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ORIGINAL ARTICLE

Effect of 2% Chlorhexidine as an Irrigant on Postoperative Symptoms Following Foraminal Instrumentation: A Randomized Clinical Trial

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ABSTRACT

Objective: To compare postoperative pain, tenderness, edema, and medication use after foraminal enlargement in a single visit, using 2.5% sodium hypochlorite (NaOCl) and 2% chlorhexidine gel (CHX). **Material and Methods:** Seventy patients with single-rooted teeth with apical periodontitis were randomized into two groups according to the irrigation protocol: control (NaOCl - 35 patients) and case (CHX - 35 patients). Pain intensity was assessed using the visual analog scale (recorded every day for seven days, on the 14th and 30th days after treatment). Edema was assessed by two independent evaluators on the 2nd, 3rd, and 7th days after treatment using photographs. Data were analyzed using Chi-square, Fisher's Exact, and Mann-Whitney U tests in SPSS. **Results:** There was a statistically significant difference in postoperative pain and tenderness between the groups on the 2nd day ($p<0.05$). There was no difference between the groups for edema ($p=1.00$) and use of medication ($p=0.77$). **Conclusion:** Chlorhexidine resulted in more significant postoperative pain and tenderness after foraminal enlargement.

Keywords: Chlorhexidine; Edema; Pain; Root Canal Irrigants; Sodium Hypochlorite.

Introduction

Foraminal instrumentation refers to the intentional and mechanical enlargement of the apical foramen to reduce intracanal bacteria load and hard tissue debris accumulation [1]. However, a systematic review showed that foraminal instrumentation in necrotic teeth with apical periodontitis causes more significant postoperative pain during the first few days after treatment [2].

Irrigant solutions play an essential role in the successful debridement and disinfection of the root canal system [3]. Several chemical products have been suggested as efficient irrigation solutions, including sodium hypochlorite (NaOCl) and chlorhexidine (CHX), which are the most widely used irrigants during endodontic treatment [3]. NaOCl has a broad antimicrobial spectrum and an effective ability to dissolve organic matter and necrotic tissue [3], while CHX shows substantivity and residual antimicrobial activity when used as an irrigating solution [4]. In addition, CHX appeared to be a promising agent as a final irrigant [5]. However, NaOCl has some disadvantages, including tissue toxicity [6], particularly at high concentrations [3], and results in the development of serious complications when apically extruded [7], and CHX is unable to dissolve necrotic pulp tissue remnants [4].

Several clinical trials have been conducted to evaluate the effect of irrigation solutions on postoperative symptoms [8-10]. However, the concentrations of the irrigation solutions and chemomechanical techniques used in these studies differed from those used in our study, which emphasizes the importance of our research.

Therefore, this prospective, double-masked, randomized study aimed to evaluate and compare the effect of 2.5% NaOCl and 2% CHX on postoperative symptoms and analgesics following foraminal instrumentation in teeth with apical periodontitis. The null hypothesis was that there is no difference in postoperative symptoms and analgesic use when NaOCl or CHX are used as an irrigant solution.

Material and Methods

Study Design, Ethical Clearance and Register

A prospective, double-masked, controlled, and randomized clinical study was performed with the approval of the research ethics committee of Fluminense Federal University/Nova Friburgo (no.2.353.996) and registered in www.clinicaltrialsdatabase.gov under the identification number NCT03704857. All volunteers participating in this clinical study received information about the procedures to be performed, including their risks and benefits. Each research participant signed and submitted an informed consent form.

Calculation of the Sample Size

The sample size was calculated using the OpenEpi calculator (https://www.openepi.com/Menu/OE_Menu.htm). Based on the results of a previous study [8], we established that 35 individuals per group would be needed to detect clinically significant disparities, considering a power of 80%, an alpha risk of 5%, a confidence interval of 95%, and mean and standard deviation of 0.75 (0.35) for the CHX group and 1.00 (0.39) for the NaOCl group.

Selection and Allocation of Patients

From October 2017 to June 2019, patients who needed endodontic treatment on uniradicular teeth with apical periodontitis were screened and treated at the Fluminense Federal University/Nova Friburgo Health Institute. Details are presented in the Consolidated Standards of Reporting Trials flow diagram (Figure 1).

