

Clinical and radiographic evaluation of testing different concentrations of sodium hypochloride as vital pulpotomy treatment in primary teeth: a randomized controlled trial

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Background/aim

Sodium hypochloride (NaOCl) was used recently as an alternative material for formocresol. The purpose of this study was to evaluate the clinical and radiographic outcome of pulpotomy treatment in deciduous molars using 2.5% NaOCl, 5% NaOCl, and Buckley's formocresol.

Participants and methods

A total of 60 primary molars teeth of 30 children aged 5–9 years were selected for the study. The selected teeth were randomly distributed into three groups treated by 2.5% NaOCl, 5% NaOCl, and formocresol. Pulpotomy was carried out using the three medications, and the teeth were restored with stainless steel crowns. The clinical and radiographic evaluations were performed at 3 and 6 months postoperatively.

Results

At the 3-month follow-up, 100% of the pulpotomy medicaments were clinically successful. At the 6-month follow-up, all pulpotomized dentitions in 2.5% NaOCl and formocresol were clinically successful. In 5% NaOCl group, gingival inflammation was observed in two teeth. Regarding the radiographic findings, at the 3-month follow-up, all pulpotomized teeth in 2.5% NaOCl group were successfully treated. Radiographic changes were seen in 5% of the teeth in the 5% NaOCl group and 5.5% of teeth in the formocresol group. At the 6-month follow-up, radiographic changes were seen in 6% of the teeth in 2.5% NaOCl group, 11% of the teeth in 5% NaOCl group, and 12.5% of the teeth in formocresol group. No significant differences were found in the clinical and radiographic outcomes among the three groups ($P > 0.05$).

Conclusion

There is no difference in the clinical and radiographic finding of pulpotomized molars using 2.5%, 5% NaOCl, and formocresol. The results show that 2.5% NaOCl is as effective as 5% NaOCl, so it could be used safely as a therapeutic agent in the treatment of deciduous teeth with pulp involvement.

Keywords:

2.5% sodium hypochlorite, 5% sodium hypochlorite, formocresol, primary dentition, pulpotomy

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Introduction

Dental caries and its subsequent pulp inflammation in the primary dentition are the biggest problems facing pediatric dentists. As direct pulp capping in exposed deciduous teeth owing to caries has poor success rate [1], vital pulpotomy is an acceptable method carried out in pediatric dentistry for treatment of carious exposures of asymptomatic vital primary teeth [2].

Pulpotomy in primary dentition is defined as 'a clinical process of removing the coronal inflamed pulp' [3], while the remaining root pulp is covered with a pulp medicament that is ideally life compatible, bactericidal, and capable of creating a biological seal and that allows the physiological process of root resorption [4].

The 'gold standard' for pulpotomy treatment in deciduous teeth is formocresol. It was introduced in 1904 by Buckley to treat nonvital permanent teeth, and then it became a popular pulpotomy medicament for primary teeth [5]. Currently used 1 : 5 dilution of Buckley's formocresol has a formula of 19% formaldehyde, 35% cresol, 15% glycerine, and water [6].

The success rate of formocresol pulpotomy varies between 70 and 98% [7,8]. This high success rate does not overcome the concerns about its toxicity.

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Formocresol is the leading cause of local pulpal inflammation, necrosis, systemic disturbances, and immunologic responses [9]. Furthermore, it can induce inflammation injuries on the adjacent tissues, including gingiva [10]. Formocresol can also cause cytotoxic, mutagenic, carcinogenic, teratogenic effects, and chromosomal damage to the dental pulp cells in tissue culture [11].

In June 2011, 'the United States Department of Health and Human Health Services issued a report that classified formaldehyde as a carcinogen for humans' [12]. Efforts are now underway in pediatric dentistry to find an appropriate alternative for this gold standard material.

