Postoperative Pain After the use of Sodium Hypochlorite gel and Solution Forms: A Randomized Clinical Study

Ertuğrul KARATAŞ, Damla ÖZSU KIRICI, Hakan ARSLAN

ABSTRACT

Objective: The present study aimed to compare the effect of sodium hypochlorite (NaOCl) gel and solution forms on postoperative pain level.

Methods: Fifty-two patients were divided into two groups according to the root canal irrigation solution. In the NaOCl solution group, the root canals were irrigated with 2 mL of 5.25% NaOCl between each pecking motion. In the NaOCl gel group, 5.25% NaOCl gel was used according to the manufacturer’s instructions. The root canal treatments were completed and the participants were given instructions to record postoperative pain levels on 24, 48, and 72 hours and 1 week after treatment using VAS.

Results: Intergroup analyses revealed that the NaOCl gel group resulted in significantly less postoperative pain than the NaOCl solution group on day 1.

Conclusion: It can be concluded that using NaOCl gel during root canal preparation results in less postoperative pain on day 1 when compared with the NaOCl solution.

Keywords: NaOCl gel, NaOCl solution, postoperative pain

HIGHLIGHTS

• This the first study comparing NaOCl gel and solution forms in terms of postoperative pain
• It has been revealed that NaOCl gel during root canal preparation results in less postoperative on day 1.
• This is the first study revealing the beneficial effect of NaOCl gel in lowering postoperative pain

INTRODUCTION

Irrigation of the root canals is an essential part of endodontic treatment because the complete elimination of microorganisms from the root canal system is impossible only with instrumentation (1). Sodium hypochlorite (NaOCl) is the most common irrigant used in endodontics because of its physicochemical and antibacterial properties (2), and its unique ability to dissolve necrotic tissue remnants (3). However, accidental injection of the solution into the periapical tissues can result in some serious complications such as; hemolysis, ulceration, allergic reaction and tissue necrosis (4). To avoid complications associated with extrusion of the solution, gel form of the NaOCl solution can be proposed. Previously, it has been reported that the gel and solution both did not interfere in the EDTA solution’s action (5). Additionally, Garcia et al. (6) have evaluated the effect of several forms of NaOCl on the microhardness of root canal dentin and reported that the NaOCl gel and solution forms have a similar effect on dentinal microhardness. Moreover, the antibacterial effectiveness of NaOCl gel and solution forms were compared and it has been reported that the antibacterial efficacy of the NaOCl gel and solution forms were similar (7). However, the tissue dissolution capacity of the NaOCl solution was higher than the gel form (7).

Another complication is postoperative pain that occurs when the solution extruded into the periapical tissues (8). Several strategies have been recommended to reduce postoperative pain include medication (9), intracanal cryotherapy (10), low-level laser therapy (11), occlusal reduction (12), and glide-path application (13). However, to date, the effect of using NaOCl gel for root canal disinfection during root canal preparation on postoperative pain has not been studied. Thus, the present study aimed to compare the effect of NaOCl gel and solution forms on postoperative pain.
level. The null hypothesis was that there would be no difference between the NaOCl gel and solution groups in terms of postoperative pain.

**MATERIALS AND METHODS**

The Ethical Committee of the Faculty of Dentistry, University of A approved the study protocol with a decision number of 2017-91. All the participants included in the study signed an informed consent form before undergoing the treatment. The sample size calculation, which was made by a program (GPower; Franz Faul, University of Kiel, Germany) according to the data obtained from a previous study (11), indicated that 18 patients were sufficient for per group with an error of alpha=0.05, effect size of 0.84 and power of 0.8. However, considering the possible loss of the participants and to increase the statistical power, 30 patients for each group were included. Randomisation of the participants was performed by using a web program (www.randomizer.org) and all the patients were blinded to the groups.

