigation), (b) Group B (passive ultrasonic activation). Marked reductions in bacterial growth were observed in samples from Group B compared to those from Group A

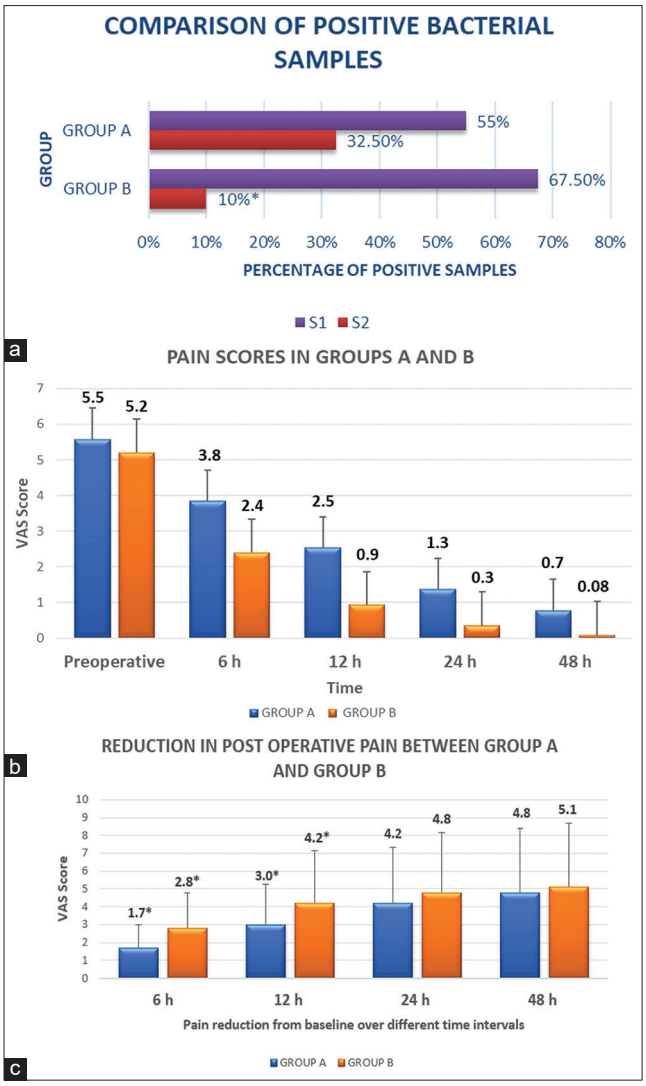

Figure 2: (a) Bacterial growth in S2 samples obtained from Groups A and B. Group B displayed significantly ($P = 0.014$) decreased bacterial growth compared to Group A, (b) The Visual Analog Scale scores of patients in Group A (side-vented needle irrigation) and Group B (Irrisafe). Significant reductions in postoperative pain were observed in both groups at all the time intervals, (c) Comparison of reduction in postoperative pain between Groups A and B. *Significant differences between the two groups ($P < 0.05$). VAS: Visual Analog Scale

dentin debris and root canal filling materials *in-vitro*.[15,16] However, no study has assessed the extent of bacterial reduction following the use of Irrisafe tips. This is the first *in vivo* study to compare the reduction in bacterial growth using the two irrigation techniques. The intermittent flush method of irrigation was used for ultrasonic activation, and it has been demonstrated that refreshing the irrigant during active ultrasonic irrigation over three cycles had a cumulative effect on debris removal from the root canal.[17]

In both groups, a significant decrease in samples showing bacterial growth was observed after cleaning, shaping, and irrigation of the canals (S2) compared to the first sample (S1). The mechanical action of the rotary instruments, the chemical nature and the flow of the irrigating solution, and the anatomic characteristics of the teeth involved could all have an impact on the results. It is well established that the use of sodium hypochlorite solution can lead to a significant decrease in bacterial counts in the root canals.[18,19]

Although both groups in the current study showed reductions in bacterial growth, passive ultrasonic irrigation with Irrisafe tips was more effective than conventional syringe irrigation in the clinical setting in removing bacteria from root canals. The passive ultrasonic irrigation group (Group B) reduced positive bacterial culture by 57%, while the side-vented needle irrigation group (Group A) reduced it by 22.5% [Figure 2a]. This variation could be due to acoustic streaming and cavitation during passive ultrasonic irrigation. These findings are consistent with previous clinical studies that found that ultrasonic irrigation reduced bacteria more effectively in single-rooted teeth.[20,21]

Some studies, however, found no evidence of a decrease in bacterial loads between ultrasonic irrigation and nonactivated techniques.[18,22] Small sample sizes and using the polymerase chain reaction (PCR) technique to evaluate bacterial presence, which does not accurately measure the actual viable microflora present, may have influenced the results in the studies.[18,22] This was also the reason for using a culture method over PCR evaluation to assess bacterial load in our study.

In the current study, there was no significant difference in preoperative pain between the two groups. The highest pain levels were observed 6 h after surgery, with a gradual decrease in pain at 12, 24, and 48 h. Previous research has found that the most intense postoperative pain occurs within the first 6 h, followed by a gradual decrease in intensity.[23,24] Although calcium hydroxide was used in this study as an interappointment dressing, its influence on reducing posttreatment pain is still not clearly established and as it was used as an intracanal medicament for both the study groups it may have if at all any, equal influence on pain reduction in both the groups in the study.[25]

As regards postoperative pain, significant differences were demonstrated between the groups in terms of pain reduction 6 and 12 h postoperatively with better pain relief in the Passive Ultrasonic Irrigation (PUI) group. Similar findings have been reported in other studies, where ultrasonic irrigation reduced pain significantly more than syringe irrigation during the first 24 h postoperatively.[26,27]

This study used only single-rooted teeth to ensure consistency during sampling. Single-rooted teeth's anatomic characteristics allow for greater penetration of irrigation needles, irrespective of irrigation technique,

which can improve the efficacy of irrigant. The anatomy of a multirooted tooth, on the other hand, is more complex; it can impede irrigant penetration and reduce the magnitude of the effect of the passive ultrasonic irrigation technique. More research is needed to compare the perception of pain and bacterial reduction in teeth with multiple canals, such as premolars and molars.

CONCLUSIONS

Passive ultrasonic irrigation resulted in a greater reduction in postoperative pain within the first 6–12 h when compared to side-vented needle irrigation. Although pain was reported more frequently in the side-vented needle irrigation group, no significant differences were found between the two groups at the 24 and 48 h time points. Furthermore, the intensity of the pain peaked at 6 h and then gradually decreased until 48 h. There was also a significant difference between the two groups in the number of negative cultures. Nonetheless, larger sample sizes and longer follow-up periods are required to validate the current study's findings.

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Conflicts of interest

There are no conflicts of interest.

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