Sodium hypochlorite (NaOCl) is a biocompatible material that is an effective hemostatic agent and is nonirritating to the exposed pulpal tissue. It was commonly used as an irrigant in endodontic treatment of permanent teeth since 1920 [13]. It has a significant effect in controlling the bleeding of the pulp and can thus be expected to inhibit the formation of a fibrin clot. Furthermore, it helps in disinfection of the canals and removal of dentin chips [14]. NaOCl can also be expected to enhance healing after vital pulpotomy procedures. It dissolves the surface necrosis of pulp tissue but has no effect on the deeper healthy pulp [2]. Most of the published studies used 5% NaOCl as a therapeutic agent in vital pulpotomy of primary teeth. However, this concentration may have a toxic effect on the vital pulp tissue [15].

There are insufficient data for the use of lower concentration, so the purpose of this study was to evaluate the effectiveness of 2.5% NaOCl, 5% NaOCl, and formocresol in the clinical and radiographic outcome of deciduous teeth treated by vital pulpotomy.

Participants and methods

Study design and ethical approval

Participants were selected from the patients attending the Paediatric Dentistry Clinic at the Nahda University of Bani-Swif, Faculty of Dentistry, who required pulpotomy treatment for their primary molars. The method used was explained to the children's parents with its possible outcomes, advantages, and disadvantages, and then consent forms were collected from the parents before any intervention. All of the study has been approved by the Ethical Committee of National Research Centre, Cairo, Egypt. A total number of 60 deciduous molar teeth (26 first primary molars and 34 s primary molars) in 30 children (15 girls

and 15 boys) were randomly divided into three treatment groups: 2.5% NaOCl ($n=20$), 5% NaOCl ($n=20$), and formocresol ($n=20$). All the teeth met the following clinical and radiographic inclusion criteria.

Clinical criteria

- (1) The presence of deep carious lesions with a live pulp.
- (2) The absence of any symptoms indicating advanced pulpal inflammation.
- (3) Larger than pinpoint mechanical exposure of pulp.
- (4) Normal bleeding at the exposure site, or at least easily cessation of hemorrhage from the pulp stump within 5 min of amputation.
- (5) The teeth must not have any mobility, swelling, pain on percussion, sinus tract, and canal infection.
- (6) The structure of the tooth would be restorable with a stainless steel crown.

Radiographic criteria

The included molars must not have any internal or external resorption, furcation lesion, pulp stone, periapical lesions, periodontal involvement, and absence of any demonstrable pathology in the root pulp.

Random sequence generation was performed by G.A.S. using random.org. Allocation concealment was performed using eight folded pieces of paper in a dark sealed envelope. Implementation of randomization process was carried out by Y.M.F.

Clinical procedure

In all groups, the teeth were anesthetized with 2% lidocaine with 1 : 100 000 epinephrine (Astra, Westborough, Massachusetts, USA) as local anesthesia and isolated with a rubber dam. The caries was removed by a high-speed diamond fissure bur no. 330 (Brasseler USA, Savannah, Georgia, USA) under water spray in a high-speed handpiece (KaVo Dental Corp., Lake Zurich, Illinois, USA). Following removal of the pulp chamber roof, the coronal pulp tissue was removed by a round carbide bur size 0.25 (Brasseler USA) using a slow-speed handpiece (KaVo Dental Corp.). The hemostasis of coronal pulp was obtained using wet sterile cotton pellets under slight pressure for ~3 min to ensure that the radicular pulp tissue is healthy.

In the first group, the cotton moistened with 2.5% NaOCl, prepared by diluting Clorox bleach containing 5% NaOCl (The Clorox Co., 10th of Ramadan, Egypt) 1 : 1 in sterile H₂O, was applied to the pulp chamber for 5 min to perform fixation. The same procedure was done in the second group but with

the using of 5% NaOCl (The Clorox Co.). In the third group, 1 : 5 dilution of formocresol-saturated cotton (Sultan Chemical, Englewood, New Jersey, USA) was used, which was compressed twice between gauze to remove excess solution and placed for 5 min on amputated pulp stumps. In all groups, if bleeding continued, the tooth was excluded from the study.