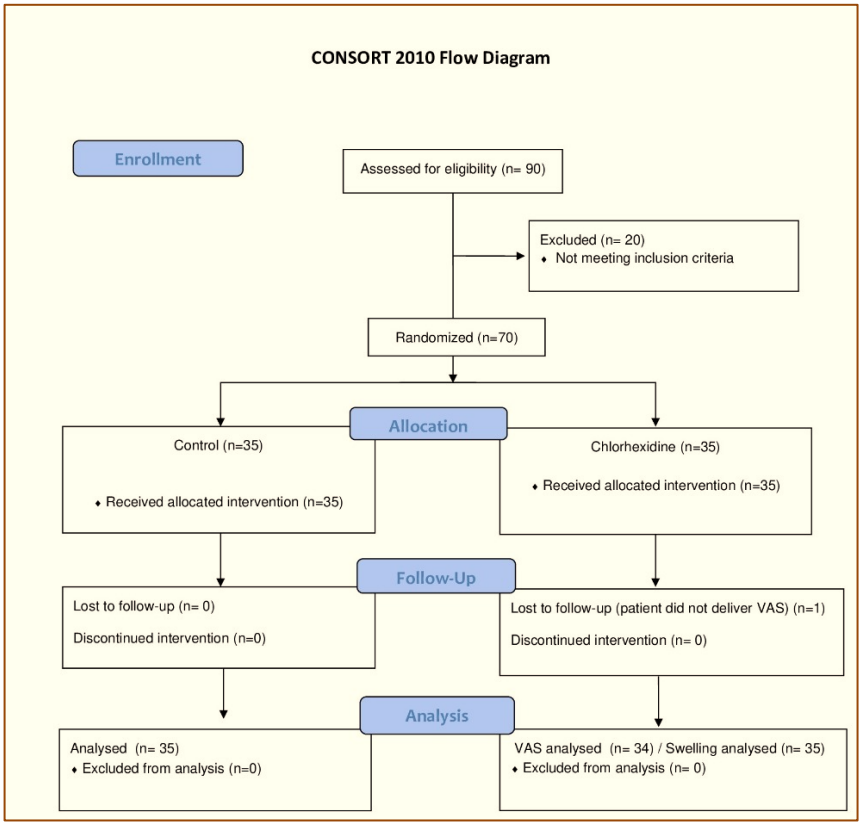

Figure 1. The Consolidated Standards of Reporting Trials flow diagram.

Patients under 18 years of age who ingested antibiotics in the last 30 days and analgesics or anti-inflammatory drugs in the previous three days (any medication that could alter their perception of pain) [10], with complicating systemic diseases, pregnant/lactating women, and with acute periapical pain and abscesses were excluded from the study.

Only patients with necrotic uniradicular teeth and radiographic evidence of apical periodontitis were included [11]. Tests for sensitivity to hot and cold were used to determine the pulp condition. This was assessed using the absence of bleeding during access to the pulp chamber.

A randomization procedure (www.random.org) was performed (E.A.B.S). All 70 patients were randomly assigned, with an allocation ratio of 1:1, to two groups: the control group (n = 35), which performed foraminal enlargement using NaOCl as the leading irrigating solution, and the case group (n = 35), which performed foraminal enlargement using CHX as the main irrigant.

The allocation sequence was distributed in opaque and sealed envelopes, numbered sequentially (E.A.B.S). Before beginning endodontic treatment, the operator (F.G.H) removed an envelope and performed the intervention according to the specific group. The patients and the outcome examiners (L.S.G; L.A.A.A; L.S.G) were blinded and were not informed of the allocation; however, due to the irrigating solutions used, the operator (F.G.H) was not blinded to the treatment.

Root Canal Treatment Procedures

All endodontic treatments were performed in a single session by a single endodontic specialist (F.G.H), using a standardized protocol. The patients' health conditions were evaluated, and after clinical and radiographic examination, the teeth were isolated with cotton rollers and subjected to sensitivity tests to hot with a heated

gutta percha stick (Dentsply Sirona, York, PA, USA) and cold with Endo Ice (Coltene/Whaledent Inc, Cuyahoga Falls, Ohio, USA), in addition to percussion and palpation tests.

