Postoperative Pain after Using 1.3% and 5.25% Sodium Hypochlorite Irrigating Solutions: A Randomized Controlled trial- part VI

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By:
Abdelaziz Abdelshakour Alfarra
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Faculty of Oral and Dental Medicine
Cairo University

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SUPERVISORS

Prof. Dr. Randa Elboghdady
Professor of endodontics
Faculty of Oral and Dental Medicine
Cairo University

Dr. Karim Galal Abd ElKader
Lecturer of Endodontics
Faculty of Oral and Dental Medicine
Cairo University
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DEDICATION

To my leader and endless love my dear father

Dr. Abdel Shakour Al-farra

Ph.D. in accounting and finance

Who is always encouraging and pushing me along the way of learning and the way of success.

To my reason of life to my soul my mother

With her sacrifice and all beautiful things in my life

To my sister

Dr. Nada Al-farra

Who offered me absolute love and help

To my brothers

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Who loved me and supported me throughout life and the course of this thesis.
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Introduction
Introduction

Postoperative pain is defined as a pain of any degree that occurs after initiation of root canal treatment. Postoperative pain is an unwanted yet unfortunately common sensation after Endodontic treatment. The incidence of postoperative pain was reported to range from 3% to 58%. It is common after few hours or days after endodontic treatment. The development of postoperative pain after root canal treatment is usually due to acute inflammatory response in the periradicular tissue.

Tooth pain causes suffering and reduces functioning. Pain is often the motivation for an individual seeking dental care. It was suggested that improved preoperative pain control can result in reduction of postoperative pain.

Development of inter-appointment pain during root canal treatment may undermine patient's confidence in their dentist. The etiologic factors in pain manifestation have not been determined precisely; however, several hypothetical mechanical, chemical and/or microbial injuries to the pulp or the periradical tissue might be involved. From the chemical causes is the irrigating solution.

The most widely used irrigant in root canal treatment is sodium hypochlorite which is used in endodontic field due to its board-spectrum antimicrobial activity against endodontic microorganisms and biofilms. Also it possesses a tissue dissolving action. The major disadvantages of sodium hypochlorite are its significant toxicity when injected into periradicular tissue, disagreeable smell and taste, corrosion of metal objects. In addition, sodium hypochlorite does not completely eradicate all bacterial species.
During endodontic therapy sodium hypochlorite solution is used at concentration ranging from 0.5% to 6, but the optimal clinical concentration of NaOCl is still controversial.

Evidence demonstrates that high concentrations of NaOCl have enhanced antimicrobial activity. However, NaOCl is tissue cytotoxic. When it comes in contact with the tissues, it causes hemolysis and ulceration, inhibits neutrophil migration, and damages endothelial and fibroblast cells, also increased cytotoxicity leads to increased postoperative pain.

Few data in literature is available about the effect of different sodium hypochlorite concentrations on incidence of postoperative pain which might need further investigations.
Review of Literature
I. Postoperative Pain (Post instrumentation)

The occurrence of postoperative pain of mild intensity is not a rare event even when endodontic treatment has followed acceptable standards. For the most part, mild pain after chemico mechanical preparation can develop in about 10–30% of the cases (1–3), in most instances the patient can bear the discomfort or can make use of common analgesics, which are usually effective in relieving the symptoms. On the other hand, the development of interappointment pain of moderate to severe intensity with accompanied swelling has been demonstrated to be an unusual occurrence.

Nekoofar et al (2003) (4) compared the pain reducing effect of oral preparations of meloxicam, piroxicam, and placebo in endodontic emergency patients. A total of fifty patients were asked to evaluate their pretreatment pain with a visual-analog scale. After root canal therapy they were randomly assigned to one of three groups: meloxicam, piroxicam, or placebo. Each patient was sent home with a visual-analog scale to fill out at 8 and 24 h after completion of therapy. The results of this study showed no significant difference between efficacy of meloxicam, piroxicam, and placebo, but a significant effect of the time factor in reducing postoperative pain in all treatment groups was observed.

Torabinejad et al (2005) (5) compared levels of postoperative discomfort after cleaning and shaping of root canals using two protocols for removal of smear layer. Seventy-three consecutive patients requiring root canal treatment were included. At random, canals were cleaned and shaped with one of the following protocols. In group 1, 5.25% sodium
hypochlorite was used as the root canal irrigant. The smear layer was removed by placing 17% EDTA in the canal for 1 min followed by a 5-ml rinse with 5.25% NaOCl. In group 2, canals were irrigated with 1.3% NaOCl; the smear layer was removed by placing MTAD in the canals for 5 min. They found that patients recorded degree of discomfort at various time intervals after cleaning and shaping on a visual analogue scale for 1 week. No significant statistical difference was found in the degree of discomfort between the two groups.