After complete hemostasis, a thick mixture of zinc oxide eugenol paste (Caulk-Dentsply, Milford, Delaware, USA) was placed in the chamber of both groups. All teeth were restored with a stainless steel crown (3M ESPE, Saint Paul, Minnesota, USA) and cemented with glassionomer cement (Ketac Cem; 3M ESPE).

Follow-up

The clinical and radiographic evaluation was conducted at 3 and 6 months postoperatively. The chief investigator performed the clinical examination without immediate knowledge of which treatment had been carried out on which tooth. A tooth was rendered clinically successful if there is an absence of spontaneous pain, pain on percussion, pathological mobility, swelling, fistula, gum inflammation, or bleeding around the teeth or stainless steel crown and intact restoration. Moreover, the radiographic success was evaluated in case there were no widening of the lamina dura, no internal or external resorption, no inter-radicular bone destruction, and no calcification of canals (Fig. 1).

The same standard viewer box was used to examine all the radiographs by investigator who was blinded to the technique and who had been previously calibrated.

Data were analyzed using descriptive statistics and making comparisons between treatment groups on clinical and radiographic parameters. Proportions were compared using nonparametric Kurskal-Wallis test. Statistical significance was set at a *P* value of 0.05.

Results

At the 3-month follow-up, 93% (28/30) of the patients with 56 deciduous molars treated with vital pulpotomy came back for clinical and radiographic evaluations. (2.5% NaOCl=18, 5% NaOCl=20, and formocresol=18). In the 2.5% NaOCl group, of the 18 teeth evaluated in the first follow-up, eight were primary first molars and 10 were primary second molars. In 5% NaOCl groups, there were seven primary first molars and 13 primary second molars; however, in the formocresol group, nine primary first molars and nine primary second molars were evaluated.

At 6-month follow-up, 83% (25/30 patients) of the patients with 51 pulpotomized deciduous molars returned for further evaluation: 17 teeth in 2.5% NaOCl group (seven first deciduous molars and 10 second deciduous molars), 18 teeth in the 5% NaOCl group (six first deciduous molars and 12 second deciduous molars), and 16 in the formocresol group (eight first deciduous molars and eight second deciduous molars) (Table 1).

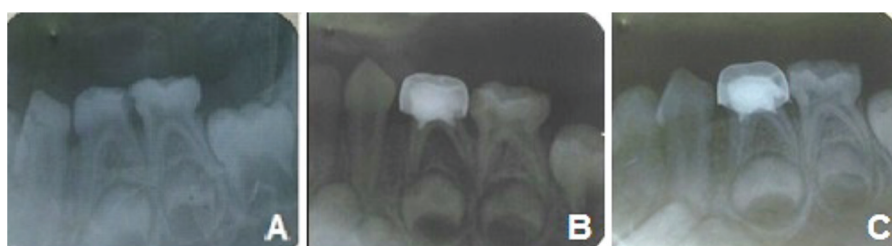
Clinical outcomes

At the 3-month follow-up, 100% (18/18) of 2.5% NaOCl, 100% (20/20) of the 5% NaOCl, and 100% (18/18) of the formocresol pulpotomies were clinically successful with no sign of swelling, mobility, fistula, or inflammation in the gingiva surrounding the tooth. At the 6-month follow-up, all pulpotomized dentitions in 2.5% NaOCl and formocresol were clinically successful, and no sign of failure was reported (Table 2). In 5% NaOCl group, inflammatory changes in the gingiva with bleeding around the crown were observed in two teeth (Table 3), but other teeth did not show any sign of pulpotomy failure.

Radiographic outcomes

At the 3-month follow-up, all pulpotomized teeth in 2.5% NaOCl group were successful regarding radiography. Radiographic changes were seen in 5%

Figure 1



Radiographic evaluation of 2.5% sodium hypochlorite (NaOCl) pulpotomy on lower first primary teeth. A) Preoperative radiograph, B) 3 month postoperative C) 6 month postoperative.

