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A Clinical and Radiographic Assessment of Sodium Hypochlorite Versus Formocresol Pulpotomy in Primary Molar Teeth: 12-month Follow-up

Zahra Bahrololoomi[1], Fatemeh Zarebidoki [2], Atefeh Shakib[3]*

[1] *Associated Professor, Social Determinants of Oral Health Research Center, Department of Pediatric Dentistry, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.*

[2] *Assistant Professor, Department of Pediatric Dentistry, Shahid Sadoughi University of Medical Sciences, Faculty of Dentistry, Yazd, Iran.*

[3] *Pedodontist*

Abstract

Objective: The aim of this study was to compare the clinical and radiographic success rates of pulpotomy in primary molars using formocresol versus sodium hypochlorite.

Methods: Twenty-three children aged 4-9 years with at least two primary molars requiring pulpotomy were randomly allocated into two groups. All teeth received stainless steel crown after conventional pulpotomy procedure with either NaOCl or formocresol. Clinical and radiographic signs/symptoms were recorded at six and 12 months. Outcomes were statistically analyzed using Fisher's exact test and Chi-square test.

Results: Clinical success rates at 6 and 12-month follow-up in both groups was 100%. At 6-month follow-up, radiographic success rate for NaOCl and formocresol groups was 100%. At 12-month recalls, in NaOCl group, 20 teeth (87%) and in formocresol group, 21 teeth (91.3%) had radiographic success. No significant difference was found in the radiographic success rates at 12 months (P=1.00). Internal root resorption was the most common radiographic pathologic finding in both groups.

Conclusion: Clinical and radiographic success rates in NaOCl group was comparable with formocresol group, so NaOCL can be suggested as an alternative for primary teeth pulpotomies. However further clinical studies with long-term follow-ups are needed.

Keywords: Formocresol; Pulpotomy; Sodium Hypochlorite; Tooth; Deciduous

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Email: dr.1370@yahoo.com

Introduction

Pulpotomy is a common therapeutic method for treatment of primary teeth in which teeth had deep carious lesions approaching the pulp and some cases also had a history of pain. This pain lasted less than 20 minutes, was provoked by chewing foods, especially sweets, did not wake the child from sleep [1].

Various medicaments are used in pulpotomy of primary teeth among which formocresol (FC) is the commonest. The reported success rate of FC pulpotomy is 70-98% [2, 3], but some studies showed the possibility of such local or systemic side effects as pulpal reactions with inflammation, necrosis, cytotoxicity, and potential mutagenic or carcinogenic effects and immunologic responses after FC use. There are also concerns

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about the effect of FC on the enamel of the succedaneums permanent teeth after pulpotomy of primary teeth [4]. Considering the side effects of FC, its substitution with a safer substance seems necessary. Therefore, in different studies, medicament and non-medicament methods have been proposed to replace FC in pulpotomy of primary teeth [5]. Sodium hypochlorite (NaOCl) is a substance used for canal irrigation, hemostasis and removing biofilms and debris [6]. It has strong biological properties that include antimicrobial activity and organic tissue dissolution capacity [7]. It presents a well-recognized in vitro antimicrobial activity although in some cases this solution fails to achieve a bacteria-free root canal under clinical coditions [7-9] The antimicrobial effect of NaOCl solutions depends on their free available chlorine, which consists of hypochlorous acid and the hypochlorite ion [8, 9]

Clinical studies in which NaOCl was used for pulpotomy of primary molars, showed that its clinical and radiographic success rate was comparable with FC and ferric sulfate [4, 10]; although there are few studies on this issue. Therefore, this study was designed to assess the clinical and radiographic success rate of primary molar pulpotomy using FC and NaOCl.

Material and Methods

This was a double-blind randomized controlled trial approved by the ethics committee of Shahid Sadoughi University of Medical Sciences (code: IR.SSU.REC.1394.107) and registered in Iranian center for registration of clinical trials (code: IRCT20150927935N5).

Totally, 25 children 4-9 years old referred to the pediatric department of dental school in Shahd Sadoughi University of Medical Sciences with at least two primary molars requiring pulpotomy entered the study. Two children (4 teeth) didn't continue the study during 12-months follow-up.

A parallel design was used, because only some of the children had at least two primary molars requiring pulpotomy. The tooth was considered the unit for randomization. On the day of the procedure before the pulpotomy was performed, the operator was given a sealed envelope that contained a letter denoting the medicament group. The patients were not informed about their group allocation. Inclusion criteria were: in clinical examination: primary molars with deep caries and pulp exposure; lack of pulp degeneration in the affected teeth (e.g. spontaneous and nocturnal pain, swelling, mobility, abscess, fistula and tenderness to percussion); in radiographic examination: lack of internal or external root resorption and furcation radiolucency; being restorable by stainless steel crowns.
Before examinations, the objectives of the study were explained for the parents and an informed consent was obtained from them.

