Brazilian Dental Journal (2015) 26(3): 216-221
http://dx.doi.org/10.1590/0103-6440201300311
ISSN 0103-6440

Postoperative Pain after Foraminal Instrumentation with a Reciprocating System and Different Irrigating Solutions

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The aim of the present study was to evaluate and compare postoperative pain after foraminal instrumentation using 5.25% sodium hypochlorite (NaOCl) or 2% chlorhexidine (CHX) gel irrigation protocol in nonvital single-rooted teeth after reciprocating instrumentation. Sixty-two volunteers presenting a single root canal diagnosed with asymptomatic necrosis and apical periodontitis were randomized into 2 experimental groups regarding the irrigation protocol (ie, 5.25% NaOCl and 2% CHX gel groups). Endodontic treatment was performed in a single session under reciprocating instrumentation with foraminal instrumentation. Volunteers were instructed to record pain intensity. Scores from 1 to 4 were attributed to each kind of pain after 24, 48, and 72 h. Kolmogorov-Smirnov and Student´s t tests were used to determine significant differences at $p<0.05$. On average, the percentage of patients that had no or mild pain after 24, 48 or 72 h was 77.4%, 88.7% and 95.1%, respectively. No statistically significant age difference was found between the groups ($p>0.05$, Student´s t test). Postoperative pain showed no statistically significant difference at any observation period when using 5.25% NaOCl or 2% CHX gel ($p>0.05$). Moreover, no significant difference was observed in the mean number of analgesic tablets used between the groups ($p>0.05$). In conclusion, the use of 5.25% NaOCl or 2% CHX gel resulted in the same postoperative pain. Therefore, it can be inferred that irrigant choice has no relation with short-term follow up regarding postoperative pain.

Key Words: irrigants, Reciproc, foraminal instrumentation, postoperative pain.

Introduction

One of the primary aims of endodontic therapy is to reduce the microbial population in the root canals of infected teeth. This is usually accomplished by mechanical preparation along with the use of irrigating solutions. Although many substances have been suggested for root canal irrigation, sodium hypochlorite (NaOCl) remains the most widely used, because of its pronounced antimicrobial activity and the ability to dissolve organic matter (1). However, NaOCl may be cytotoxic to periradicular tissues, particularly at high concentrations (1). A recent retrospective study showed that 42% diplomates of the American Board of Endodontics reported having at least one NaOCl accident in their practice career (2). For this reason, postoperative pain is a major concern when highly concentrated NaOCl solutions are used in nonvital teeth because of the extravasation risk of the irrigant into these tissues.

Chlorhexidine (CHX) has been proposed as a potential substitute for NaOCl given its optimum antimicrobial action, high substantivity and low toxicity (3-5) which might reduce postoperative pain during endodontic treatment.

The apical limit of root canal instrumentation is another controversial topic in root canal therapy. There is some evidence that cleaning, debridement and enlargement of the apical foramen during root canal instrumentation allow a greater reduction of intracanal bacteria load and less hard tissue debris. This maneuver may overcome the limitations of irrigation in the apical area, optimizing root canal disinfection (6,7). A recent study suggested that foraminal instrumentation should be performed for the sake of endodontic treatment predictability without considerably increasing postoperative pain (8). However, up to now, no clinical study has shown whether different irrigants during foraminal instrumentation procedures provide more favorable results in terms of postoperative pain.

The purpose of the present study was to evaluate and compare the postoperative pain after foraminal instrumentation using 5.25% NaOCl or 2% CHX gel irrigation protocol in nonvital single rooted teeth. The tested null hypothesis was that there is no difference in postoperative pain reported by the patients using 5.25% NaOCl or 2% CHX gel as irrigating solution during

instrumentation procedures.

Material and Methods

After Ethics Committee approval (protocol number 024/2013), all volunteers invited to participate in this parallel clinical trial were informed of the procedures protocols, risks and benefits, and their right to self-determination regarding participation. A written consent was signed and a copy was delivered to all volunteers.