Healthy patients (American Society of Anaesthesiology [ASA] I) having molar teeth diagnosed with a periapical diagnosis of symptomatic apical periodontitis and a pulpal diagnosis of symptomatic irreversible pulpitis without radiolucency and with a preoperative pain of more than 50 on 10 cm visual analog scale (VAS) were included in the study. Electric pulp tester (EPT) (Digitest, Parkell, Edgewood, NY, USA) and cold test (Roeko Endo Frost, Coltene, Langenau, Germany) were used to test the sensibility of the teeth. Also, a percussion test was performed using finger and end of an instrument. Exclusion criteria were as follows: teeth having previous root canal treatment, root fracture, swelling, pathological mobility, a pocket depth of more than 3 mm and patients who are older than 65 years old or younger than 18, and taking antibiotics or analgesic within one month prior to the study. Teeth having radiographic lesions were excluded. Only teeth having healthy or widened periodontal ligament were included.

All the teeth had been anaesthetised using 1.8 ml 4% articaine with 1:100,000 epinephrine (Ultracaine DS Forte; Aventis, Istanbul, Turkey) before the isolation of the teeth with rubber dam. For maxillary molars, local infiltration anaesthesia was performed and for mandibular molars, mandibular anaesthesia was performed. Access cavities were prepared and the coronal thirds of the root canals were instrumented using Reciproc R25 files (VDW GmbH, Munich, Germany). Following root canal irrigation with 2 mL of 5.25% NaOCl (Chloraxid, Cerkamed, Poland), the working lengths were determined using an apex locator (Raypex 6,VDW). Then, all the root canals were prepared using Reciproc instruments according to the manufacturer’s instructions at full working length.

NaOCl solution group: During preparation, the root canals were irrigated with 2 mL of 5.25% NaOCl (Chloraxid, Cerkamed) between each pecking motion.

NaOCl gel group: During preparation, 5.25% NaOCl gel (Chloraxid, Cerkamed) was used according to the manufacturer’s instructions. The NaOCl gel was applied directly into the canal by using the applicator and root canal preparation was performed. The root canals were then flushed with 2 mL of saline.

The root canals were then irrigated with 2 mL of 5.25% NaOCl (Chloraxid, Cerkamed, Poland) between each pecking motion. The NaOCl gel was applied directly into the canal by using the applicator and root canal preparation was completed.

The root canals were then irrigated with 6 mL of 17% EDTA for the final irrigation once the root canal preparation was completed. The root canals were dried with paper points and obturated with gutta-percha cones and sealer (Sealapex, Kerr Corporation, Orange, CA) using cold lateral condensation technique. Then the permanent restorations were performed with resin composite (3M ESPE, St Paul, MN). The participants were given instructions to record postoperative pain levels on 24, 48, and 72 hours and 1 week after treatment using VAS and analgesic taken on the questionnaire. In case of the patient was referred to an unscheduled appointment, it was also recorded.

**Statistical analysis**

All the statistical analyses were conducted by using IBM® SPSS® Statistics 20 software (IBM SPSS Inc., Chicago, IL, USA) at a significance level of 5% (P=0.05). Since the data were not normally distributed, the Mann-Whitney U test was used to compare the pre- and postoperative pain values between the groups. Linear regression analyses were carried out to determine the confounding effects introduced by covariates (tooth number, gender, treatment group, age, analgesic intake, and preoperative pain level). Chi-square test was used to analyze nominal data (gender, analgesic intake, and tooth number).

**RESULTS**

Five participants from the solution group and 4 participants from the gel group were lost during follow-up. Statistical analyses revealed that there was no significant difference between the groups in terms of demographic data (P>0.05) (age, gender, tooth number, and analgesic intake) (Table 1). The distribution of the teeth was as follows; first upper molars were 11 and 11, second upper molars 6 and 7, first lower molars were 7 and 6, and second lower molars were 1 and 2 for the solution and gel groups respectively.