Before the beginning of treatment, all patients used mouthwash with 0.12% chlorhexidine for 1 minute (Periogard alcohol-free, Colgate Palmolive Company, Cambridge, Ohio, USA). After administration of local anesthesia with 2% lidocaine with 1:100,000 epinephrine (Alphacaine; DFL Indústria e Comércio Ltda, Taquara, RJ, Brazil), endodontic cavity access was performed using a high-speed sterile diamond spherical drill (KG Sorensen, Cotia, São Paulo, Brazil) and Endo-Z bur (Dentsply Sirona, York, PA, USA). After pulp chamber trepanation, a rubber dam was done, followed by disinfection with the 2.5% sodium hypochlorite solution (NaOCl) (Fórmula & Ação, São Paulo, SP, Brazil). With the aid of a #15 K-file (Dentsply Sirona, York, PA, USA), the working length (WL) was established using the electronic apical locator RomiApex A-15 (Romidan, Kiryat Ono, Israel) at the mark "00". A #10 K-file (Dentsply Sirona, York, PA, USA) was used throughout the instrumentation phase to maintain the patent length.

Initial instrumentation with sizes #10, #15, #20, #25, and #30 K-files (Dentsply Sirona, York, PA, USA) was performed under constant irrigation. Then, Reciproc 40 or 50 (VDW GmbH, Munich, Germany) was used, and its selection was determined according to the amplitude of the root canal. In cases where a #30 K-file did not go passively to the WL, R40 was selected, and these cases were classified as medium. In cases where a #30 K-file passed passively to the WL, R50 was selected, and these cases were classified as large, according to the manufacturer's protocol. The system files were coupled to the VDW Silver engine (VDW GmbH, München, Germany) and then introduced into the root canals through linear inlet and outlet movements, with slight apical pressure and amplitudes not exceeding 3-4 mm [12]. Instrumentation was performed at mark "00", determined by the apical locator. Reciprocating single-use files were discarded after the instrumentation of the root canal.

In the control group, each insertion of the reciprocating instrument was followed by irrigation of the canal with 2.5% NaOCl (Fórmula & Ação, São Paulo, SP, Brazil) solution. The smear layer was removed with 3 mL of 17% EDTA for 3 minutes, and the root canal was irrigated again with 3 mL of 2.5% NaOCl. In the case group, root canals were flooded with the 2% CHX gel (Fórmula & Ação, São Paulo, SP, Brazil) before each reciprocating instrument insertion and then rinsed with 3 mL of 0.9% saline solution.

The smear layer was removed with 3 mL 17% EDTA for 3 minutes and then irrigated with 3 mL of saline to completely remove the EDTA. A Max-i-Probe 30-G needle (Dentsply Sirona, York, PA, USA) was used in both groups to dispense the solutions up to 3 mm below the working length [10]. All teeth received the same volume of irrigating solution: 15 mL [13].

After instrumentation, the root canals were dried with absorbent paper tips from the Reciproc System (VDW) and filled with gutta-percha R40 or R50 and MTA Fillapex cement (Angelus Odonto, Londrina, PR, Brazil), using the lateral condensation technique. To create an intra-orifice barrier, Coltosol F (Vigodent, Coltene / Whaledent Inc, Cuyahoga Falls, OH, USA) was used, followed by temporary restoration with Maxxion R glass ionomer (FGM, Joinville, SC, Brazil).

Assessment of Pain and Edema

The analysis of postoperative pain and tenderness was performed using the visual analog scale (VAS), in which pain levels were classified as follows: no pain (0), mild pain (1-3), moderate pain (4-6), or intense pain (7-10) [14]. Pain assessment was performed on the 1st, 2nd, 3rd, 4th, 5th, 6th, 7th, 14th, and 30th day after the end of treatment. In this study, the outcome assessors were the patients themselves. The blinding success was tested by asking the patients to guess their study groups [15]. All participants (100%) reported being unable to guess their study groups.

All patients were instructed to contact the dentist responsible (L.S.A) for care in case of severe pain or any other complication. In the case of severe pain, the anti-inflammatory (ibuprofen 400 mg) was prescribed according to a pre-established protocol [14].

Based on the criteria of Morse et al. [16], edema was subjectively assessed on the 2nd, 3rd, and 7th day after treatment by clinical analysis, comparing the patient's initial photograph. Two independent and blinded authors clinically evaluated this symptom (k = 0.90) as follows: 1. Light: there is no distortion of the face but a slight swelling of the gums, cheeks, or chin; 2. Moderate: a superficial distortion of the cheek or chin; and 3. Severe: there is a serious distortion of the part involved.