Patient Selection

Approximately 460 patients attended endodontic practice during recruitment, which lasted one year. Among these patients, 62 were selected to take part in this clinical trial. Inclusion criteria were defined as follows: healthy (ASA I) adults over 18 years of age (n=62) participated in this prospective and randomized clinical trial. None of the patients enrolled in this clinical trial was taking any medication that could alter his/her perception of pain (analgesics or non-steroidal anti-inflammatory drugs - NSAIDs). They presented single canal teeth diagnosed with asymptomatic necrosis confirmed by a negative response to heat, cold, percussion and palpation tests, clear radiographic observation of a single canal without any sign of pulp obliteration or calcifications from the pulp chamber to the apex, and evidence of apical periodontitis (8). The heat test was performed using a pre-heated gutta-percha cone placed on the middle third of the buccal surface of the teeth and the cold test was performed with the aid of a cold spray (Endo-Frost; Coltène-Whaledent, Langenau, Germany) placed on a cotton pellet and immediately applied on the middle third of the buccal surface of the candidate tooth. If no response was seen after 10 s, the test result was considered negative.

Exclusion criteria included other diagnoses such as deep periodontal pockets, persistent exudate, or if there was failure to achieve apical patency. Immunosuppressed, immunocompromised or pregnant patients were also excluded.

The patients were randomly assigned to one of the groups by means of a restricted adaptive randomization procedure. In one group, 5.25% NaOCl (B´Herzog; Rio de Janeiro, RJ, Brazil) was used as the irrigant solution during treatment, while for the other group, 2% CHX gel (EndoGel; Essencial Pharma, Itapetininga, SP, Brazil) and 0.9% saline solution were used. CHX gel consisted of a gel base (1% natrosol) and CHX at pH 7.0.

Treatment Protocol

After local infiltration with 3.6 mL of 2% lidocaine with 1:100,000 epinephrine anesthetic solution (Alphacaine; DFL Indústria e Comércio Ltda, Rio de Janeiro, RJ, Brazil), a rubber dam was placed, and the access cavity was prepared using sterile carbide burs. If the patient recorded any pain sensation during the procedure, a supplemental local infiltration with 1.8 mL of 2% lidocaine with 1:100,000 epinephrine was administered.

First, an initial exploration of the root canal was performed with size 10, 15 and 20 K-files (VDW, Munich, Germany), under constant irrigation, to establish the apparent root canal length. Only cases where a 30 K-file did not go passively to the working length were selected. These cases were classified as medium and R40 was recommended, according to the manufacturer's protocol. Then, a R40 Reciproc instrument (VDW) was advanced in the root canal until reaching 2/3 of the radiographic estimated working length (WL), and then, moved in a slow and gentle in-and-out pecking motion with 3 mm amplitude limit. After three complete pecking movements, the instrument was removed from the canal and its flutes were cleaned by insertion into a spoon-box. At this point, the root canal was irrigated as described below. The WL was confirmed by an electronic apex locator (Novapex; Forum Technologies, Rishon Le-Zion, Israel). For both groups, the WL was established at the "0.0" reading of the electronic apex locator. Root canal preparation with R40 instrument was then completed reaching the full WL, using the same kinematics described above.

In the NaOCl group, each insertion of the R40 instrument was followed by canal irrigation with 3 mL of a 5.25% NaOCl solution. The smear layer was then removed with 3 mL of 17% EDTA for 3 min and the canals were irrigated again with 3 mL of 5.25% NaOCl.

In the CHX group, the root canals were flooded with the 2% CHX gel before each insertion of the R40 instrument and afterwards rinsed with 3 mL of 0.9% saline solution. The smear layer was then removed with 3 mL of 17% EDTA for 3 min, and the canals were irrigated again with 3 mL of saline solution.

In both groups, the irrigation solutions were kept in and dispensed using a 30-G Max-i-Probe needle (Dentsply Maillefer, Ballaigues, Switzerland) up to 3 mm short of the WL, verified by rubber stops.

All teeth received the same volume of irrigants. After instrumentation, the root canals were dried with absorbent paper points (Denstply Maillefer) and filled with gutta-percha (Odous; Odous De Deus Ltda, Belo Horizonte, MG, Brazil) and AH Plus sealer (Dentsply De Trey, Konstanz, Germany) using warm vertical compaction with the continuous-wave technique (Touch'n Heat; SybronEndo) and gutta-percha backfill. After endodontic treatment, all patients received postoperative instructions for taking analgesics (400 mg ibuprofen) in case they experienced pain (8).

