

ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Influence of different forms of calcium hydroxide and chlorhexidine intracanal medicaments on the outcome of endodontic treatment of teeth with chronic apical periodontitis

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SUMMARY

Introduction/Objective The aim of this study was to determine clinical and radiographic periapical healing of teeth with apical periodontitis treated with different formulations of calcium hydroxide (CH) – paste (CH-paste) and gutta-percha points (CH-GP) – as well as those of chlorhexidine (CHX) – gel (CHX-gel) and gutta-percha points (CHX-GP) – 12 months after therapy.

Methods Eighty patients with chronic apical periodontitis were randomly allocated to four treatment groups according to the intracanal medicament used: CH-paste, CH-GP, CHX-gel, and CHX-GP group. Seventy-eight patients were analyzed clinically and radiographically 12 months postoperatively. The periapical index (PAI) was used for the radiographic evaluation of treatment.

Results Overall outcome was classified according to radiographic evaluation only, since clinical success was observed in all the patients. In all the groups, significant reduction in PAI scores was observed ($p < 0.001$). The proportions of healed teeth (PAI ≤ 2) were 73.7%, 60%, 68.4%, and 65% in CH-paste, CH-GP, CHX-gel and CHX-GP group, respectively, with no significant differences between the groups.

Conclusion The results suggest that there are no differences between investigated CH- and CHX-delivery systems regarding treatment outcome of teeth with apical periodontitis.

Keywords: calcium hydroxide; chlorhexidine; periapical diseases; root canal therapy; treatment outcome

INTRODUCTION

Microorganisms play a key role in the development and persistence of apical periodontitis and the success of endodontic therapy depends on their reduction. Mechanical instrumentation and irrigation significantly reduce but do not completely eliminate microbiota present in the root canal [1]. Therefore, the use of an interappointment intracanal dressing has been recommended to supplement the antibacterial effects of chemomechanical procedures and maximize bacterial reduction [2].

Calcium hydroxide (CH) is one of the most effective antibacterial dressings during endodontic therapy due to its antimicrobial activity, tissue-dissolving ability, detoxification of lipopolysaccharides, and induction of repair by formation of hard tissue [3]. Despite the favorable properties of CH, other substances, such as chlorhexidine (CHX), have been proposed with the aim of targeting bacteria resistant to CH [4].

Effectiveness of intracanal medicament depends not only on its antibacterial effect but

also on its bioavailability directly influenced by the delivery system. CH is commonly mixed with aqueous, viscous, or oily vehicles, while CHX has been used in the form of liquid or gel. Another delivery method for intracanal dressing is the use of gutta-percha points impregnated with medicament, either CH or CHX. According to the manufacturer, these points are easy to insert and remove from the canal, and they have the ability to release large quantities of medicament from their surface in a time-dependent fashion. To date, almost all research about medicated gutta-percha points considered only their *in vitro* antibacterial activity, with contrasting results [5–11]. More recently, antibacterial effects of medicated gutta-percha points were evaluated in clinical settings [12, 13]. Investigations found no difference between CH gutta-percha points (CH-GP) and CH paste [12, 13] or CHX gutta-percha points (CHX-GP) [13]. Regardless of the reported antibacterial efficacy of medicated gutta-percha points from some *in vitro* and *in vivo* studies, clinical decision making should be based

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on the outcome of clinical research, because antibacterial efficacy and successful therapeutic treatment might not always coincide with each other [5–13]. Long-term effectiveness of CH-GP as intracanal medicament was investigated in just a few studies, mainly case reports. CH-GP were showed to be successful in the treatment of different types of periapical lesions [14], root resorption [14, 15], and for apexification treatment [16].

Thus, the aim of this study was to determine the 12-month clinical and radiographic periapical healing of teeth with apical periodontitis treated with different formulations of CH (paste and gutta-percha points) and CHX (gel and gutta-percha points). The null hypothesis tested was that the type of intracanal medicament (CH vs. CHX) or its formulation (paste and gel vs. gutta-percha points) had no influence on the clinical and radiographic healing of teeth with apical periodontitis.

METHODS

Patient selection

The study was approved by the Ethics Committee of the Faculty of Medicine and conformed to the principles embodied in the Declaration of Helsinki. A sample was selected from patients referred to the Endodontic Department of the Faculty for nonsurgical root canal treatment between 2011 and 2013.