**TABLE 1. Distribution of patients according to age, gender, tooth number and analgesic intake**

|          | NaOCl solution | NaOCl gel | P value |
|----------|----------------|-----------|---------|
| n        | 25             | 26        |         |
| Mean age | 34.36±15.1     | 39.62±16.5| 0.262   |
| Gender   |                |           | 0.683   |
| Female   | 12             | 11        |         |
| Male     | 13             | 15        |         |
| Tooth number |          |           | 0.856   |
| #2       | 3              | 5         |         |
| #3       | 5              | 3         |         |
| #14      | 6              | 8         |         |
| #15      | 3              | 2         |         |
| #19      | 4              | 2         |         |
| #30      | 3              | 4         |         |
| #31      | 1              | 2         |         |
| Analgesic intake |     | 9         | 4       | 0.091   |
TABLE 2. Linear Regression findings for group, gender, age and tooth number on the dependent variable “postoperative pain level on day 1”

|                      | B*   | Standard Error | Beta  | P value |
|----------------------|------|----------------|-------|---------|
| Group                | -13.193 | 5.225          | -0.358 | 0.015   |
| Gender               | 0.499 | 5.362          | 0.014 | 0.926   |
| Age                  | 0.098 | 0.151          | -0.89  | 0.521   |
| Preoperative pain level | -0.346  | 0.247          | -0.202 | 0.168   |
| Tooth number         | -0.357 | 0.264          | -0.191 | 0.183   |
| Analgesic intake     | -0.133 | 6.019          | -0.003 | 0.983   |

TABLE 3. Pre and postoperative pain levels according to the groups

|                      | NaOCl solution | NaOCl Gel | P value |
|----------------------|----------------|-----------|---------|
| Preoperative         | 74.0±10.5      | 76.12±11.2 | 0.492   |
| 1st day              | 34.4±19.2      | 20.77±15.4 | 0.018   |
| 2nd day              | 12.8±17.8      | 4.81±10   | 0.077   |
| 3rd day              | 3.8±8.9        | 1.92±6.7  | 0.381   |
| 7th day              | 0              | 0         | -       |

Linear regression analyses showed that the postoperative pain level on the 1st day was only affected by the type of the NaOCl (P<0.05). Preoperative pain level, age, gender, tooth number, and analgesic intake did not affect the postoperative pain level on day 1 (P>0.05) (Table 2).

Intergroup analyses revealed that both groups were comparable with regard to preoperative pain levels (P>0.05). The NaOCl gel group resulted in significantly less postoperative pain than the NaOCl solution group on day 1 (P<0.05). However, there was no statistically significant difference between the groups in terms of postoperative pain levels on the 2nd, 3rd, and 7th days (P>0.05) (Table 3).

DISCUSSION

According to the result of the present study, it has been revealed that using NaOCl gel for root canal disinfection results in less postoperative pain on day 1 when compared with the NaOCl solution group. Thus, the null hypothesis that no differences existed between the NaOCl gel and solution groups in terms of postoperative pain was rejected. As it was previously mentioned, there is no study evaluating the effect of NaOCl gel on postoperative pain, therefore present results cannot be compared with previous studies.

Endodontic postoperative pain is affected by several factors such as preoperative pain level (14), the number of appointments (15), irrigation method (16), the method of the determination of the working length (17), type of the tooth (18), type of the instrument (19), movement kinematic of the instrument (20), extrusion of root canal filling material (21) and apically extruded debris (22). In the present study, all these factors were standardized except for the amount of apically extruded debris. Thus, the result of the present study can be explained by the difference in the amount of apically extruded debris between the groups. Because there could be a positive correlation between the amount of apically extruded debris and the risk of flare-ups (23). Similarly, Siqueira et al. (24) have stated that one of the principal causes of postoperative pain is apical extrusion of contaminated debris into the periapical tissues. Although the present study did not assess the amount of apically extruded debris, it has been mentioned that the risk of extrusion of NaOCl solution into periapical tissues can be reduced with the use of the gel form of the NaOCl (5). Therefore, it can be speculated that the amount of apically extruded debris was higher in the NaOCl solution group and this resulted in more postoperative pain in this group. Moreover, extrusion of the solution into the periapical area might have been resulted in pain regardless of the amount of apically extruded debris. Since the NaOCl is cytotoxic (25), inflammatory reactions could be induced by the NaOCl solution in the periapical area (26) which resulted in more postoperative pain in the solution group.

