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Post-operative pain following single-visit endodontic treatment using sodium hypochlorite versus chlorhexidine as intracanal disinfectants: An *in vivo* study

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Abstract:
Post-operative pain after single visit root canal treatment remains a common clinical challenge and the optimal irrigant for balancing pain control with antimicrobial efficacy is uncertain. Therefore, it is of interest to compare the post-operative pain and antibacterial efficacy of 3% sodium hypochlorite and 2% chlorhexidine in 80 patients undergoing single-visit endodontic treatment. Chlorhexidine produced significantly lower pain scores at 6 and 24 hours and reduced analgesic use, whereas sodium hypochlorite achieved significantly greater bacterial reduction ($p < 0.05$). No significant differences in pain were observed between groups at 48 or 72 hours, indicating comparable late post-operative outcomes. Thus, data provide evidence for selecting irrigants according to clinical priorities, supporting personalised endodontic irrigation strategies that balance patient comfort with antimicrobial effectiveness.

Keywords: Endodontic, post-operative pain, sodium hypochlorite, chlorhexidine, intracanal irrigant, single-visit root canal treatment, visual analogue scale (VAS)

Background:
Root canal treatment (RCT) is the definitive management for irreversible pulpitis and pulp necrosis, aiming to eliminate infection, shape the root canal system and provide a hermetic seal **[1].** Despite technical advances, post-operative pain broadly defined as pain or discomfort occurring within 72 hours of treatment remains one of the most frequently reported complications, with published incidences ranging from 25% to 60% depending on pre-operative diagnosis, treatment modality and irrigation protocol **[2].** Pain after endodontic therapy arises from mechanical, chemical and microbial perturbation of the periapical tissues. Extrusion of irrigant, dentinal debris or microorganisms beyond the apical foramen initiates an inflammatory cascade that underpins both immediate and delayed post-operative pain episodes **[3].** Irrigation is an indispensable component of chemomechanical preparation. An ideal endodontic irrigant should possess broad spectrum antimicrobial activity, the ability to dissolve organic tissue, low cytotoxicity to periapical tissues and biocompatibility **[4].** Sodium hypochlorite (NaOCl), used in concentrations of 0.5–5.25%, has remained the gold standard irrigant for over a century owing to its outstanding tissue dissolving capacity and bactericidal efficacy against planktonic bacteria and biofilms, including the notoriously resistant *Enterococcus faecalis* **[5].** However, NaOCl carries well-documented cytotoxic potential; periapical extrusion, even in small volumes, can trigger intense inflammatory reactions and severe pain flare-ups **[6].** Chlorhexidine gluconate (CHX), available in 0.2–2% solutions, offers a complementary profile: excellent substantivity with up to 12 hours of residual antimicrobial activity, low surface tension facilitating penetration into dentinal tubules and markedly lower cytotoxicity compared with NaOCl **[7].** Nevertheless, CHX cannot dissolve necrotic tissue and is incompatible with NaOCl, forming the cytotoxic precipitate parachloroaniline when the two solutions contact each other **[8].** Single visit endodontic treatment (SVET) has gained wide clinical acceptance on the grounds of reduced chair time, fewer appointments and comparable long term prognosis to multi visit treatment **[9].** However, the absence of an inter-appointment dressing phase places greater reliance on intracanal irrigation for microbial control, potentially amplifying the influence of irrigant choice on post-operative outcomes. Clinical studies comparing NaOCl and CHX for post-operative pain have yielded inconsistent results, with some favouring CHX for reduced early pain and others demonstrating equivalence **[10].** Therefore, it is of interest to compare the post-operative pain at multiple time points following SVET using 3% NaOCl versus 2% CHX in a uniform cohort of mandibular molars, using the Visual Analogue Scale (VAS) as the primary outcome measure.

Materials and Methods:
Study design and setting:
This prospective, randomised, parallel-arm, double-blind *in vivo* study was conducted at the Department of Conservative Dentistry and Endodontics, Pacific Dental College & Research Center, Udaipur, Rajasthan, India, between January 2022 and December 2023. The study was approved by the Institutional Ethics Committee (Ref. PDCRC/IEC/2021/47) and registered with the Clinical Trials Registry – India (CTRI/2022/01/039412). All participants provided written informed consent prior to enrolment.

Inclusion criteria:
[1] Age 18–55 years, either sex
[2] Mandibular first or second molar requiring root canal treatment
[3] Clinical and radiographic diagnosis of symptomatic irreversible pulpitis or pulp necrosis with or without symptomatic apical periodontitis
[4] Presence of at least two-thirds of root length on periapical radiograph
[5] Provision of written informed consent

Exclusion criteria:

[6] Pregnancy or lactation
[7] Systemic conditions requiring antibiotic prophylaxis or affecting pain perception (uncontrolled diabetes, immunosuppression, chronic pain syndromes)
[8] Known allergy to local anaesthetics, NaOCl or CHX
[9] Use of analgesics, antibiotics or anti-inflammatory drugs within 48 hours prior to treatment
[10] Teeth with calcified canals, internal or external resorption, incomplete root formation or non-restorable crown
[11] Retreatment cases

Sample size:

Based on a pilot study mean VAS difference of 9.4 mm between irrigant groups at 24 hours (SD 14.2 mm), a two-tailed $\alpha = 0.05$ and power of 80%, a minimum of 36 participants per group was required. Accounting for a 10% dropout rate, 40 patients per group (total n = 80) were enrolled.