Analysis of Postoperative Pain and Statistical Analysis

Assessment of postoperative pain was conducted for 3 days after the initial session. Pain was recorded as absent, slight, moderate or severe, and scores from 1 to 4 were attributed to each classification of pain (8): no pain (1), the patient feels well; slight pain (2), if the patient is distracted, he/she does not feel the pain and no analgesic is required; moderate pain (3), the patient feels moderate pain even while concentrating on some other activity and analgesic is required; and severe pain (4), the patient is no longer able to perform any type of activity, needs to lie down and seek dentist help (analgesics had little or no effect in relieving the pain). The number of analgesic tablets used was also recorded.

The findings were recorded for statistical evaluation using SPSS software version 19.0 (SPSS Inc, Chicago, IL, USA). Chi-Square test, Kolmogorov-Smirnov and Student's t tests were used to determine significant differences assuming α=5%.

Results

A total of 62 volunteers (23 men and 39 women) were enrolled in this study (Fig. 1). Chi-square test showed the homogeneity between groups in the proportion of male and female patients ($p>0.05$). The mean age (mean±standard deviation) of the patients were 43.9±12.2 years in the NaOCl group and 41.8±13.5 years in the CHX group. No statistically significant differences in age between the 2 groups were found ($p>0.05$, Student's t test), as seen in Table 1. Regarding postoperative pain, no statistically significant differences were seen between the groups at any observation period ($p>0.05$, Table 2). In addition, no significant difference among the groups was observed in the mean number of used analgesic tablets ($p>0.05$, Table 3). The percentage of subjects reporting no or mild pain after 24 h for the NaOCl and CHX groups was 74.1% and 80.6%, respectively (Fig. 2). After 48 h, 87.1% of the NaOCl group and 90.3% of the CHX group reported no or mild

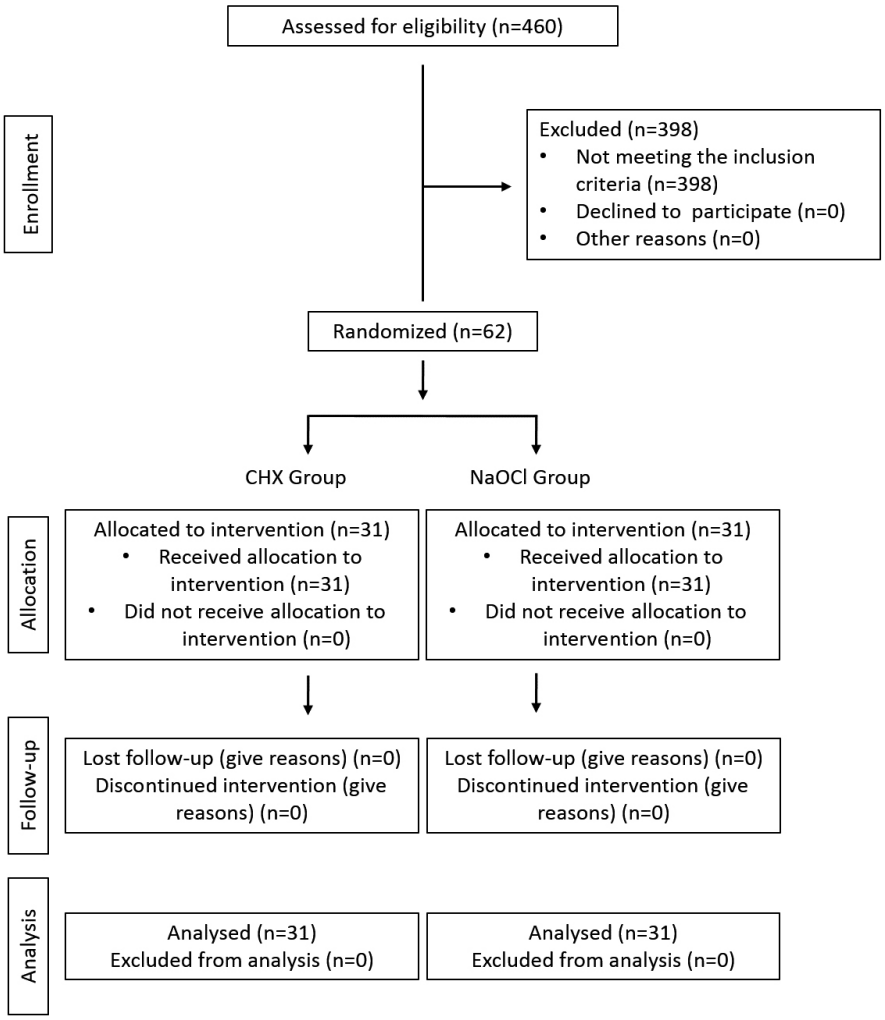

Figure 1. Consort flow diagram.