The inclusion criteria for the study were as follows: 1) healthy subjects age 18 years and older, both sexes; 2) single-rooted and single-canal teeth with nonvital pulps, confirmed by negative response to sensitivity pulp test (cold and electric stimulation tester); 3) the presence of periapical radiolucencies (minimum size $\geq 2 \times 2$ mm); 4) no previous endodontic therapy of the involved tooth; 5) the absence of tooth or root fracture of the involved tooth; 6) the absence of periodontal pocket (> 4 mm) of the involved tooth.

The exclusion criteria were the following: 1) the absence of enough tooth structure for rubber dam isolation; 2) patients with contributory medical history; 3) patients who received antibiotic therapy during previous six months.

Once eligibility was confirmed and after written and verbal informed consent was obtained, the patient was randomly assigned to one of the following four groups according to the intracanal medicament used: CH-paste (Calxyl-blue, OCO Products GMBH, Dirnstein, Germany), CH-GP (Roeko Calcium hydroxide Plus Points, Coltene/Whaledent, Langenau, Germany), CHX-gel (Consepsis V, Ultradent, South Jordan, UT, USA), and CHX-GP (Roeko Active Points, Coltene/Whaledent, Langenau, Germany). The sample was randomized using computer-generated random numbers, by a person who did not belong to the research group. The group assignment was passed on to the clinician, endodontic specialist, only at the time of treatment. Operator blinding could not be performed due to different colors and forms of used medicaments.

The minimum sample size per group was determined with the method described by Zhong [17]. Sixteen teeth

per group were calculated to be required to obtain a power of 80% at the 5% level of significance, with minimal clinically significant mean difference between groups of 0.5 units (standard deviation ± 0.5 unit) using the periapical index (PAI) scale [18]. Assuming possible losses of 20% during the 12-month follow-up period, the number of teeth per group was adjusted to 20.

Clinical procedures

Each tooth was polished with pumice and isolated from the oral cavity with a rubber dam. Antisepsis of the crown and operative field was conducted according to a previously described decontamination protocol [19]. All subsequent procedures were performed aseptically. Caries lesion and/or leakage restoration were removed and a standard access cavity was prepared. The canal working length was established using the apex locator (Raypex® 5, VDW, GmbH, Munich, Germany) and confirmed radiographically. Canal instrumentation was performed using the step-back technique with K-type files (0.02 taper ISO) and Gates–Glidden drills (both from Dentsply/Maillefer, Ballaigues, Switzerland) to the apical size of at least #35 depending on both the initial size of the root canal and root anatomy. Canal was irrigated with 2 mL of 1% sodium hypochlorite after each file size. When instrumentation was completed, the canal was flushed with 5 mL of 17% ethylenediaminetetraacetic acid followed by 5 mL of 1% sodium hypochlorite. After drying the canal with sterile paper points, intracanal medicament was placed in the root canal. For teeth assigned to the CH-paste group, a lentulo spiral was used to fill the canal with the paste. In the CHX-gel group, the gel was placed into the root canals by means of a syringe and needle. Teeth in the CH-GP and CHX-GP groups were dressed by using medicated gutta-percha point inserted to full working length into the canal with a drop of sterile water, according to the manufacturer's instructions. The access cavity was sealed with temporary filling (Cavit, 3M ESPE AG, Seefeld, Germany) and glass ionomer cement (Fuji IX, GC, Tokyo, Japan). After 15 days with intracanal medication, root canal was obturated with gutta-percha and AH Plus sealer (Dentsply, DeTrey, GmbH, Konstanz, Germany) using cold lateral compaction technique. Definitive restoration was obtained within one month after the completion of treatment.

Assessment of treatment outcome

The comparisons of clinical and radiographic findings at the 12-month follow-up with that documented at preoperative examination were used for the assessment of outcome of endodontic therapy. One investigator, uninvolved in the treatment of the subjects, performed all follow-up examinations.

Clinical outcome measures were the evaluation of the presence of pain, percussion, and palpation sensitivity, soft tissue status, tooth mobility, marginal bone level at 12 months. Absence of spontaneous pain and percussion or palpation sensitivity, absence of sinus tract, absence

of soft-tissue swelling, absence of tooth mobility and no increase in periodontal probing depth compared with baseline values were used as clinical criteria for treatment success (healing).

Radiographic outcome measure was the change in periapical radiolucencies at the 12-month follow-up. The radiograph at the follow-up was made by using the individual patient's bite registration and the same exposure settings used for the preoperative image. PAI score was used for radiographic evaluation of treatment success [18]. The index consists of five categories numbered 1–5 as follows: 1 – normal periapical structures; 2 – small changes in bone structure; 3 – changes in bone structure with some mineral loss; 4 – periodontitis with well-defined radiolucent area; 5 – severe periodontitis with exacerbating features; scores of 3 or higher represent disease.