Attar et al (2008) (6) compared single-dose ibuprofen pretreatment for postoperative endodontic pain. Thirty-nine patients were randomly assigned to 3 groups: placebo, ibuprofen tablets, or ibuprofen liquigels. Patients recorded their pain levels before and at the end of treatment, then every 6 hours for 24 hours after administration of the medications and standard endodontic treatment. Pain evaluations were done by using 3 pain scales. No significant differences in postoperative pain levels were found between either single-dose ibuprofen formulation or the placebo control group. This study suggests that single-dose pretreatment analgesia alone in endodontic pain patients will not significantly reduce postoperative pain below the reduction in pain from endodontic treatment.

Arias et al (2009) (7) compared the incidence, degree, and length of postoperative pain in three hundred endodontically treated teeth, with and without apical patency, in relation to some diagnostic factors (vitality, presence of preoperative pain and mandible of treated tooth) of the questionnaires received back, apical patency was maintained during shaping procedures with #10 K-file in one group and not in the other. There was significantly less post endodontic pain when apical patency was maintained in non vital teeth. If pain appeared, its duration was
longer when apical patency was maintained in teeth with previous pain or located in the mandible. Maintenance of apical patency does not increase the incidence, degree, or duration of postoperative pain when considering all variables together.

ElMubarak et al (2010) (8) evaluated postoperative pain after root canal treatment. Two hundred and thirty-four patients were conventionally endodontically treated in a single visit or multiple visits. The chemico mechanical preparation of root canals was done by a modified double-flared technique with combination of hand instruments. Postoperative pain was recorded by each patient by using visual analogue scale in well-defined categories at 2 time intervals, twelve hours and twenty four hours. There was no significant difference in postoperative pain between single-visit and multiple-visit root canal treatment.

Gondim et al (2010) (9) compared the postoperative level of pain after root canal therapy, using either endodontic needle irrigation or a negative apical pressure device. One hundred and ten asymptomatic single-rooted anterior and premolar teeth were treated endodontically with two different irrigation techniques. The first group used an endodontic irrigating syringe and the second group used an irrigation device based on negative apical pressure. Postoperatively, the patients were prescribed ibuprofen 200 mg to take every 8 hours, if required. Pain levels were assessed by an analog scale questionnaire after 4, 24, and 48 hours, during the 0 to 4; 4 to 24 and 24 to 48 hour intervals after treatment, the pain experience with the negative apical pressure device was significantly lower than when using the needle irrigation. The outcome of this investigation indicated that the use of a negative apical pressure irrigation device can result in a significant reduction of postoperative pain levels in comparison to conventional needle irrigation.
Nixdorf et al (2010) \(^{(10)}\) evaluated the frequency of nonodontogenic pain in patients who had undergone endodontic procedures; nonsurgical root canal treatment, retreatment, and surgical root canal treatment. Seven hundred and seventy articles retrieved and reviewed were searched in four databases electronically, complemented by hand searching. A summary estimate of nonodontogenic tooth pain frequency was derived using random-effects meta-analysis. Nonodontogenic pain is not an uncommon outcome after root canal therapy and may represent half of all cases of persistent tooth pain. These findings have implications for the diagnosis and treatment of painful teeth that were previously root canal treated because therapy directed at the tooth in question would not be expected to resolve nonodontogenic pain.