Randomisation and blinding:

Participants were randomised 1:1 using a computer generated block randomisation sequence (block size 4) prepared by a statistician not involved in treatment. Sealed opaque envelopes were opened immediately before irrigation commenced. The irrigating solutions were prepared by a pharmacy technician in identical unlabelled syringes. The operating clinicians, outcome assessors and patients were blinded to group allocation. Unblinding occurred only after database lock.

Treatment protocol:

All procedures were performed by a single calibrated endodontist under rubber dam isolation. After administration of inferior alveolar nerve block with 2% lignocaine and 1:80,000 epinephrine, access cavities were prepared using standard endodontic burs. Working length was established with an electronic apex locator (Root ZX II, J. Morita and Japan) and confirmed radio graphically. Canal shaping was performed using a rotary NiTi system (ProTaper Gold, Dentsply Sirona, USA) to apical size F2 or F3 according to canal anatomy. In Group A (NaOCl), irrigation was performed with 3% sodium hypochlorite solution (5 mL per canal per instrument change) using a 27-gauge side vented needle. In Group B (CHX), 2% chlorhexidine gluconate solution was used in identical volumes and delivery technique. A final flush of 5 mL sterile normal saline was used in both groups to remove residual irrigant. Canals were dried with paper points and obdurate with gutta percha and AH Plus sealer (Dentsply DeTrey, Germany) using lateral compaction. Access cavities were restored with intermediate restorative material (IRM) at the same visit. No inter-appointment intracanal medicament was placed. Patients were not prescribed prophylactic analgesics; rescue analgesia (tablet ibuprofen 400 mg) was provided and patients instructed to take it only if pain was intolerable.

Outcome measures:

The primary outcome was post-operative pain intensity measured on a 100mm Visual Analogue Scale (VAS; 0 = no pain, 100 = worst imaginable pain) at 6, 24, 48 and 72 hours post-treatment. Patients recorded scores on pre-printed diaries and returned them at 72 hours. Secondary outcomes included analgesic consumption (number of ibuprofen tablets taken), incidence of pain flare-up (VAS ≥ 54 mm requiring unscheduled visit) and microbiological colony count reduction (pre-versus post-instrumentation paper-point samples processed in a microbiology laboratory blinded to group allocation).

Statistical analysis:

Data were analysed using SPSS version 26.0. Continuous variables are expressed as mean ± SD. The independent-samples t-test was used to compare VAS scores between groups at each time point. The Mann–Whitney U-test was applied where data were non-normally distributed (Shapiro–Wilk test). Chi-square test was used for categorical comparisons. A two-tailed p-value < 0.05 was considered statistically significant.

Results:

Eighty patients were randomised 40 to each group. Two patients in Group A and one in Group B were lost to follow-up; complete data from 77 patients (Group A n = 38, Group B n = 39) were analysed. The two groups were comparable at baseline with respect to age, sex, pre-operative pain score, pulpal diagnosis and canal number **(Table 1).** Mean pre-operative VAS scores were 68.4 ± 11.2 mm in Group A and 66.9 ± 12.1 mm in Group B ($p = 0.58$). Both groups demonstrated a progressive, significant reduction in pain over 72 hours ($p < 0.001$ within each group). At 6 hours, mean VAS was significantly higher in Group A (47.6 ± 14.1 mm) than Group B (38.2 ± 12.4 mm; $p = 0.003$). The difference persisted at 24 hours (Group A: 31.4 ± 11.3 mm; Group B: 22.1 ± 9.8 mm; $p = 0.001$). By 48 hours, VAS scores were 14.8 ± 8.6 mm and 11.3 ± 7.4 mm respectively ($p = 0.07$) and by 72 hours the groups converged to 6.2 ± 4.9 mm versus 4.8 ± 4.1 mm ($p = 0.19$). These data are summarized in **Table 2.** Analgesic consumption was significantly higher in Group A: 27 of 38 patients (71.1%) took at least one ibuprofen tablet compared with 17 of 39 (43.6%) in Group B ($p = 0.01$). Mean tablet consumption per patient was 1.8 ± 0.9 (Group A) versus 1.1 ± 0.8 (Group B; $p = 0.002$). Pain flare up occurred in 5 patients in Group A (13.2%) and 2 in Group B (5.1%); the difference did not reach statistical significance ($p = 0.24$). Microbiological analysis showed a significantly greater reduction in colony-forming units in Group A (94.3 ± 4.1%) compared with Group B (81.7 ± 7.8%; $p < 0.001$), as detailed in **Table 3.**