Table 1 Distribution of primary molars at 3- and 6-month follow-up

	3 months		6 months	
	First molar	Second molar	First molar	Second molar
2.5% NaOCl	8	10	7	10
5% NaOCl	7	13	6	12
Formocresol	9	9	8	8

NaOCl, sodium hypochloride.

Table 2 Clinical and radiographic results of 2.5% sodium hypochloride, 5% sodium hypochloride, and formocresol pulpotomy treatment outcomes at 3 and 6 months

	Clinical [n (%)]				Radiographic [n (%)]			
	3 months		6 months		3 months		6 months	
	Success	Failure	Success	Failure	Success	Failure	Success	Failure
2.5% NaOCl	18 (100)	0	17 (100)	0	18 (100)	0	16 (94)	1 (6)
5% NaOCl	20 (100)	0	16 (89)	2 (11)	19 (95)	1 (5)	16 (89)	2 (11)
Formocresol	18 (100)	0	16 (100)	0	17 (94)	1 (5.5)	14 (87.5)	2 (12.5)

Table 3 Distribution of types of failure on different treatment groups (2.5% sodium hypochloride, 5% sodium hypochloride, and formocresol)

	Clinical evaluation			Radiographic evaluation		
	2.5% NaOCl	5% NaOCl	Formocresol	2.5% NaOCl	5% NaOCl	Formocresol
Pain	0	0	0	–	–	–
Mobility	0	0	0	–	–	–
Swelling	0	0	0	–	–	–
Inflammation	0	2	0	–	–	–
Internal resorption	–	–	–	1	3	1
External resorption	–	–	–	0	0	0
Furcation involvement	–	–	–	0	0	2

(1/20) of the 5% NaOCl and 5.5% (1/18) of the formocresol pulpotomy treatment groups (Table 2). Both of the failure teeth have internal resorption (Table 3). At the 6-month follow-up, pathological changes in the periapical radiograph were detected in 6% (1/17) of the 2.5% NaOCl, 11% (2/18) of the 5% NaOCl, and 12.5% (2/16) of the formocresol pulpotomy treatment groups (Table 2). Three of these failures were associated with internal resorption (one with 2.5% NaOCl; two with 5% NaOCl), and a furcation involvement was associated with two formocresol failure teeth (Table 3).

No significant differences were found in the clinical and radiographic outcomes among the three groups (2.5% NaOCl, 5% NaOCl, and formocresol) ($P>0.05$).

Discussion

An effective pulpotomy medicament must gain physiologic compatibility between pulp and surrounding tissues and result in clinical and radiographic success. Formocresol has great fixative properties and also has the possibility of mummifying a broad zone of remaining pulpal tissue after removal of coronal infected pulp; this results in high success rate for the tooth treated

with this medicament [16]. However, formocresol pulpotomy demonstrated an increase in chromosomal breaks and aberrations in the peripheral lymphocytes indicating that it has a mutagenic effect on the pediatric patient. Furthermore, a pulp tissue of primary teeth is rich with undifferentiated stem cells which in the presence of formaldehyde demonstrated a high tendency for mutagenesis [17]. Because of this mutagenic and carcinogenic potential, the American Association of Endodontics in 1998 published a report that restricted the use of paraformaldehyde-containing filling materials or sealers for endodontic purposes. Many medicaments have been evaluated, with variable cost and success rate, as an alternative for formocresol [18]. NaOCl was first used during the World War I as an antiseptic for cleaning wounds before the introduction of antibiotics [19]. Since then, it has been successfully used as an irrigant in endodontic treatment. NaOCl has been verified to be biocompatible and nonirritating to exposed pulpal tissue [6].