Statistical Analysis

The statistical program SPSS version 20.0 (IBM Corp, Armonk, NY, USA) was used for data processing. The Student's t-test was used to compare the mean age between the groups. Groups, tooth, and sex/arch position/use of medication/occurrence of edema were compared between groups using the Chi-square test or Fisher's exact test. To assess whether VAS values were normally distributed, the Kolmorogov-Smirnov test was applied. As the data did not show normal distribution ($p<0.05$), the Mann-Whitney U test was used to assess the difference between the groups regarding postoperative pain and tenderness on the 1st, 2nd, 3rd, 4th, 5th, 6th, 7th, 14th, and 30th day after endodontic treatment. A significance level of 5% ($p < 0.05$) was adopted in all tests.

Results

Ninety patients were initially assessed for eligibility; 20 were excluded because they did not meet the inclusion criteria. Seventy patients were included in this study (35 in each group). One patient in the CHX group was excluded during the follow-up for not returning the VAS (Figure 1).

Table 1 describes the participants' demographic characteristics and dental distribution. There was no statistical difference between the groups in relation to the mean age (p=0.19), sex (p=1.00), arch position (p=0.80), and groups of teeth (p=0.75). The mean age (mean and standard deviation) of patients in the NaOCl group was 41.02 (13.63) years, and of patients in the CHX group, 36.97 (12.26) years.

The sample consisted of 21 women and 14 men in both groups. Regarding the arch position, 24 maxillary and 11 mandibular teeth were included in the NaOCl group, whereas in the CHX group, 22 were maxillary and 13 mandibular teeth. Regarding the groups of teeth, 23 maxillary anterior teeth, one maxillary premolar tooth, six mandibular anterior teeth, and five mandibular premolar teeth were included in the NaOCl group; in the CHX group, 22 maxillary anterior teeth, seven mandibular anterior teeth, and six mandibular premolar teeth were included.

Table 1. Demographic characteristics and dental distribution of the participants.

Characteristics	NaOCl	CHX	p-value
Age [Years; SD]	41.02 (13.63)	36.97 (12.26)	0.19*
Sex			
Women	21 (60.0)	21 (60.0)	1.00**
Men	14 (40.0)	14 (40.0)	
Arch Position			
Maxillary	24 (68.6)	22 (62.9)	0.80***
Mandibular	11 (31.4)	13 (37.1)	
Tooth Groups			
Maxillary			
Anterior	23 (65.7)	22 (62.9)	0.75**

Premolar	1 (2.9)	0 (0.0)
Mandibular		
Anterior	6 (17.1)	7 (20.0)
Premolar	5 (14.3)	6 (17.1)

SD: Standard Deviation; NaOCl: Sodium Hypochlorite; CHX: Chlorhexidine; *Student's T-Test; **Chi-Square Test; ***Fisher's Exact Test.

The mean and standard deviation/median of the visual analog scale values for postoperative pain and tenderness on the days evaluated are described in Tables 2 and 3. There was a statistically significant difference ($p<0.05$) between the groups regarding postoperative pain and tenderness on day 2 ($p=0.03$; $p=0.02$, respectively).

Table 2. The mean and standard deviations / median pain values on the visual analog scale.

Days (VAS)	NaOCl		CHX		p-value*
	Mean (SD)	Median (Q1-Q3)	Mean (SD)	Median (Q1-Q3)	
Day 1	0.97 (1.88)	0.00 (0.00-1.00)	2.05 (2.87)	0.50 (0.00-4.00)	0.10
Day 2	0.62 (1.69)	0.00 (0.00-0.00)	1.88 (2.77)	0.00 (0.00-4.00)	**0.03**
Day 3	0.71 (1.94)	0.00 (0.00-0.00)	1.35 (2.48)	0.00 (0.00-2.00)	0.06
Day 4	0.48 (1.46)	0.00 (0.00-0.00)	0.91 (2.23)	0.00 (0.00-0.00)	0.61
Day 5	0.34 (1.08)	0.00 (0.00-0.00)	0.55 (1.52)	0.00 (0.00-0.00)	0.65
Day 6	0.25 (0.74)	0.00 (0.00-0.00)	0.29 (1.03)	0.00 (0.00-0.00)	0.54
Day 7	0.11 (0.40)	0.00 (0.00-0.00)	0.20 (0.91)	0.00 (0.00-0.00)	0.71
Day 14	0.25 (1.06)	0.00 (0.00-0.00)	0.17 (0.62)	0.00 (0.00-0.00)	0.98
Day 30	0.05 (0.33)	0.00 (0.00-0.00)	0.11 (0.47)	0.00 (0.00-0.00)	0.54

SD: Standard Deviation; NaOCl: Sodium Hypochlorite; CHX: Chlorhexidine; Q1, Q3: 1st and 3rd quartile (25%, 75%, respectively); *Mann-Whitney Test ($p<0.05$): bold font indicates statistical significance.