Seltzer et al. (22) stated that the most common cause of postoperative pain is microbial injury, which is caused by microorganisms and their products, to the pulp or periradicular tissues which are induced (or) exacerbated during root canal treatment. Thus, another explanation of the present results could be that NaOCl gel exhibited better antibacterial activity than the NaOCl solution during the preparation of the root canals. In contrast, Zand et al. (27) have reported that the antibacterial efficacy of the NaOCl gel was less than that of the NaOCl solution. It is well known that the antibacterial efficacy of the NaOCl increases with its concentration (28). In contrast, previous studies demonstrated that the antimicrobial effectiveness of NaOCl is not affected by its concentration (29-31). However, further in-vivo studies evaluating the antibacterial efficacy of NaOCl gel and solution are needed to verify our explanations.

It was shown by Peters et al. (32) that the use of a gel during preparation negatively affects torque on NiTi instruments and torque values were significantly reduced by the EDTA solution. In the present study, while NaOCl gel and solution forms were compared, Peters et al. compared EDTA solution and gel forms during preparation. It is well known that the chelating action of EDTA leads to reduced torque that occurs during preparation (33). Therefore, a direct comparison cannot be performed. Additionally, in the present study, the root canals were irrigated with 2 mL saline between each pecking motion in the gel group, to reduce the torque during preparation. In the present study, periapical radiographs were used to assess the number of root canals. However, it is well known that CBCT imaging is better than periapical radiography for assessing the number of root canals (34). Without CBCT evaluation it is possible to miss an extra root canal during endodontic treatment. The number of root canals may contribute to the level of postoperative pain (35). Therefore, this might be one of the limitations of the present study.

CONCLUSION

Within the limitations of the present study, it can be concluded that using NaOCl gel during root canal preparation results in less postoperative pain on day 1. This is the first study revealing the beneficial effect of NaOCl gel in lowering postoperative pain. Thus, further studies are needed.
Disclosures

Conflict of interest: There are no any conflict of interest.

Ethics Committee Approval: The Ethical Committee of the Faculty of Dentistry, University of A approved the study protocol with a decision number of 2017-91.

Peer-review: Externally peer-reviewed.

Financial Disclosure: There is no any financial support.

Authorship contributions: Concept – E.K.; Design – E.K.; Supervision – H.A.; Funding - None; Materials - D.O.K.; Data collection &/or processing – None; Analysis and/or interpretation – E.K.; Literature search – None; Writing – E.K.; Critical Review – None