pain. After 72 h, moderate pain was observed in only 3.2% of the NaOCl group and 6.4% of the CHX group. Only one patient in the NaOCl group reported severe pain after 24 h.

Discussion

Discomfort after endodontic treatment is usually ascribed to a tissue response caused by one or more factors, including failure at the cleaning and shaping stages, extrusion of infected debris and damage to the periradicular tissue when foraminal enlargement is performed (9). Over-instrumentation may be a mechanical cause, whereas chemical factors include extrusion of intracanal dressings, filling materials or irrigants (10). Irrigation is a necessary and important step throughout all root canal system preparation, but it may lead to extrusion of irrigating solutions whether manual or rotary instruments are used (11). Therefore, it is logical to assume that the use of a nontoxic and biocompatible substance is required to avoid or diminish postoperative discomfort. The most used auxiliary chemical substances in endodontic therapy are NaOCl and CHX at different concentrations.

In the present study, the volunteers were randomized into 2 experimental groups. In one group, foraminal instrumentation was performed using NaOCl as the irrigant while in the other group a combination of CHX and saline solution was used during foraminal instrumentation. As no statistically significant difference was observed between the groups ($p<0.05$), it can be suggested that the irrigating solutions used in the present study had little or no influence on postoperative pain during foraminal instrumentation. Therefore, both solutions can be applied to promote better disinfection during endodontic instrumentation, resulting in more treatment predictability concerning short-term follow up regarding postoperative pain.

Regarding the different irrigating solutions used in the present study, a recent clinical trial showed no significant differences in postoperative pain when endodontic treatment was performed without foraminal instrumentation in patients with chronic apical periodontitis using 5.25% NaOCl or 2% CHX gel with saline solution (12). In addition, another randomized clinical study comparing 5.25% NaOCl and 2% CHX showed statistically significant difference in postoperative pain only at the 6-h time-point, where pain was more intense in the NaOCl group. No statistically significant difference was observed in any other tested time-point (13). In both studies, however, no foraminal instrumentation was performed. To the best of the authors' knowledge, there was no available data on postoperative pain during foraminal instrumentation comparing different irrigating solutions.

Besides the fact that both irrigants apparently decrease bacterial population, a sterile instrumented root canal is far away from reality. Both NaOCl and CHX irrigants are supported by literature to be safely used during root canal treatment (3-5,12,13). However, it is important to notice that these successful outcomes in the literature are no indicators of long-term success, but in fact, only predictors of postoperative procedures. This fact had been recently demonstrated in a systematic review of endodontic irrigants (14). The conclusions of this review showed that there is still insufficient reliable evidence showing the superiority of NaOCl or CHX. Also, the strength and reliability of the supporting evidence was variable, suggesting that future

Table 1. Demographic features

	NaOCl (n=31)	CHX (n=31)
Age (years)	43.9±12.2	41.8±13.5
Sex	10 men and 21 women	13 men and 18 women

p>0.05 - Student's t test.

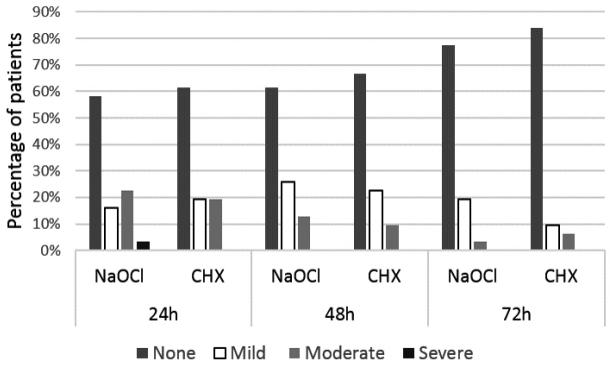

Figure 2. Percentage of subjects in the NaOCl and CHX groups with no, mild, moderate and severe postoperative pain at each time point.