Table 3. The mean and standard deviations / median tenderness values on the visual analog scale.

Days (VAS)	NaOCl		CHX		p-value*
	Mean (SD)	Median (Q1-Q3)	Mean (SD)	Median (Q1-Q3)	
Day 1	1.05 (1.98)	0.00 (0.00-2.00)	2.23 (2.83)	1.00 (0.00-4.00)	0.07
Day 2	0.77 (1.94)	0.00 (0.00-1.00)	2.02 (2.69)	0.50 (0.00-4.00)	**0.02**
Day 3	0.80 (1.95)	0.00 (0.00-0.00)	1.47 (2.52)	0.00 (0.00-2.00)	0.07
Day 4	0.54 (1.78)	0.00 (0.00-0.00)	0.91 (2.26)	0.00 (0.00-0.25)	0.32
Day 5	0.45 (1.57)	0.00 (0.00-0.00)	0.64 (1.64)	0.00 (0.00-0.00)	0.47
Day 6	0.34 (1.13)	0.00 (0.00-0.00)	0.29 (1.00)	0.00 (0.00-0.00)	0.53
Day 7	0.22 (1.03)	0.00 (0.00-0.00)	0.26 (0.82)	0.00 (0.00-0.00)	0.64
Day 14	0.37 (1.41)	0.00 (0.00-0.00)	0.26 (0.79)	0.00 (0.00-0.00)	0.70
Day 30	0.20 (0.90)	0.00 (0.00-0.00)	0.08 (0.37)	0.00 (0.00-0.00)	0.98

Footnote: SD: Standard Deviation; NaOCl: Sodium Hypochlorite; CHX: Chlorhexidine; Q1, Q3: 1st and 3rd quartile (25%, 75%, respectively); *Mann-Whitney Test ($p<0.05$): bold font indicates statistical significance.

Tables 4 and 5 describe the percentages of patients who did not report pain, mild pain, moderate pain, and severe pain during the postoperative pain and pain following touch assessments, respectively.

In the NaOCl group, on the first day, one patient (2.85%) experienced severe pain during the postoperative period, and two patients (5.71%) experienced moderate pain. On the second day, only one patient (2.85%) experienced severe and moderate postoperative pain. On the third day, two patients (5.71%) experienced severe pain in the postoperative period, and one patient (2.85%) experienced moderate pain. On the fourth day, only one patient (2.85%) experienced severe and moderate postoperative pain. On the fifth day, only two patients (5.71%) experienced moderate postoperative pain. On the fourteenth day, one patient (2.85%) experienced moderate postoperative pain (Table 4).

In the CHX group, four patients (11.76%) experienced moderate pain, and five patients (14.70%) experienced severe pain on the first day. Five patients (14.70%) experienced moderate pain, and four patients (11.76%) experienced severe pain on the second day. Two patients (5.88%) experienced moderate pain, and three patients (8.82%) experienced severe pain on the third day. On the fourth day, one patient (2.94%) reported moderate pain, and two patients (5.88%) reported severe pain. Two patients (5.88%) experienced moderate pain on the fifth day. On the sixth and seventh day, only one patient (2.94%) reported moderate pain (Table 4).

Table 4. Percentages of patients reporting no pain, mild pain, moderate pain, and severe pain.

Days (VAS)	NaOCl				CHX			
	None N (%)	Mild N (%)	Moderate N (%)	Severe N (%)	None N (%)	Mild N (%)	Moderate N (%)	Severe N (%)
Day 1	23 (65.71)	9 (25.71)	2 (5.71)	1 (2.85)	17 (50.00)	8 (23.52)	4 (11.76)	5 (14.70)
Day 2	27 (77.14)	6 (17.14)	1 (2.85)	1 (2.85)	19 (55.88)	6 (17.64)	5 (14.70)	4 (11.76)
Day 3	29 (82.85)	3 (8.57)	1 (2.85)	2 (5.71)	21 (61.76)	8 (23.52)	2 (5.88)	3 (8.82)
Day 4	29 (82.85)	4 (11.42)	1 (2.85)	1 (2.85)	27 (79.41)	4 (11.76)	1 (2.94)	2 (5.88)
Day 5	30 (85.71)	3 (8.57)	2 (5.71)	0 (0.00)	28 (82.35)	4 (11.76)	2 (5.88)	0 (0.00)
Day 6	30 (85.71)	5 (14.28)	0 (0.00)	0 (0.00)	31 (91.17)	2 (5.88)	1 (2.94)	0 (0.00)
Day 7	32 (91.42)	3 (8.57)	0 (0.00)	0 (0.00)	32 (94.11)	1 (2.94)	1 (2.94)	0 (0.00)
Day 14	32 (91.42)	2 (5.71)	1 (2.85)	0 (0.00)	31 (91.17)	3 (8.82)	0 (0.00)	0 (0.00)
Day 30	34 (97.14)	1 (2.85)	0 (0.00)	0 (0.00)	32 (94.11)	2 (5.88)	0 (0.00)	0 (0.00)