All radiographic films obtained preoperatively and at follow-up were coded blind and organized in a random order. To improve calibration and inter-examiner agreement, two experienced endodontists who had not been involved in the treatment or the follow-up appointments analyzed a series of radiographs (not related to the study samples) representing a wide range of periapical bone densities, before study evaluation. After this, they independently analyzed the study radiographs under moderate illumination at a light table. In cases of disagreement, joint re-evaluation was performed and consensus were achieved. After one month, the examiners repeated the entire analysis of study radiographs. Inter- and intra-examiner agreement produced a Cohen kappa above 0.71 and 0.81, respectively.

At 12-month follow-up, a tooth was classified as healed if it presented no clinical signs or symptoms and had PAI ≤ 2 , or as unhealed if clinical signs or symptoms were presented and/or had PAI ≥ 3 .

Statistical analysis

SPSS 19.0 for Windows (IBM Corp., Armonk, NY, USA) was used for statistical analysis. The distribution of the variables: sex, dental arch involved and tooth type was evaluated using the χ^2 test, while age was analyzed using ANOVA. The Kruskal–Wallis followed by Mann–Whitney U-test and Wilcoxon signed rank test were used for

intergroup and intragroup comparison of PAI scores, at baseline and at the 12-month follow-up, respectively. To determine the difference in proportion of healed teeth between the groups and to identify variables that may influence the treatment outcome, the χ^2 was used. The level of $p < 0.05$ was chosen for statistical significance.

RESULTS

Demographic data

At the start of the treatment, 80 healthy persons (29 males) were recruited. The mean age was 37.58 (range 18–76) years. From each patient, only one tooth was included; 20 teeth per each group. Two of the 80 teeth included in the study were lost at the 12-month follow-up (one in the CH-paste and one in the CHX-gel group).

Comparisons between the groups showed no statistical difference in the distribution of age, sex, tooth type, or dental arch involved (Table 1).

Treatment outcome

At 12-months examination none of the patients had any clinical symptoms and/or abnormal findings. The PAI scores at baseline and at the 12-month follow-up for CH-paste, CH-GP, CHX-gel and CHX-GP are presented in Table 2. No significant differences between the groups were observed for both baseline examination and the 12-month control. Intragroup analysis revealed that in all treatment protocols PAI score decreased significantly ($p < 0.001$). An improvement in the PAI score was found in all patients except for three cases (15%) in the CH-GP group. Successful healing (PAI ≤ 2) was observed in 73.7%, 60%, 68.4%, and 65% of cases in groups CH-paste, CH-GP, CHX-gel and CHX-GP, respectively ($p = 0.832$).

Influence of other selected variables on treatment outcome in the total material is presented in Table 3. The only factor that showed a positive favorable influence on radiographic healing was the existence of a preoperative periapical lesion smaller than 5 mm ($p = 0.001$).

Table 1. Demographic characteristics of study population, tooth type, and dental arch by group

Intracanal medicament form	n	Age mean \pm SD	Male n (%)	Female n (%)	Tooth type			Dental arch	
					incisor n (%)	canine n (%)	premolar n (%)	maxilla n (%)	mandible n (%)
CH-paste	19	39.58 \pm 10.96	7 (36.8)	12 (63.2)	9 (47.4)	4 (21)	6 (31.6)	12 (63.2)	7 (36.8)
CH-GP	20	37.55 \pm 17.86	5 (25)	15 (75)	13 (65)	2 (10)	5 (25)	10 (50)	10 (50)
CHX-gel	19	39.53 \pm 17.32	6 (31.6)	13 (68.4)	10 (52.6)	3 (15.8)	6 (31.6)	14 (73.7)	5 (26.3)
CHX-GP	20	34.65 \pm 11.12	9 (45)	11 (55)	9 (45)	2 (10)	9 (45)	14 (70)	6 (30)
Total	78	37.78 \pm 14.56	27 (34.6)	51 (65.4)	41 (52.6)	11 (14.1)	26 (33.3)	50 (64.1)	28 (35.9)
p		0.692	0.596		0.765			0.424	

CH-paste – calcium hydroxide paste; CH-GP – calcium hydroxide gutta-percha points; CHX-gel – chlorhexidine gel; CHX-GP – chlorhexidine gutta-percha points

Table 2. Periapical status according to Periapical Index (PAI) before and after a 12-month follow-up for each group

