Original Article

Comparing a Combination of Saline and Chlorhexidine with Saline as Root Canal Irrigation Solutions in Pulpectomy of the Primary Molars in 6-9 Years Old Children, A Double Blind Clinical Trial

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Abstract

Introduction: Using irrigation solutions in pulpectomy procedures for children is the best technique to dissolve and remove the soft necrotic materials during instrumentation. Normal saline solution (NSS) has no antibacterial activity and only results in root canal cleaning during irrigation. The 2% chlorhexidine gluconate (CHX) solution significantly decreases bacterial colonies, compared to NSS. The present study was performed to evaluate the success of irrigation by NSS and CHX combined solution, in comparison to NSS. **Materials and Methods:** The current study was conducted on 60 children aged 6–9 years allocated to the two groups of test and control. All the participants had one primary molar tooth with signs and symptoms of irreversible pulpitis. During pulpectomy of the 30 teeth, the standard technique, consisting of irrigation with 0.9% NSS was used for the control group. The 30 teeth of the remaining subjects in the case group were irrigated with an equal volume of 0.2% CHX and NSS combination. Clinical radiographic follow-ups were scheduled at 6 and 12 month post-operation intervals. **Results:** The success rates at 12 month follow-up from clinical and radiographic viewpoints in the control group were 83% and 73%, respectively. For the case group, success rates of 97% and 90% were reported clinically and radiographically, respectively. There were no significant diffferences between the case and control groups at 6- (P= 0.492) and 12- (P= 0.195) month clinical follow-ups. On the other hand, the two groups were siginificantly different regarding the 6-month radiographic follow-up (P=0.038); however, such difference was not significant at the 12-month follow-up (P=0.095). **Conclusion:** The one-year follow-up showed that there is no diffference between CHX and NSS as irrigation solutions for cleaning the root canals of primary teeth with irreversible pulpitis.

Keywords: Chlorhexidine gluconate, Normal saline solution, Primary molar, Pulpectomy

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Introduction

Adequate irrigation of the root canal system with chemical agents at the time of mechanical cleaning will remove soft and hard tissue remnants from different parts of the root canal system that are inaccessible by instruments (1). compared to permanent teeth make it more important to use irrigation solutions along with mechanical instruments in order to clean the root canal system. These differences include a higher number of accessory canals, foramina and porosities on the pulpal floor, as well as ribbon-like configuration of the root canals of primary teeth.

The pulp system of these teeth is filamentous and soft that cause complete removal of the pulp remnants to be almost impossible. The apical foramen is few millimeters away from the radiographic apex (2). Considering the higher incidence of root perforation and more difficulty in cleaning the root canals, clinical studies have reported a success rate of 65–100% for pulpectomy procedures of the primary teeth (3).

Although technical errors during treatment can lead to failure in treatment, failure might be seen even in cases that apparently have been treated well. This failure could be attributed to the presence of the microorganisms in root canal and apical part of the root (4). Both aerobic and anaerobic bacteria are found in the microbial flora of pulp and periapical lesions. In this context, after extraction of an infectious tooth, 70% of the microbial flora is anaerobic (5).

In primary teeth, infection spreads rapidly due to the large spaces of the bone marrow, thin bone trabeculae, and the proximity of the developing buds of permanent teeth to the root(s) of primary teeth. The dentists' awareness of the microbial flora in primary teeth and complexity of the root canal systems results in using effective antibacterial agents in pulpectomy procedures (6).

The most commonly used intracanal irrigation solutions are sodium hypochlorite (NaOCl), hydrogen peroxide (H_2O_2), chlorhexidine (CHX) and normal saline solution (NSS or NaCl) (7). NaOCl inhibits bacterial metabolism by oxidizing the sulfide group in the enzymatic system of the bacteria. NaOCl exhibits equal antibacterial activity at 0.5% and 5% concentrations. Therefore, due to the toxic effects of this solution, application of the 0.5% concentration has been recommended. Utilizing NaOCl alone cannot completely eliminate bacteria from the root canal system even after several consecutive appointments (8).