NaOCl: Sodium Hypochlorite; CHX: Chlorhexidine.

Regarding the assessment of tenderness, on the first day, in the NaOCl group, two patients (5.71%) experienced severe pain. Two patients (5.71%) also experienced severe tenderness on the second day. On the third day, two patients (5.71%) reported severe pain, and one patient (2.85%) reported moderate pain. On the fourth day, two patients (5.71%) experienced severe pain. One patient (2.85%) experienced severe and moderate tenderness on the fifth day. On the sixth, seventh, fourteenth, and thirtieth day, no patient reported severe tenderness; however, one patient (2.85%) experienced moderate pain on the sixth, seventh, and thirtieth day, and two patients (5.71%) experienced moderate pain on the fourteenth day (Table 5).

In the CHX group, five patients (14.70%) experienced severe pain, and four (11.76%) experienced moderate tenderness on the first day. On the second day, three patients (8.82%) experienced severe pain, and seven patients (20.58%) experienced moderate pain. On the third day, only one patient (2.94%) experienced moderate pain, and three (8.82%) experienced severe pain. On the fourth day, one patient (2.94%) reported moderate pain, and two (5.88%) experienced severe pain. On the fifth, sixth, and seventh day, there were reports of moderate pain in three patients (8.82%), two (5.88%) patients, and one (2.94%) patient, respectively (Table 5).

Table 5. Percentage of patients reporting tenderness.

Days (VAS)	NaOCl				CHX			
	None N (%)	Mild N (%)	Moderate N (%)	Severe N (%)	None N (%)	Mild N (%)	Moderate N (%)	Severe N (%)
Day 1	22 (62.85)	11(31.42)	0 (0.00)	2 (5.71)	16 (47.05)	9 (26.47)	4 (11.76)	5 (14.70)
Day 2	26 (74.28)	7 (20.00)	0 (0.00)	2 (5.71)	17 (50.00)	7 (20.58)	7 (20.58)	3 (8.82)
Day 3	27 (77.14)	5 (14.28)	1 (2.85)	2 (5.71)	19 (55.88)	11 (32.35)	1 (2.94)	3 (8.82)
Day 4	30 (85.71)	3 (8.57)	0 (0.00)	2 (5.71)	26 (76.47)	5 (14.70)	1 (2.94)	2 (5.88)
Day 5	30 (85.71)	3 (8.57)	1 (2.85)	1 (2.85)	27 (79.41)	4 (11.76)	3 (8.82)	0 (0.00)
Day 6	30 (85.71)	4 (11.42)	1 (2.85)	0 (0.00)	31 (91.17)	1 (2.94)	2 (5.88)	0 (0.00)
Day 7	32 (91.42)	2 (5.71)	1 (2.85)	0 (0.00)	30 (88.23)	3 (8.82)	1 (2.94)	0 (0.00)
Day 14	32 (91.42)	1 (2.85)	2 (5.71)	0 (0.00)	30 (88.23)	4 (11.76)	0 (0.00)	0 (0.00)
Day 30	33 (94.28)	1 (2.85)	1 (2.85)	0 (0.00)	32 (94.11)	2 (5.88)	0 (0.00)	0 (0.00)

NaOCl: Sodium Hypochlorite; CHX: Chlorhexidine.

Figures 2 and 3 show each group's performance in relation to the VAS. CHX group reported more significant postoperative pain throughout the evaluation period, except on the fourteenth day (NaOCl group: 0.25 and CHX group: 0.17). Regarding tenderness, the CHX group had the highest values, except on days 6 (NaOCl group: 0.34 and CHX group: 0.29), 14 (NaOCl group: 0.37 and CHX group: 0.26), and 30 (NaOCl group: 0.20 and CHX group: 0.08).