PAI	Before treatment				12-month control				p
	CH-paste n = 20	CH-GP n = 20	CHX-gel n = 20	CHX-GP n = 20	CH-paste n = 19	CH-GP n = 20	CHX-gel n = 19	CHX-GP n = 20	
1	0	0	0	0	12	8	10	10	< 0.001
2	0	0	0	0	2	4	3	3	< 0.001
3	3	2	4	5	5	4	5	7	< 0.001
4	13	12	10	11	0	3	1	0	< 0.001
5	4	6	6	4	0	1	0	0	< 0.001
p	0.681				0.434				

CH-paste – calcium hydroxide paste; CH-GP – calcium hydroxide gutta-percha points; CHX-gel – chlorhexidine gel; CHX-GP – chlorhexidine gutta-percha points

Table 3. Bivariate association between selected variables and success rate (PAI ≤ 2) in total sample

Variables	n	Success (PAI ≤ 2) n (%)	p
Age (years)			
< 38	46	30 (65.2)	0.810
≥ 38	32	22 (68.8)	
Sex			
Female	51	33 (64.7)	0.801
Male	27	19 (70.4)	
Tooth type			
Anteriors	52	32 (61.5)	0.210
Premolars	26	20 (76.9)	
Tooth location			
Maxilla	50	30 (60)	0.134
Mandible	28	22 (78.6)	
Size of lesion (mm)			
< 5	62	47 (77)	0.001
≥ 5	26	14 (23)	
Root-filling*			
Acceptable	64	46 (71.9)	0.058
Unacceptable	14	6 (42.9)	

n – number of teeth;

*Acceptable filling – the filling ends 0–2 mm short of the radiographic apex with no voids visible within the material or between the material and the root canal walls; unacceptable filling – the filling material ends more than 2 mm from the radiographic apex or extruded beyond the apex and/or visible voids within or between the material and the root canal walls

DISCUSSION

In this study, clinical and radiographic parameters of apical periodontitis healing were evaluated concerning different form of intracanal medicaments, paste and gutta-percha points for CH, and gel and gutta-percha points for CHX. To the best of our knowledge, this is the first clinical study assessing the effect of these points on periapical healing. All types of medicaments resulted in similar periapical healing patterns.

In the present study, the patients were randomly assigned to treatment groups and no significant difference was found between them in terms of preoperative factors (age, sex, tooth type, dental arch, and PAI score at baseline). Root canal treatment was performed according to a standardized protocol by one experienced endodontist, representing specialty practice settings. Since clinical success of treatment was observed in all the patients, overall outcome was classified according to radiographic evaluation. Limited diagnostic ability of periapical radiography has been well

reported on. It has been shown that cone-beam computed tomographic imaging is more accurate than radiography for identifying periapical lesions. However, periapical radiography has been used in almost all endodontic outcome studies so far and has been adopted as a standard of practice. In addition, cone-beam computed tomographic is not recommended for routine diagnosis of periapical pathosis and the assessment of the root canal treatment outcome [20]. The applied criteria for treatment outcome were based on those suggested by Ørstavik et al. [18] accepted as a valid and reliable tool for measuring radiographic changes in apical bone density. The variability in radiographic reading is well recognized due to subjectivity of radiographic assessment. To overcome this shortcoming radiographic evaluation in our study was performed by two examiners with a substantial level of intra- and inter-examiner agreement. One-year observation period for radiological outcome in this study was chosen as most of the teeth with preoperative apical periodontitis heal during the first year after treatment [21, 22].

All treatment protocols led to significant decrease in PAI scores. About 73.7% of teeth could be judged as healed in the CH-paste group, 60% in the CH-GP, 68.4% in the CHX-gel, and 64% in the CHX-GP group. The healing rate observed in the CH-paste group corroborates the results of previous studies in which the calcium hydroxide has been used for intracanal medication of teeth with apical periodontitis [21, 22, 23]. Concerning CHX, the only available clinical report showed a healing rate of 94% in two to four years of follow-up after treatment with 2% CHX in the form of liquid, a rate much higher than for CHX in our study [24]. Disagreement with our findings may be due to difference in chemomechanical preparation, delivery system used for medication, and the time frame for outcome observation. However, if a decrease in PAI score was used as a favorable outcome, the number of healed teeth in our study would concur well with that obtained by the mentioned study [24].