CHX is more effective than NaOCl in decreasing microbial flora and is available at 0.2%, 1%, and 2% concentrations. The time required to achieve a negative bacterial culture by 0.2% CHX is 30 sec to 1 min. profuse irrigation significantly diminishes bacterial colonies in the root canal (9). On the other hand, NSS has no antibacterial activity and only results in root canal cleaning during irrigation (10).

Effective irrigation of the root canal system is possible when a combination of irrigation solutions is used (11). To decrease bacterial counts and to achieve thorough cleaning of the root canal(s), at least two irrigation solutions are needed (12). In the standard pulpectomy treatment, NSS is used and CHX is the most commonly used antibacterial agent for irrigation of the root canal(s) (1). In a study, 2% CHX has exhibited significantly higher toxicity for periodontal ligament (PDL) cells, compared to 0.2% CHX (7).

Some studies have revealed the efficacy of CHX in irrigation of the root canals (7, 8, 10, 12). Moreover, cytotoxic effects have been reported for CHX and H_2O_2 (7). Therefore, in the present study, a combination of irrigation solutions was used to decrease the cytotoxic effect of CHX to some extent. In the present study, NSS was used as the standard irrigation solution during pulpectomy for the control group and a combination of NSS and CHX was used for the test group during pulpectomy treatment of the primary molar teeth. The outcomes were compared clinically and radiographically at postoperative intervals of 6 and 12 months.

Materials and Methods

This a double-blind clinical trial was carried out in the Department of Pediatric Dentistry, Faculty of Dentistry, Kerman University of Medical Sciences, Kerman, Iran. The procedures were completed by a postgraduate student in pediatric dentistry under the supervision of a pedodontist. A total of 60 primary molar teeth requiring pulpectomy treatment due to irreversible pulpitis were selected and randomly assigned to two groups based on lottery.

The inclusion criteria entailed age range of 6–9 years, health of the child, absence of any systemic disease, child consent, presence of at least one primary molar tooth with symptoms and signs of irreversible pulpitis such as abscess, sinus tract, spontaneous pain, tenderness to percussion, and obvious radiolucency, in addition to having restorable tooth. The exclusion criteria included systemic condition, presence of a follicular or dentigerous cyst beneath the primary tooth, resorption of more than one-third of the root length, inability to isolate the tooth, unrestorable tooth, advanced internal resorption, and periradicular radiolucency affecting the permanent tooth bud (10, 12).

Following obtaining informed consent forms, the procedure was performed as follow: local anesthesia, placement of a rubber dam, removal of caries, access cavity preparation by a sterile bur, elimination of the pulp from the pulp chamber and root canals with barbed broaches, root canal preparation shorter than the

radiographic apex up to file #35, removal of organic debris with periodic irrigation for 30 sec with a syringe containing either NSS or a combination of 0.2% CHX and NSS.

The operator was blind to the type of irrigation solutions. A 5 mL syringe was used for all the irrigation procedures and equal proportions of CHX and NSS were used for the combination irrigation. A side-perforated needle with a soft tip was used for irrigation. In order to blind the operator to the type of the irrigation solution, the nurse in the department as a third person prepared the solutions and the irrigation syringes for both groups. The syringes were covered so that it was not possible for the operator to identify the solutions. However, it should be pointed out that NSS and the combination of CHX and NSS have almost the same color.

The root canals were dried with paper points and were obturated with zinc oxide eugenol (ZOE) using a Lentulo spiral filler and the pulp chamber was sealed with reinforced ZOE. The tooth crowns were restored with stainless steel crown. Antibiotics were administered to the children when the alveolar abscess was not drained. The subjects were followed by the postgraduate student at 6- and 12- month intervals. The results were confirmed by two pedodontists who were calibrated for the evaluation of clinical and radiographic symptoms and signs, as well as filling the follow-up checklists. The postgraduate student and the two pedodontists were blind to the type of the solutions used at the 6- and 12- month follow-ups.

In the clinical follow-ups, the criteria for success encompassed lack of pathologic tooth mobility, absence of tenders to percussion, and not having pain. In the radiographic follow-up, the criteria for success were absence of the PDL widening, no radiolucency in the furcal area and apex, no involvement of the underlying permanent tooth bud, and no interference with the physiologic resorption of the root(s) of primary tooth and eruption of the permanent tooth (10). Figures 1, 2, and 3 show periapical radiographs of a primary right second molar tooth before treatment and at 6- and 12-month intervals after treatment in the case group.