At first, the tooth was anesthetized using lidocain 2% and epinephrine 1/80000 (Daroupaksh co., Tehran, Iran). After isolation of selected teeth with a rubber dam, caries were removed and then pulpal chamber accessed by a fissure diamond bur N≠330 (Tizkavan, Tahran, Iran) in a water-cooled high-speed hand-piece. For removing pulp tissue, a spoon excavator was used and after saline irrigation, cotton pellets were inserted in place for 5 minutes to induce hemostasis. If bleeding continued, the patient was excluded from the study, and if hemostasis was induced, treatment was continued in both groups. In first group, a 1:5 dilution of Buckley's FC (SSA, Produits Dentaires, Switzerland) was used for 5 minutes and in the

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second group, NaOCl 5% (Sehhat, Tehran, Iran) was applied by a cotton applicator in the pulp chamber for 30 seconds. Then, in both groups, reinforced zinc oxide eugenol (Kemdent, UK) was inserted in the access cavity and in the same session, teeth were restored by stainless steel crowns (3M/ESPE, Dental Products, St. Paul, MN, USA).

All procedures were performed by postgraduate pedodontist. Clinical and radiographic outcome assessments were made by one independent experienced pedodontist who was blind to the treatment at follow-up visits. The success of treatment was determined as the absence of spontaneous pain, mobility, swelling, fistula and tenderness to percussion. Radiographic success was determined as lack of internal or external resorption, and inter-radicular and periapical radiolucency. All radiographs were taken by Plammeca Oy (Helsinki, Finland) using E films (Skydent, Slovakia). and the images were re-evaluated by the same specialists after 7 days (intra-examiner agreement>90%). Data were analyzed by SPSS (Ver. 20) using Fisher's exact test and ci square test. The p value <0.05 was considered significant.

Results

This study was started with 25 children 4-9 years old (13 females and 12 males) with mean age of 6.5 years. Fifty primary molars were randomly allocated into two treatment groups. Two children (4 teeth) didn't continue the study during 12-months follow-up. Therefore, 23 patients were evaluated.

Table 1 shows the distribution of the teeth in two groups. There was not a statistically significant difference between two groups regarding gender, age, tooth type and tooth location (P>0.05)

Clinical findings:

From 46 pulpotomized teeth at 6 and 12-month recalls, 100% of the cases in both FC and NaOCl groups showed clinical success.

Radiographic findings:

At 6-month recall, 100% of cases in both groups showed radiographic success (Fig. 1). After 12 months, in NaOCl group, three teeth (13%) showed internal resorption, among which two teeth showed external resorption and involvement of inter-radicular bone as well; and in FC group, failure was observed in two teeth (8.7%), among which one tooth showed internal resorption (Fig 2) and another tooth showed both internal resorption and involvement of inter-radicular bone. The most frequent radiographic failure was internal resorption without insignificant difference between groups (P>0.05).

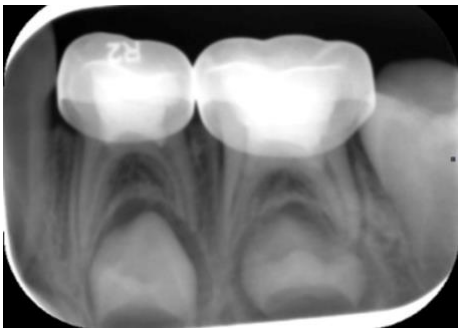

Figure 1. successful treatment of NaOCL pulpotomy of lower left second primary molar after 12 months follow-up.

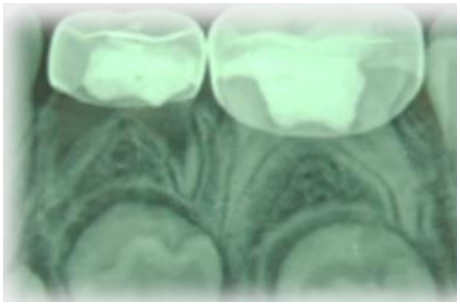

Figure 2. Radiographic failure of FC pulpotomy on lower left first primary molar with internal root resorption after 12 months follow-up.

The 12-month radiographic success rate was 87% and 91.3% in NaOCl and FC groups, respectively, and the difference was not statistically significant (P = 1.00) (table 2).

Table 1. Distribution of pulpotomied primary molars according to the type of teeth.

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Treatment group	Number of teeth											
	First primary molar at 6 months			Second primary molar at 6 months			First primary molar at 12 months			Second primary molar at 12 months		
	Maxillary	Mandibular	Total	Maxillary	Mandibular	Total	Maxillary	Mandibular	Total	Maxillary	Mandibular	Total
FC	9	5	14	4	7	11	8	5	13	3	7	10
NaOCl	6	10	16	9	0	9	5	10	15	8	0	8

Table 2. Comparison of the clinical and radiographic success rate in primary molars pulpotomied by FC and NaOCl at 6 and 12-month follow-ups.