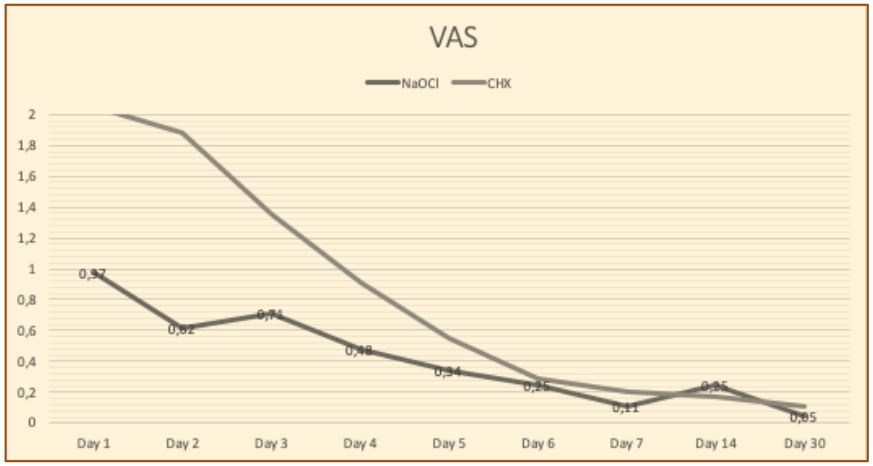

Figure 2. Performance of groups, control, and case in relation to VAS in terms of postoperative pain.

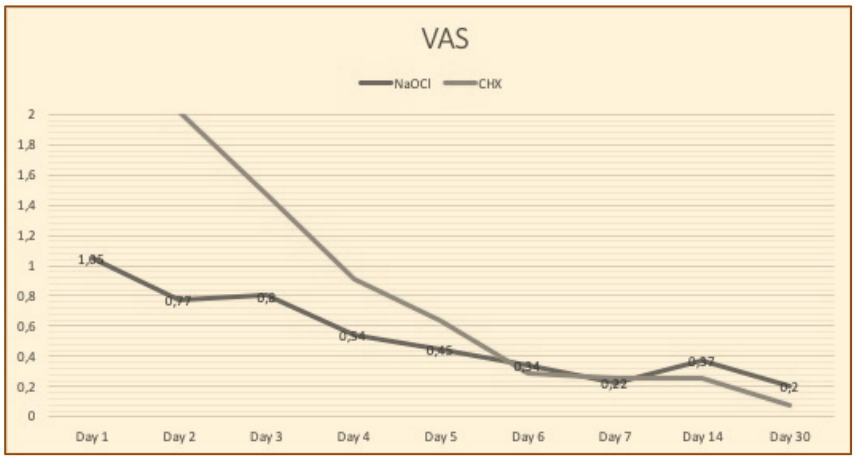

Figure 3. Performance of groups, control, and case in relation to VAS in terms of tenderness.

In both groups, three (8.60%) patients presented edema after endodontic treatment. There were no statistically significant differences in the evaluated periods (p=1.00). Concerning medication use in the postoperative period, seven (20.0%) patients in the NaOCl group and eight (22.9%) in the CHX group used ibuprofen. There were no statistically significant differences between groups (p=0.77).

Discussion

Minimizing postoperative pain after endodontic treatment is still a challenge for dentists and has been reported with concern in the literature since the late 1880s [17]. Several factors can cause pain after endodontic therapy. These include failure in chemical-mechanical preparation, necrotic and vital pulp remains, and the presence of microorganisms and toxins in the root canal system [18,19]. Chemical factors such as the extrusion of irrigating solutions, intracanal medication, and filling material (gutta-percha) can also trigger pain [20]. All

patients selected for participation in this study were diagnosed with pulp necrosis and the presence of apical periodontitis with no painful symptoms; preoperative pain is one of the predictors of postoperative pain [21].

Modern endodontics provides evidence, through prospective and randomized clinical studies, of the reliability of single-session endodontic therapy [23-25], although some authors have demonstrated that factors such as the extrusion of irrigating solutions cause inflammation in the periradicular tissues, triggering postoperative pain in teeth with apical periodontitis [3,26-28]. Opinions differ among authors regarding the best irrigation solution and the ideal disinfection protocol that causes the least possible harm to periapical tissues [3,29-31]. Therefore, in this study, we compared sodium hypochlorite (NaOCl) at 2.5% and chlorhexidine (CHX) gel at 2% concerning postoperative pain, tenderness, occurrence of edema, and postoperative use of medication after endodontic treatment with foraminal enlargement.