Calcium hydroxide was used as a dressing material in most studies dealing with treatment outcome, with very few exceptions [23]. There are only a few studies which demonstrated that the type of intracanal medicaments significantly influence the outcome. The use of calcium hydroxide medicament resulted in better treatment outcome than no dressing or the one containing corticosteroids [20, 25]. In the present study, the outcome of endodontic therapy of teeth with apical periodontitis did not significantly differ between the groups. Thus, from the clinical point of view, the healing pattern seems largely unrelated

to the type and delivery system of intracanal medicament used, suggesting that both CH- and CHX-based medicaments can be used in therapy of primary chronic apical periodontitis. However, there was a tendency toward more favorable outcome in teeth medicated with CH-paste (75%) in comparison with CH-GP (60%). Considering the facts that both CH formulations placed in root canal for 15 days showed similar efficacy in periapical healing, and that CH-GP contain more than two times as much CH than CH-paste (58% vs. 23%), it can be assumed that bioavailability of CH in CH-GP is lower. Accordingly, release kinetics of calcium and hydroxyl ions from CH-GP was lower than that of other form of CH [12, 26, 27]. In addition, CH-GP presented short-term alkalinity and minor antimicrobial activity in comparison to CH-paste [9, 10, 11, 28]. In contrast to CH, CHX by itself possess significant pharmacokinetics characteristics, adsorption on oral mucosa and the microbial cell wall (antimicrobial substantivity), which enable its long-lasting antibacterial effect. Some authors found that CHX gel seemed to be more effective than CHX-GP in the reduction of bacterial counts in situ and in the inhibition of bacterial colonization of the dentin in vitro [5, 29]. Comparing mentioned in vitro and in situ findings considering only bacterial effectiveness with our results concerning outcomes obtained from clinical settings gel of 2% CHX and gutta-percha points of 5% CHX showing similar rate of periapical healing, it could be suggested that in clinical settings there are no differences between investigated CHX delivery systems in their bioavailability. Considering the influence of medicated gutta-percha points on periapical tissue healing, there is only data about CH-GP, mainly from clinical case series showing CH-GP to

be very successful in treating teeth with persistent periapical inflammation [14]. Moreover, Bezgin et al. [16] found acceptable results in apexification treatment using CH-GP and recommended these points as an apexification agent in cases where CH apexification is indicated. However, direct comparison of the present study with studies mentioned above concerning healing outcome is difficult to make, due to differences in the study population, diagnosis, and the treatment protocol. Further studies, including larger sample sizes, are needed to elucidate clinical effectiveness of medicated gutta-percha points on periapical healing.

In this study we also analyzed possible influence of other variables on treatment outcome. For the total material, only the size of the periapical lesion had significant impact. Teeth with a preoperative lesion greater than 5 mm had lower healing rate than teeth with smaller lesions. Having in mind that the healing process is a function of time, a favorable outcome of a smaller-sized lesion should be applicable to a larger-sized lesion if sufficient time was allowed for healing to take place [30].

CONCLUSION

Under the conditions of this study, there are no differences between investigated CH- and CHX-delivery systems regarding treatment outcome of teeth with apical periodontitis. Definitive conclusions about the influence of the type of intracanal medicament on periapical healing cannot be drawn and further randomized controlled trials to identify the most appropriate medication regime (type and method) are needed.

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Утицај различитих облика калцијум-хидроксида и хлорхексидина као интерсеансних медикамената на исход ендодонтског лечења зуба са хроничним периапексним лезијама

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САЖЕТАК

Увод/Циљ Циљ овог истраживања је био да се испита клинички и радиографски исход лечења зуба са апексним периодонтитисом 12 месеци после завршене терапије и примене различитих облика калцијум-хидроксида (КХ): паста (КХ-паста) и гутаперка поени (КХ-ГП) и хлорхексидина (ХХ): гел (ХХ-гел) и гутаперка поени (ХХ-ГП).

Метод Рандомизовано је 80 испитаника са хроничним периапексним лезијама у четири групе на основу врсте коришћеног интерсеансног медикамента: КХ-паста, КХ-ГП, ХХ-гел и ХХ-ГП. Дванаест месеци после завршеног лечења прегледано је 78 испитаника и урађени су ретроалвеоларни снимци. За процену радиографског успеха лечења коришћен је периапикални индекс (ПИ).

Резултати Исход лечења је класификован на основу радиошког налаза јер је код свих испитаника забележен клинички успех лечења. У свим испитиваним групама је забележено значајно смањење вредности ПИ ($p < 0,001$). Излечење (ПИ ≤ 2) уочено је код 73,3% зуба у групи КХ-паста, 60% у КХ-ГП групи, 68,4% у групи ХХ-гел и код 65% зуба у групи ХХ-ГП, при чему разлике између група нису биле статистички значајне.

Закључак Резултати овог истраживања показују да не постоји разлика у исходу лечења зуба са апексним периодонтитисом после примене испитиваних облика КХ и ХХ.

Кључне речи: калцијум-хидроксид; хлорхексидин; периапексно обољење; ендодонтски третман; исход лечења