	Success rate, N (percent)							
Treatment group	Clinical				Radiographic			
	6 month		12 month		6 month		12 month	
	Success	Failure	Success	Failure	Success	Failure	Success	Failure
FC	23 (100)	0	23 (100)	0	23 (100)	0	21 (91.3)	2 (8.7)
NaOCl	23 (100)	0	23 (100)	0	23 (100)	0	20 (87)	3 (13)

Discussion

The first objective of pulp therapy is maintaining the integrity and health of oral tissue. It is necessary to try to maintain pulp vitality [11]. Pulp therapy has been successfully performed for severely destructed primary molars by Buckley's FC since 1904. Controversy to use this substance was due to its potential mutagenic and carcinogenic effect; so other drugs have been introduced with different success rates and costs [12].

Previous studies used NaOCl 2.5 to 5.25 percent. In the current study, similar to Al-Mutairi et al.[13], Vargas et al.[4], Vostak et al.[10], and Tzu-Ying Li studies[14], NaOCl 5% was used. Only in the studies conducted by Ruby et al.[12] and Shabzendehdar et al.[15] NaOCl 3% was used. Akay et al.[16] Who assessed the effect of NaOCl on disinfection before application of the substance covering pulp, used NaOCl 5% [16]. According to the studies and considering the difficulties in preparing NaOCl 3%, concentration of 5% was used in the present study.

In the current study, clinical success rate of NaOCl and FC at 6 and 12-month recalls was 100%. Radiographic success rate at 6-month recall was 100% in both groups which was consistent with the results of Farsi et al. [17], although other studies reported success rate to be between 86-99% [4, 10, 12-15, 18]. Radiographic success rate at 12-month recall was 91.3% and 87% in FC and NaOCl groups,

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respectively, which was in agreement with some other studies [12, 13, 15].

Al_Mutairi et al. found 12-month clinical and radiographic success rate of NaOCl to be 94.6 and 86.5%, respectively [13]. They used a method similar to our study. In the study conducted by Ruby et al. the success rate of NaOCl was 100%, though with a lower radiographic success rate, i.e. 90%. They didn't find a significant difference between the success rate of NaOCl and FC which was consistent with the results of the current study; although they used NaOCl 3% [12].

In the study of Shabzendehdar et al. in agreement with the current study, there was not a significant difference between two substances. They used NaOCl 3%, but duration of substance application was 30 s, similar to the current study. Another difference between the studies was that they performed pulpotomy only on mandibular first molars and their participants had at least one tooth requiring pulpotomy [15]. Tzu-Ying Li et al. conducted a retrospective study with a larger sample size and a longer duration of recall (24 months).

The most frequent radiographic finding in the present study was internal resorption which was observed in 21.7% of teeth at 12-month recall. Although no clinical signs were seen in these teeth which was consistent with the results of the previous studies [4, 10, 14, 15, 18].

We couldn't find a satisfactory explanation for the internal resorption occuring after pulpotomy; even though during pulpotomy it is possible that abnormal pulpal tissue remains in the place, and if the inflammation extends to the entrance of the pulp canal, odontoclasts will be attracted to the area [19].

Internal resorption may occur due to zinc oxide eugenol use, because eugenol is irritant for pulp and may induce pulp inflammation. The fixing effect of FC can probably prevent the irritating effect of eugenol, and the hemostatic properties of NaOCl may prevent the necrosis layer to be formed [20].

Bony changes may lead to the formation of abscess, fistula, pain and mobility of the tooth, while internal resorption is limited to the tooth and is from dental origin which was explained earlier. Internal resorption is not so important clinically, and it is possible that the problem occurs after pulpotomy without any alarming signs for the patient and the dentists, and it may be accidentally discovered in radiography[21].

Other radiographic failures include external resorption and bone lucency which are among bony changes which are more important than internal resorption in their effect on the development of permanent teeth. These changes were fortunately less frequent than internal resorption in the current study.

The failures after treatment of vital pulp and eventual failure in the formation of a calcified bridge on the vital pulp depends on the patient's age, the degree of surgical trauma, pressure during sealing, selection of inappropriate covering substance, low patient's resistance threshold and the presence of microorganisms and the eventual infection.

In summary, the reason for difference between studies is probably due to different methods, age range of the participants, difference in tooth type, design of the study and sample size.

It is recommended that clinical studies with larger sample size and longer duration of recalls be performed.

Conclusion

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The findings of the current study showed that clinical and radiographic success rate of NaOCl is comparable to FC. A substance covering the pulp should have bacteriocidal and biocompatibility properties with low cost. NaOCl has all these properties and is inexpensive and easily available.

Conflicts of interest

The authors deny conflicts of interest to this study.

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