Table 1: Baseline characteristics of study participants

Variable	Group A: NaOCl (n = 38)	Group B: CHX (n = 39)
Age, mean ± SD (years)	34.6 ± 9.2	33.9 ± 8.7
Female, n (%)	21 (55.3)	22 (56.4)
Pre-op VAS, mean ± SD (mm)	68.4 ± 11.2	66.9 ± 12.1
Diagnosis: Irreversible pulpitis, n (%)	24 (63.2)	25 (64.1)
Diagnosis: Pulp necrosis, n (%)	14 (36.8)	14 (35.9)
First molar, n (%)	26 (68.4)	27 (69.2)
Number of canals, mean ± SD	3.6 ± 0.5	3.7 ± 0.5

Table 2: Post-operative VAS pain scores at each time point (mean ± SD, mm)

Time point	Group A: NaOCl	Group B: CHX	p-value
6 hours	47.6 ± 14.1	38.2 ± 12.4	0.003
24 hours	31.4 ± 11.3	22.1 ± 9.8	0.001
48 hours	14.8 ± 8.6	11.3 ± 7.4	0.07
72 hours	6.2 ± 4.9	4.8 ± 4.1	0.19

Table 3: Secondary outcomes

Outcome	Group A: NaOCl	Group B: CHX
Analgesic use, n (%)	27 (71.1)	17 (43.6)
Mean tablets/patient (± SD)	1.8 ± 0.9	1.1 ± 0.8
Pain flare-up, n (%)	5 (13.2)	2 (5.1)
CFU reduction, mean % (± SD)	94.3 ± 4.1	81.7 ± 7.8

Discussion:

This randomised *in vivo* study showed that CHX produced significantly lower early post-operative pain than NaOCl at 6 and 24 hours following single visit endodontic treatment, while both irrigants performed equivalently from 48 hours onwards. The antimicrobial superiority of NaOCl, however, was confirmed by significantly greater colony-forming unit reduction. These findings reflect the well characterised pharmacological trade-off between the two irrigants and have direct clinical implications for patient counseling and analgesic prescribing. The mechanism underlying the higher early pain scores with NaOCl most plausibly relates to its cytotoxic potential. Even small volumes of periapically extruded NaOCl trigger prostaglandin mediated acute inflammation through oxidative damage to periapical tissues, a reaction substantially less pronounced with CHX **[11].** This interpretation is supported by our finding of greater analgesic consumption in the NaOCl group, consistent with recent systematic review evidence indicating that NaOCl concentrations above 2.5% are associated with higher post-operative pain at early time points **[12].** The convergence of VAS scores at 48 and 72 hours in our study suggests that the inflammatory response elicited by NaOCl resolves rapidly under the protective effect of ibuprofen rescue analgesia, a pattern also observed by Karatas *et al.* **[13].** The superior antimicrobial performance of NaOCl (94.3% CFU reduction) over CHX (81.7%) is consistent with multiple *in vitro* and clinical studies confirming the irreplaceable tissue-dissolving action of hypochlorite, particularly against obligate anaerobes and biofilm-embedded *E. faecalis* **[14].** CHX's residual substantivity does confer prolonged bacteriostatic activity, but cannot fully compensate for its inability to dissolve necrotic pulp tissue, which serves as a nutrient substrate for persistent microorganisms. Importantly, the failure to achieve the same degree of microbial elimination with CHX may have long-term implications for periapical healing outcomes that extend beyond the 72-hour window of the current study. Pain flare-up rates (13.2% NaOCl vs 5.1% CHX) trended in favour of CHX but did not reach statistical significance, likely due to the modest sample size. A meta-analysis pooling data across larger trials would provide better-powered estimates of this outcome **[15, 16].** Practical considerations also bear on irrigant selection: CHX leaves a surface precipitate, cannot be mixed with NaOCl and is not biodegradable, raising environmental concerns **[17, 18].** Clinically, a sequential protocol NaOCl for the bulk of instrumentation followed by a saline rinse and final EDTA chelation may represent a pragmatic compromise that exploits antimicrobial potency while reducing periapical cytotoxicity. Limitations of the study include restriction to mandibular molars (limiting generalisability to anterior and premolar teeth), a 72-hour follow-up that does not capture healing or retreatment rates and the use of a single concentration for each irrigant. Future studies should evaluate multiple concentrations, include microCT assessment of irrigant penetration depth and report long-term periapical outcomes **[19].**

Conclusion:

Following single-visit endodontic treatment of mandibular molars, chlorhexidine gluconate produced significantly lower early post-operative pain at 6 and 24 hours compared with sodium hypochlorite, with equivalent pain levels by 48 and 72 hours. Sodium hypochlorite showed superior antimicrobial efficacy. Both irrigants are clinically viable; the choice should be guided by the relative importance of early pain reduction versus maximal bacterial elimination in individual patient contexts.

Conflict of interest: The authors declare no conflict of interest

Funding: No external funding was received for this study

Ethical approval:

The study was approved by the Institutional Ethics Committee, Pacific Dental College & Research Center, Udaipur (Ref. PDCRC/IEC/2021/47) and registered with the Clinical Trials Registry – India (CTRI/2022/01/039412). All participants provided written informed consent.

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