Data were analyzed in SPSS software (version 22) by using Chi-square test, independent-samples t-test, McNemar test and Wilcoxon signed ranks tests. $P<0.05$ was considered as statistically significant.

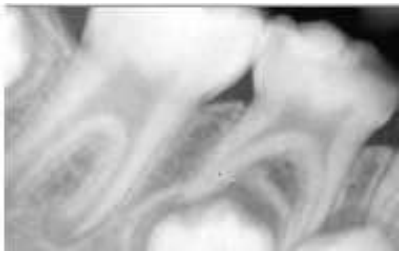

Figure 1. Periapical radiograph showing a primary right second molar tooth before treatment in the case group

Figure 2. Periapical radiograph showing a primary right second molar tooth at 6-month interval after treatment in the case group

Figure 3. Periapical radiograph showing a primary right second molar tooth at 12-month interval after treatment in the case group

Results

In the present study, sixty children aged 6–9 years with the mean age of 7.2±1.1 years consisting of 35 boys (58.3%) and 25 girls (41.7%), who had one primary molar tooth with irreversible pulpitis were selected. The participants underwent pulpectomy procedures in the two groups of control (NSS) and case (CHX+NSS) and were evaluated clinically and radiographically at 6 and 12 months intervals.

Clinical and radiographic success rates of the two groups at 6 and 12 months are showed in Table I. No molar demonstrated failure in the CHX+NSS group at the 6-month clinical evaluation, whereas two molars (6.7%) in the NSS group indicated failure at this time. There was no significant difference between the clinical success rates of the two groups (P-value=0.15) after 6 months. At the 12-month evaluation, one molar (3.3%) in the CHX+NSS group and five molars (16.7%) in the NSS group showed clinical failure. Moreover, no significant difference was observed regarding the clinical success

rate between the two groups (P-value=0.08). In other words, the control and test groups were not significantly different at neither of the time point.

At the 6-month evaluation, two molars (6.7%) in the CHX+NSS group radiologically showed failure, compared to eight molars (26.7%) failure in the NSS group. There was a significant difference in terms of radiographic success rate between the two groups (P-value=0.04) after six months. Three molars (10%) in the CHX+NSS group and nine molars (30 %) in the NSS group had signs of failure at the 12-month radiological evaluation. In addition, the two groups were not significantly different concerning the radiographic success rate (P-value=1).

Figures 1 and 2 show the frequency of the clinical and radiographic signs and symptoms of the two groups before treatment, in addition to 6 and 12 months after treatment.

Table II demonstrates comparison regarding the clinical parameters (luxation, percussion, and abscess) between the two groups at three times.

Table I. Clinical and radiographic success rates of the control (NSS) and case (CHX+NSS) groups at follow-ups of 6 and 12 months

Group	Clinical success				Radiographic success			
	6 months		12 months		6 months		12 months	
	N	%	N	%	N	%	N	%
CHX+NSS	30	100	29	96.7	28	93.3	27	90
NSS	28	93.3	25	83.3	22	73.3	21	70

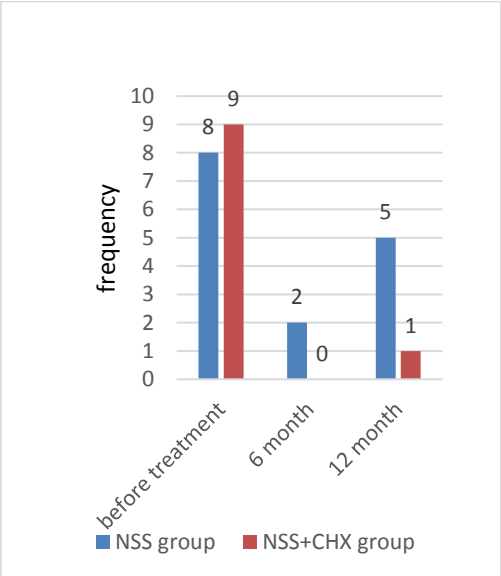

Figure 1. Frequency of the clinical signs and symptoms of the two groups before treatment, as well as 6 and 12 months after treatment