Table 2. Mean and standard deviation of pain scores in the NaOCl and CHX groups at different time points

Group	24 h	48 h	72 h
NaOCl	1.70±0.93	1.51±0.72	1.25±0.51
CHX	1.58±0.80	1.41±0.67	1.25±0.56

p>0.05 - Student's t test.

Table 3. Mean and standard deviation of number of analgesic tablets used in the NaOCl and CHX groups at different time points

Group	24 h	48 h	72 h
NaOCl	0.52±0.97	0.32±0.83	0.19±0.32
CHX	0.47±0.91	0.35±0.79	0.14±0.29

p>0.05 - Student's t test.

trials should report both clinician-relevant and patient-preferred outcomes at clearly defined preoperative as well as long-term time points.

Reciproc instruments were used in the present study to perform foraminal instrumentation. It is known that the reciprocating movement somehow mimics manual movement (15) and, to some extent, recent studies showed that it outperformed conventional continuous rotary nickel-titanium preparation (16,17). However, some concerns regarding the possibility of higher number of postoperative pain cases have been raised. In two recent studies, single-file reciprocating system was associated with higher postoperative pain when compared to full-sequence rotary (18,19). This higher incidence of postoperative pain could be related to a higher apical extrusion of bacteria, dentin chips, irrigants and inflamed or necrotic pulp tissue, which may elicit postoperative pain. Previous studies concluded that full-sequence rotary instrumentation was related to less debris extrusion than reciprocating single-file systems (20,21). However, this fact does not represent a consensus in the recent specific literature. In a recent study, reciprocating single-file systems extruded fewer bacteria apically than a conventional multi-file rotary system (22). Moreover, other studies showed no differences between rotary and reciprocating movements regarding debris extrusion (23,24).

In fact, the low pain rates observed in the present study may be explained by the taken high trans-operatory care. Reciproc instruments were used in a slow in-and-out pecking motion associated to careful canal disinfection and file cleaning after each three movements to prevent dentin chips accumulation. Furthermore, a specific irrigation protocol was performed, reducing even more the possibility of debris accumulation and extrusion using a Max-i-Probe needle, which avoids the positive pressure directly to the apex (25).

In this study, use of 5.25% NaOCl or 2% CHX gel resulted in similar levels of postoperative pain. Therefore, it may be concluded that both irrigants are acceptable regarding short-term postoperative pain during root canal instrumentation with foraminal instrumentation.

Resumo

O objetivo do presente estudo foi avaliar e comparar a dor pós-operatória após a instrumentação foraminal usando NaOCl 5,25% ou gel de CHX 2% em dentes não vitais unirradiculares após instrumentação reciprocante. Sessenta e dois voluntários, apresentando um único canal radicular diagnosticado com necrose assintomática e periodontite apical, foram randomizados em dois grupos experimentais de acordo com o protocolo de irrigação (ou seja, grupos de NaOCl 5,25% e CHX gel 2%). O tratamento endodôntico foi realizado em uma única visita sob instrumentação reciprocante com instrumentação foraminal. Os voluntários foram instruídos a registrar a intensidade da dor. Escores de 1-4 foram atribuídos a cada tipo de dor após 24, 48 e 72 h. Testes de Kolmogorov-Smirnov e t de Student foram utilizados para determinar diferenças significativas em p<0,05. Em média, o percentual de pacientes que teve nenhumaou leve dor após 24, 48 ou 72 h foi de 77.4%, 88.7% e 95.1%, respectivamente. Não foi encontrada diferença de idade estatisticamente significante entre os grupos (p>0,05, teste t de Student). A dor pós-operatória não apresentou diferença estatisticamente significativa em qualquer período de observação ao usar NaOCl 5,25% ou CHX gel 2% (p>0,05). Além disso, não foi observada diferença significativa no número médio de comprimidos analgésicos utilizados entre os grupos (p>0,05). O uso de NaOCl 5,25% ou CHX gel 2% resultou na mesma dor pós-operatória. Portanto, pode-se inferir que a escolha do irrigante não tem relação com um acompanhamento a curto prazo em relação a dor pós-operatória.

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Received October 31, 2014
Accepted January 5, 2015