Nixdorf et al (2010) \(^{(11)}\) evaluated the frequency of persistent pain, regardless of etiology, after endodontic treatment. Persistent tooth pain was defined as pain present 6 months after endodontic treatment. Included in the review were pulpectomy, nonsurgical root canal treatment, surgical root canal treatment and retreatment. Of seven hundred and seventy articles retrieved and reviewed, twenty six met inclusion criteria. A total of 5,777 teeth were enrolled, and 2,996 had follow-up information regarding pain status. They identified one hundred sixty eight teeth with pain and derived a frequency of 5.3% (95% confidence interval), 3.5%-7.2%, for persistent all-cause tooth pain. High and statistically significant heterogeneity among studies (80%) was present. In subgroup analysis, prospective studies had a higher pain frequency (7.6%) than retrospective studies did (0.9%). Quality of study reporting was identified as the most influential reason for study heterogeneity. The frequency of all-cause persistent tooth pain after endodontic procedures was estimated to be 5.3%, with higher report quality studies suggesting >7%.
Wang and Hume (2010) (12) compared the incidence and intensity of postobturation pain after one- or two-visit root canal treatment (RCT) on anterior teeth with vital pulps and a single root and canal in a randomized controlled trial. One hundred patients requiring RCT were assigned randomly into two groups of fifty patients each. The canals of all teeth were prepared using engine driven rotary proTaper nickel−titanium instruments in a crown-down technique and irrigated with 2.5% NaOCl. The teeth in group 1 were filled with AH Plus sealer and gutta-percha, while those in group 2 medicated with a calcium hydroxide paste. A modified verbal descriptor scale was used to measure preoperative pain and post-obturation pain at 6, 24, 48 h and 1 week after operation. They found, that patients in both groups reported no pain or only slight pain within each post-obturation interval, only one in group 1 and one in group 2 had flare-ups and slight swelling. There was no statistically significant difference in the incidence and intensity of post-obturation pain experienced by the two groups. The incidence and intensity of postobturation pain experience following one- or two-visit RCT on teeth with vital pulps and a single canal were not significantly different.

Jaclyn et al (2011) (13) evaluated the influence of root canal treatment on pain prevalence and severity and estimated the prevalence and severity of pretreatment, treatment, and post treatment pain in patients receiving root canal treatment. Defined searching of MEDLINE, Embase, Cochrane, and PsycINFO databases identified 5,517 articles including seventy two studies for meta-analysis. They found a L’Abbe plots were used to evaluate pain prevalence and severity. L’Abbe plots revealed that pain prevalence and severity decreased substantially after treatment. Mean pretreatment, 24-hour post treatment, and 1-week post treatment pain prevalence's with associated standard deviations were 81 (28%), 40 (24%), and 11 (14%), respectively. Pretreatment and post
treatment pain severities, on a 100-point scale, were 54 (24%), 24 (12%), and 5 (5%), respectively. Pretreatment root canal–associated pain severity was moderate, dropped substantially within 1 day of treatment, and continued to drop to minimal levels in 7 days.

Wells et al (2011) (14) compared ibuprofen versus ibuprofen/acetaminophen used for postoperative endodontic pain in symptomatic patients, with a pulpal diagnosis of necrosis and an associated periapical radiolucency. They were experiencing moderate to severe preoperative pain. Seventy-one adult patients presenting for emergency endodontic treatment with a symptomatic maxillary or mandibular tooth were included in the study. The patients were randomly divided into 2 groups then an emergency debridement of the tooth was completed with hand and rotary instrumentation. At the end of the appointment, the patients randomly received capsules of either 600 mg ibuprofen or 600 mg ibuprofen combined with 1000 mg acetaminophen. Patients also received a 6-day diary to be completed after anesthesia wore off and every morning for 5 days. Postoperative data were analyzed by randomization test and step-down Bonferroni method of Holm. There were decrease in pain levels and analgesic use over time for the ibuprofen and ibuprofen/acetaminophen groups. There was no statistically significant difference between the 2 groups for analgesic use or escape medication use.

Yingying et al (2011) (15) compared the healing rate and post-obturation pain of single- versus multiple-visit root canal treatment for teeth with infected root canals. An exhaustive literature search combined with specified inclusion criteria was performed to identify randomized or quasi-randomized controlled trials (RCTs or quasi-RCTs), comparing root canal treatment in single and multiple appointments (2 or more
visits) in patients with infected root canals. No significant difference was observed in the healing rate between single- versus multiple-visit root canal treatment, as well as the incidence of medium-term post-obturation pain. As to the short-term follow up, the prevalence of post-obturation pain was significantly lower in single-visit than in multiple-visit group. They conclude on the basis of current studies, the healing rate of single- and multiple-visit root canal treatment is similar for infected teeth. Patients experience less frequency of short-term post-obturation pain after single-visit than those having multiple-visit root canal treatment.