Disinfection of the root canal system should follow protocols in which the antibacterial irrigating solution plays an important role [32]. From a microbiological point of view, NaOCl and CHX can be used to treat teeth with infected root canals [13]. NaOCl is the most used irrigant in endodontics because it is an excellent solvent for organic matter; it has broad antimicrobial activity, fast-acting, and low cost [33]. On the other hand, its disadvantages include its high toxicity and corrosive effect on metals. The mechanism by which NaOCl destroys bacteria is unclear; however, it may involve a combination of factors that include attacking cell membrane lipids, resulting in the loss of intracellular content, inhibiting protein synthesis, oxidation of bacterial protein amino acids, and breaking down DNA in addition to chlorination of the amino acid ring [33,34]. Some essential characteristics of CHX include its broad antimicrobial spectrum, substantivity, and low cytotoxicity [35]. Its primary disadvantage is its inability to dissolve organic matter [30].

To our knowledge, studies on postoperative symptoms during foraminal instrumentation associated with irrigation solutions are scarce. In the present study, there was a statistically significant difference ($p < 0.05$) between the NaOCl and CHX groups regarding postoperative pain and tenderness on the 2nd day. In addition, on the 1st and 3rd day, the values were borderline, reinforcing the existence of an association. Contradictory results were found in the study by da Silva et al. [10], in which they did not report a statistically significant difference between the groups. This disagreement may have occurred due to the difference in the concentration of NaOCL used (5.25%). In the present study, the CHX group showed a more significant change in pain 48 hours after the endodontic treatment, which may be related to the substantivity characteristic of the solution. Substantivity is the ability of CHX to absorb negatively charged surfaces in the mouth (such as teeth and mucous membranes), resulting in CHX being slowly dispensed from these retention sites, allowing antimicrobial activity to continue for several hours [3]. Moreover, previous studies observed that the use of CHX as an irrigating solution for the root canal system inhibited microbial activity for 48 hours [36], seven days (in liquid and gel forms) [37], four weeks [38], and for up to 12 weeks [39]. Another issue that may be associated with more significant postoperative pain response in the CHX group is the fact that the gel, which is more viscous than NaOCl, does not find the same facility to return in counter flow through the space between the reciprocating file and the canal wall, eventually being pushed in greater volume towards the apex, generating overflow of this material and allowing it to continue acting in the periradicular tissues, triggering the painful symptoms.

In the present study, a few patients had edema and needed medication, confirming the correct application of the eligibility criteria when selecting participants. In addition, they were only medicated when requested, reducing erroneous estimates in this study, as medication could affect the intensity of the scores reported on the VAS. However, the results showed no difference between the groups, stating that this factor did not influence this assessment.

Our conclusions must be interpreted cautiously since this study's limitations include the subjective analysis of the pain scale and edema. The pain threshold of each individual is variable and subjective. In this study, postoperative pain and tenderness were measured using the VAS, a method widely used because it is appropriate for assessing pain intensity and is easily accepted by patients despite being an instrument that fails to determine the origin of pain [40]. Edema was evaluated through photographs of the participants during the established periods. However, to minimize subjectivity, this assessment was carried out by two independent researchers who did not participate in the procedures, using the criteria recommended by Morse et al. [16].

Given the scarcity of clinical studies investigating the influence of auxiliary chemicals on postoperative symptoms related to endodontic treatment with foraminal enlargement, further randomized clinical studies are needed to identify the most appropriate clinical protocol for managing postoperative pain based on the instrumentation technique employed. In addition, future prospective clinical trials that investigate the correlation between postoperative pain/tenderness and necrotic and vital pulp remains in the presence of microorganisms, and their toxins and different preparation and filling techniques or filling materials are necessary.

Conclusion

Chlorhexidine group had the worst results in terms of postoperative pain and tenderness. There was no significant difference between the groups in terms of postoperative edema and use of medication.

Authors' Contributions

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EABS	https://orcid.org/0000-0003-1308-7048	Conceptualization, Methodology, and Writing - Review and Editing.
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All authors declare that they contributed to a critical review of intellectual content and approval of the final version to be published.

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Conflict of Interest

The authors declare no conflicts of interest.

Data Availability

The data used to support the findings of this study can be made available upon request to the corresponding author.

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