REFERENCES

1. Siqueira JF Jr, Guimarães-Pinto T, Rôças IN. Effects of chemomechanical preparation with 2.5% sodium hypochlorite and intracanal medication with calcium hydroxide on culturable bacteria in infected root canals. J Endod 2007; 33(7):800–5.
2. Gernhardt CR, Eppendorf K, Kozlowski A, Brandt M. Toxicity of concentrated sodium hypochlorite used as an endodontic irrigant. Int Endod J 2004; 37(4):272–80.
3. Zehnder M. Root canal irrigants. J Endod 2006; 32(5):389–98.
4. Pontes F, Pontes H, Adachi P, Rodini C, Almeida D, Pinto D Jr. Gingival and bone necrosis caused by accidental sodium hypochlorite injection instead of anesthetic solution. Int Endod J 2008; 41(3):267–70.
5. Zand V, Lofti M, Rahimi S, Mokhtari H, Kazemi A, Sakhamanesh V. A comparative scanning electron microscopic investigation of the smear layer after the use of sodium hypochlorite gel and solution forms as root canal irrigants. J Endod 2010; 36(7):1234–7.
6. Garcia AJ, Kuga MC, Palma-Dibb RG, So MV, Matsumoto MA, Faria G, et al. Effect of sodium hypochlorite under several formulations on root canal dentin microhardness. J Investig Clin Dent 2013; 4(4):229–32.
7. Luz LB, Santana R, Prates AW, Froelich J, de Melo TA, Montagner F, et al. Antimicrobial action, pH, and tissue dissolution capacity of 2.5% sodium hypochlorite gel and solution. J Health Biol Sci 2019; 7(2):121–5.
8. Tanomaru Filho M, Leonardo MR, Silva LA, Anibal FF, Faccioli LH. Inflammatory response to different endodontic irrigating solutions. Int Endod J 2002; 35(9):735–7.
9. Attar S, Bowles RW, Baisden WR, McClanahan SB. Evaluation of pretreatment analgesia and endodontic treatment for postoperative endodontic pain. J Endod 2008; 34(6):652–5.
10. Keskin C, Ozdemir O, Uzun I, Gulier B. Effect of intracanal cryotherapy on pain after single-visit root canal treatment. Aust Endod J 2017; 43(2):83–8.
11. Arslan H, Doğanay E, Karataş E, Ünlü MA, Ahmed HMA. Effect of low-level laser therapy on postoperative pain after root canal retreatment: a preliminary placebo-controlled, triple-blind, randomized clinical trial. Int Endod J 2017; 43(11):1765–9.
12. Parirokh M, Rekabi A, Ashouri R, Nakhaei N, Abbott PV, Gorjestani H. Effect of occlusal reduction on postoperative pain in teeth with irreversible pulpitis and mild tenderness to percussion. J Endod 2013; 39(1):1–5.
13. Pasqualini M, Mollo L, Scotti N, Cantatore G, Castellucci A, Migliaretti G, et al. Postoperative pain after manual and mechanical glide path: a randomized clinical trial. J Endod 2012; 38(1):32–6.
14. Tanalp J, Sunay H, Bayrli G. Cross-sectional evaluation of post-operative pain and flare-ups in endodontic treatments using a type of rotary instruments. Acta Odontol Scand 2013; 71(3-4):733–9.
15. Erdem Hepsenoglu Y, Eyyuboglu TF, Ozcan M. Postoperative pain intensity after single- versus two-visit nonsurgical endodontic retreatment: a randomized clinical trial. J Endod 2018; 44(9):1339–46.
16. Topçuoğlu HS, Topçuoğlu G, Arslan H. The effect of apical positive and negative pressure irrigation methods on postoperative pain in mandibular molar teeth with symptomatic irreversible pulpitis: a randomized clinical trial. J Endod 2018; 44(8):1210–5.
17. Arslan H, Güven Y, Karataş E, Doğanay E. Effect of the simultaneous working length control during root canal preparation on postoperative pain. J Endod 2017; 43(9):1422–7.
18. Arias A, de la Macorra JC, Hidalgo JJ, Azabal M. Predictive models of pain following root canal treatment: a prospective clinical study. Int Endod J 2013; 46(8):784–93.
19. Topçuoğlu HS, Topçuoğlu G. Postoperative pain after the removal of root canal filling material using different techniques in teeth with failed root canal therapy: a randomized clinical trial. Acta Odontol Scand 2017; 75(4):249–54.
20. Arslan H, Khalilov R, Doğanay E, Karatas E. The effect of various kinematics on postoperative pain after instrumentation: a prospective, randomized clinical study. J Appl Oral Sci 2016; 24(5):503–8.
21. Lopes LPB, Herkth FJ, Vianna ECB, Gualberto Júnior EC, Marques AAF, Sponchiado Júnior EC. Effect of photobiomodulation therapy on postoperative pain after endodontic treatment: a randomized, controlled, clinical study. Clin Oral Investig 2019; 23(1):285–92.
22. Seltzer S, Naïdorff IJ. Flare-ups in endodontics: I. Etiological factors. J Endod 1985; 11(11):472–8.
23. Siqueira JF Jr, Barnett F. Interappointment pain: mechanisms, diagnosis, and treatment. Endod Topics 2004; 7(1):93–109.
24. Siqueira JF Jr, Rôças IN, Favieri A, Machado AG, Bahya SM, Oliveira JC, et al. Incidence of postoperative pain after intracanal procedures based on an antimicrobial strategy. J Endod 2002; 28(6):457–60.
25. Marins JS, Sassone LM, Fidel SR, Ribeiro DA. In vitro genotoxicity and cytotoxicity in murine fibroblasts exposed to EDTA, NaOCl, MTAD and citric acid. Braz Dent J 2012; 23(5):527–33.