Pasqualini et al (2012) evaluated the incidence of postoperative pain after glide path performed with Path File (PF) (DENTSPLY Maillefer, Ballaigues, Switzerland) versus stainless-steel K-file (KF). In one hundred and nine subjects, the mechanical glide path was performed with nickel-titanium (NiTi) rotary PF; in one hundred and sixty subjects, the manual glide path was performed with stainless-steel KF. Postoperative pain, analgesics consumption, and the number of days to complete pain resolution were evaluated in the following 7 days. The postoperative pain prevalence curves in PF group evidenced a more favorable trend in terms of time to pain resolution compared with the KF group. However the mean analgesics intake per subject was significantly higher in the KF group compared with the PF group. They conclude that the glide path with NiTi Rotary PF leads to less postoperative pain and faster symptom resolution.

II. Sodium hypochlorite Root Canal Irrigants:

The irrigant that satisfies most of the requirements for a root canal irrigant is sodium hypochlorite (NaOCl). It has the unique ability to dissolve necrotic tissue and the organic components of the smear layer. It also kills sessile endodontic pathogens organized in a biofilm.
There is no other root canal irrigant that can meet all these requirements, even with the use of methods such as lowering the pH increasing the temperature or adding surfactants to increase the wetting efficacy of the irrigant \(^{(22, 23)}\). However, although sodium hypochlorite appears to be the most desirable single endodontic irrigant, it cannot dissolve inorganic dentin particles and thus cannot prevent the formation of a smear layer during instrumentation \(^{(24)}\).

A. Antimicrobial activity of NaOCl:

Several \textit{in vitro} studies have been performed on the antibacterial activity of NaOCl. \textbf{Walker in 1936} \(^{(25)}\), introduced the use of double-strength chlorinated soda (5% NaOCl) solution as a root canal irrigant in endodontic practice, which has continued worldwide ever since with no study definitively showing any other irrigant to be more effective.

\textbf{Siqueira et al (1997)} \(^{(26)}\) evaluated the effectiveness of 4% NaOCl against Enterococcus faecalis \textit{in vitro} reporting that it was significantly more effective than saline solution (control group) in disinfecting the root canal.

In another study, \textbf{Siqueira et al (1998)} \(^{(27)}\) compared the antibacterial activity of several irrigants against four black-pigmented anaerobic bacteria and four facultative bacteria through an agar diffusion test. Their findings showed that the antibacterial effectiveness of 4% NaOCl and 2.5% NaOCl was significantly greater than other tested agents.

\textbf{Sen et al (1999)} \(^{(28)}\) evaluated the antifungal properties of 1% NaOCl, 5% NaOCl and 0.12% CHX against Candida albicans using cylindrical dentine tubes. They found C. albicans to be more resistant in the presence of smear layer. When smear layer was absent, NaOCl started to display antifungal activity after 30 minutes.
Waltimo et al (1999) evaluated the susceptibility of seven strains of *C. albicans* to four disinfectants: NaOCl, IKI, CHX acetate and calcium hydroxide. In addition, all possible pairs of the disinfectants were tested to compare the effect of the combination and its components. *C. albicans* cells were highly resistant to calcium hydroxide. NaOCl (5% and 0.5%) and iodine (2%) potassium iodide (4%) killed all yeast cells within 30s, whilst CHX acetate (0.5%) showed complete killing after 5min. Combinations of disinfectants were equally or less effective than the more effective component. All *C. albicans* strains tested showed similar susceptibility to the medicaments tested.

Gomes et al (2001) evaluated the effectiveness of five concentrations of NaOCl (0.5%, 1%, 2.5%, 4% and 5.25%) and two forms of chlorhexidine gluconate (CHX) (gel and liquid) in three concentrations (0.2%, 1% and 2%) in the elimination of *E. faecalis*. They found that all irrigants were effective in killing *E. faecalis*, but at different times. CHX in the liquid form at all concentrations tested (0.2%, 1% and 2%) and NaOCl (5.25%) were the most effective irrigants. However, the time required by 0.2% chlorhexidine liquid and 2% chlorhexidine gel to promote negative cultures was only 30s and 1min, respectively.

Spratt et al (2001) evaluated the effectiveness of NaOCl (2.25%), 0.2% CHX, 10% povidone iodine, 5ppm colloidal silver and phosphate buffered solution (PBS) (as a control) against monoculture biofilms of five root canal isolates including *P. intermedia*, *Peptostreptococcus miros*, *Streptococcus intermedius*, *F. nucleatum*, *E. faecalis*. Results showed that NaOCl was the most effective antimicrobial agent followed by the iodine solution.

Ferguson et al (2002) studied the in vitro susceptibility of *C. albicans* to various irrigants and medicaments. The minimum inhibitory