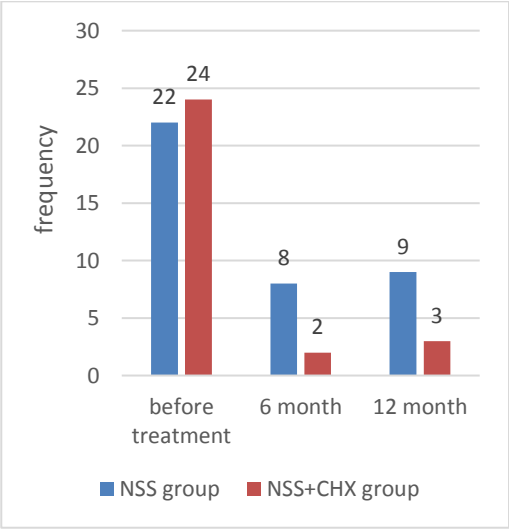

Figure 2. Frequency of the radiographic signs and symptoms of the two groups before treatment, as well as 6 and 12 months after treatment.

Table II. Frequency and comparison of the clinical signs and symptoms in the control (NSS) and case (CHX+NSS) groups before treatment, in addition to 6 and 12 months after treatment

Clinical sign	Group	Before treatment	P-value*	6 months	P-value*	12 months	P-value*
luxation	NSS	0	1	1	1	5	0.195
	CHX +NSS	1		0		1	
Abscess	NSS	0	0.492	0	**	0	**
	CHX+ NSS	2		0		0	
Percussion	NSS	8	0.542	1	1	0	**
	CHX +NSS	6		0		0	
Total	NSS	8	1	2	0.492	5	0.195
	CHX+ NSS	9		0		1	

*: Chi-square test to compare the two groups.

**: The signs and symptoms were the same in the two groups and Chi-square Test failed.

Table III summarizes comparison concerning the radiographic parameters (radiolucency in the furcal area and apex, involvement of the follicle, interference with the physiologic resorption of the deciduous tooth roots and widening of the PDL) between the two study groups at three times.

Table IV demonstrates comparison results regarding the clinical parameters (luxation, percussion, and abscess) in each group between three times.

Table V shows the results of comparison in terms of radiographic parameters (radiolucency in the furcal area and apex, involvement of the follicle, interference with the physiologic resorption of the deciduous tooth roots and widening of the PDL) in each group at three times.

Table III. Frequency and comparison of the radiographic signs between the control (NSS) and case (CHX+NSS) groups before treatment, in addition to 6 and 12 months after treatment

Radiographic sign	Group	Before treatment	P-value*	6months	P-value*	12months	P-value*
Radiolucency in the furcal area and apex	NSS	2	1	4	0.112	4	0.112
	CHX+NSS	3		0		0	
Involvement of the follicle	NSS	0	**	0	0.353	1	0.353
	CHX+NSS	0		1		0	
Interference with the physiologic resorption of the deciduous tooth root(s)	NSS	2	1	4	0.16	4	1
	CHX+NSS	3		1		3	
Widening of the PDL	NSS	18	1	0	**	0	**
	CHX+NSS	18		0		0	
Total	NSS	22	0.787	8	0.038	9	0.095
	CHX+NSS	24		2		3	

*: Chi-square test for comparing the two groups.

**: The signs were the same in the two groups and Chi-square Test failed.

Table IV. Comparison of the clinical signs and symptoms in each group between the three times of pre-treatment, in addition to 6 and 12 months post-treatment

Clinical sign	Group	Pre-treatment and 6 months post-treatment (P-value)*	Pre-treatment and 12 months post-treatment (P-value)*	6 and 12 months post-treatment (P-value)*
Luxation	NSS	1	0.063	0.219
	CHX +NSS	1	1	1
Abscess	NSS	1**	1**	1**
	CHX+ NSS	0.5	0.5	1**
Percussion	NSS	0.039	0.008	1
	CHX +NSS	0.031	0.031	1**
Total	NSS	0.109	0.509	0.375
	CHX+ NSS	0.008	0.016	1

*: McNemar test for comparing the three times in each group.