Rosenfeld *et al.* [20] and Hafez *et al.* [21] demonstrated that the application of NaOCl selectively digested the superficial necrotic three or four layers of pulp tissue while maintaining the vitality of the deeper layers. It can clean bacteria, superficial inflamed tissue, and

dentine debris from the exposure site. Ranly [5] and Chompu-Inwai *et al.* [22] reported that hemostasis is best achieved with NaOCl irrigant. All of these findings support the use of NaOCl as a medical agent for pulpotomy in primary teeth. A high success rate with the use of NaOCl as pulpotomy medicament ranging from 82 to 100% was demonstrated by various studies [22,23]. From the histological point of view, Haghgoo and Abbas [24] noted pulp regeneration and also dentin bridge formation following NaOCl pulpotomy.

This randomized clinical trial study was performed to compare the clinical and radiographic outcome of vital pulpotomy treatment in deciduous molars using 2.5% NaOCl, 5% NaOCl, and formocresol. The results of this study regarding the use of 5% NaOCl as a medicament for vital pulpotomy treatment demonstrate that the clinical success rates at 3 and 6 months were 100 and 89%, respectively, and the radiographic success rates at 3 and 6 months were 95 and 89%, respectively. The most common pathologic finding reported in this study with the use of 5% NaOCl for pulpotomized primary teeth is internal root resorption. A similar clinical randomized study was done by Vargas *et al.* [25] after using 5% NaOCl as a primary molar pulpotomy agent. Their study reported 100 and 91% clinical and radiographic success rates, respectively, at 6-month follow-up and 100 and 79% clinical and radiographic success rates, respectively, at 12-month follow-up. Radiographic failure in their study was internal root resorption. Another randomized study was done by Al-Mutairi and Bawazir [26] that reported 95 and 87.5% clinical and radiographic success rates, respectively, after 6-month follow-up using of NaOCl as a pulpotomy medicament. Moreover, the internal resorption is the most popular radiographically evident failure.

Jabarifar *et al.* [4] reported the clinical and radiographic success rates of pulpotomy by 5% NaOCl to be 100 and 93.3%, respectively, in the 6-month follow-up. The highest rate of therapeutic failure was reported for furcation involvement as widening of periodontal ligament space. In a recent retrospective study done by Li *et al.* [27], the 5% NaOCl pulpotomies demonstrate a clinical success rates of 100, 97, and 97% at 6, 12, and 24 months, respectively. The radiographic success rate were 99, 89, and 77%, respectively. Internal root resorption was still the most common pathologic change found in the radiographic analysis. Regarding the use of 2.5% NaOCl as a medicament for vital pulpotomy treatment, the result of this study showed that the

clinical success rates were 100% at 3- and 6-month follow-up, and the radiographic success rates at 3 and 6 months were 100 and 94%, respectively. Internal root resorption was the most common pathologic finding reported with the use of 2.5% NaOCl.

The concentration of less than 5% of NaOCl was less investigated by the researchers. Only two studies worked with the concentration of 3% or less NaOCl. The first study was done by Vostatek *et al.* [3] The authors used a concentration of 2.5% NaOCl in pulpotomy treatment for 131 deciduous molars over an average time of 10.5 months. They revealed 95% clinical and 82% overall radiographic success rates.

On the contrary, Ruby *et al.* [2] investigated the success rate of 3% NaOCl in comparison with formocresol. They reported 100% clinical success rate at 6 and 12 months follow-up whereas the radiographic success was 86% at 6 months with NaOCl and 80% at 12 months. Meanwhile, this study reported internal resorption as the main reason for failure in three cases and furcation involvement was reported in the other three cases.

The results of this study showed that no significant difference was observed between the clinical and radiographic findings in deciduous molar pulpotomy using 2.5% NaOCl, 5% NaOCl, and formocresol in the 3- and 6-month follow-up. This was in agreement with Chompu-Inwai *et al.* [22], Ruby *et al.* [2], Al-Mutairi and Bawazir [26], and Jabarifar *et al.* [4].

Conclusion

There are no clinical and radiographic differences found when using 2.5 NaOCl, 5% NaOCl, and formocresol in primary molars pulpotomy. Moreover, 2.5% NaOCl is as effective as 5% NaOCl, so it could be used safely as a clinical replacement of formocresol in the treatment of pulpal-involved primary molar teeth.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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