**: Willcoxon Signed Ranke Test for comparing the three times in each group.

Table V. Comparison of the radiographic signs of each group between the three times of pre-treatment, in addition to 6 and 12 months post-treatment

Radiographic sign	Group	Pre-treatment and 6 months post-treatment (P-value)*	Pre-treatment and 12 months post-treatment (P-value)*	6 and 12 months post-treatment (P-value)*
Radiolucency in the furcal area and apex	NSS	0.5	0.625	1
	CHX+NSS	0.25	0.25	1**
Involvement of the follicle	NSS	0.15**	1	1
	CHX+NSS	1	0.15**	1
Interference with the physiologic resorption of the deciduous tooth root(s)	NSS	0.5	0.5	1
	CHX+NSS	0.5	1	0.5
Widening of the PDL	NSS	0.0001	0.0001	1**
	CHX+NSS	0.0001	0.0001	1**
Total	NSS	0.0001	0.002	1
	CHX+NSS	0.0001	0.0001	1

*: McNemar test for comparing the three times in each group.

**: Willcoxon Signed Ranke Test for comparing the three times in each group.

Discussion

The success of endodontic treatment in primary teeth strongly depends on achieving an adequate level of disinfection in the root canals. Favorable disinfection is not possible with only mechanical instrumentation because a major portion of the infected root canal remains untouched. The necrotic pulpal tissue and dentin debris remain in the dentinal tubules, accessory canals, and resorption lacunae. Microorganisms and their products are eliminated effectively from a clinical point of view by biocompatible irrigation solutions helping the disinfection process for the organic debris (3, 13).

The results of the present study showed that applying a combination of CHX and NSS for root canal irrigation during pulpectomy procedures of primary molar teeth with irreversible pulpitis led to equal success rate in clinical and radiographical aspects, compared to NSS solution.

In the study performed by Jolly et al., 60 children aged 6–12 years and affected by acute apical abscess in maxillary primary second molar teeth were randomly assigned to four groups (N=15). The following irrigation solutions were used for the study groups during the pulpectomy procedure: 2% CHX, 4% calcium hydroxide, dimethyl sulfoxide (DMSO), and NSS as the control

group. Microbial samples were taken from the distobuccal root canal before irrigation and three days after treatment and were all cultured. In all the four groups, a significant decrease was noted in the colony counts of aerobic bacteria, with the greatest decrease in the 2% CHX group. Therefore, the latter solution was reported as the most effective antimicrobial agent (1).

In another study conducted by Louwakul et al. (10), 64 mandibular deciduous molar teeth in 42 children (with a mean age of 5.29±1.45 years) were selected for pulpectomy treatment in one session by one researcher and were randomly assigned to CHX irrigation solution group and NSS group. Clinical and radiographic evaluations were carried out by two researchers in a blinded study design. The findings revealed that although the success rate was significantly higher in the CHX group at the 6-month interval, there was no significant difference between the two groups at the 12- and 18-month intervals. This research, consistent with the present study, indicates that the success rate in the case and control groups are equal in long follow-up.

In a study completed by Ruiz-Esparza et al. (8), 40 primary teeth with necrotic pulps were randomly allocated to two irrigation groups with 2% CHX and NSS. In both groups, the microbial samples were taken by sterile paper points once after gaining access to the root canal and before initial irrigation and another time after instrumentation and final irrigation before obturation. The authors reported that CHX diminished bacterial counts within the root canals more effectively than NSS. However, further studies and longer follow-up periods are recommended for CHX as root canal irrigation during pulpectomy procedures of the primary molar teeth with irreversible pulpitis.

Some limitations of the current study included inconsistency between the status of the tooth pulps in clinic, as well as the clinical and radiographic criteria based on which they were selected. In such condition, the subject was replaced by another one. If the child did not cooperate during the treatment, he/she was excluded from the study and replaced by another participant. Moreover, when guardian of the child did not sign the consent form, treatment was rendered in one session. For the mentioned cases, if the treatment continued up to the second session, the patient was excluded and replaced by another subject.

Conclusion

According to the findings of this study, one-year follow-up showed that combination of the CHX and NSS was not different form the NSS as irrigation solution for cleaning the root canals of the primary teeth affected by irreversible pulpitis.

Conflict of Interests

The authors have declared no conflict of interests for the present study.

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