Formocresol versus Calcium Hydroxide Direct Pulp Capping of Human Primary Molars: Two Year Follow-Up

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Objectives: *Clinical and radiographic evaluation of the premedicated direct pulp capping using formocresol (PDC) versus conventional direct pulp capping using calcium hydroxide (CDC) in human carious primary molars.* ***Study design:*** *A total of 120 vital primary molars with pinpoint exposure during caries removal in 84 patients aged 4-5 years were selected. In the PDC group (n = 60), 20% Buckley's formocresol solution, and in the CDC group (n = 60), calcium hydroxide powder were applied to the exposure sites followed by placement of zinc oxide-eugenol base. Teeth were restored with preformed stainless steel crowns. Clinical and radiographic evaluations of the treatment outcomes were performed at regular intervals of 6 and 12 months, respectively, for two years post-operatively.* ***Results:*** *The prevalence of spontaneous pain, sensitivity on percussion, and fistula were significantly higher in the CDC group compared to the PDC group ($P < 0.05$). The number of teeth exhibiting periapical/furcal radiolucency or external/internal root resorption was also higher in the CDC group ($P < 0.05$). The clinical success rate of the PDC was 90% compared to the 61.7% of the CDC ($P < 0.05$). The radiographic success rates of the PDC and CDC groups were 85% and 53.3%, respectively ($P < 0.05$).* ***Conclusion:*** *It seems formocresol premedicated direct pulp capping could safely be used as a substitute for conventional direct pulp capping.*

Keywords: *Calcium hydroxide, direct pulp capping, formocresol, primary molar.*
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INTRODUCTION

The aim of direct pulp capping (DPC) is to preserve as much pulp vitality as possible through encouraging the young healthy pulp to initiate a dentin bridge at the exposure site.[1] However, direct pulp capping in the primary dentition has been shown to be less successful than pulpotomy, despite the ability of the vital primary pulp tissue to heal without radical pulp therapy.[2] One explanation may be the existence of undifferentiated mesenchymal cells in the primary pulp which may become odontoclasts, leading to the internal resorption.[1,2] In addition, the procedural considerations have been proposed to contribute to a poor success rate.[1]

A variety of materials may be used to cap the pulp including calcium hydroxide, zinc oxide-eugenol cement, corticosteroids, antibiotics, polycarboxylate cements, inert materials, collagen fibers, and eventually cytokines.[2-6] Nonetheless, calcium hydroxide has yielded the best overall success, ranking it as the gold standard material for DPC.[1] However, the clinical success rate of calcium hydroxide in primary teeth is well below that of permanent teeth, possibly because of microleakage as well as induction of internal resorption.[1,4,7-9] Presence of tunnels in dentin barrier, extensive dentin formation obliterating the pulp chamber, high solubility in oral fluids, and lack of adhesion and degradation after acid etching are other problems associated with calcium hydroxide or its compounds.[10-12]

The high success rate of pulpotomy in primary dentition calls forth a tempting scenario; is it plausible to use formocresol in DPC of primary dentition? The rationale behind this proposed modality is that the pulp inflammation is often confined to the exposure site at the coronal pulp and a modified less invasive variant of the pulpotomy may be sufficient. This treatment modality, which could be called "micropulpotomy", replaces calcium hydroxide cement, as an incriminated agent of DPC failure, with zinc oxide-eugenol dressing. Moreover, when the pulp is medicated with formocresol at the exposure site, there is no virtual contact of the capping material with the vital pulp.[13] The purpose

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of the present study was to investigate the clinical efficiency of this proposed treatment modality using formocresol direct pulp capping and zinc oxide-eugenol sealing versus conventional DPC technique using calcium hydroxide in human primary molars.

MATERIALS AND METHOD

Study population

The subjects were selected for this randomized clinical trial from 4–5 year-old children attending the Department of Pediatric Dentistry at Tabriz University of Medical Sciences School of Dentistry, Tabriz, Iran, according to the following criteria:

1. Complete physical and mental health without any confounding medical history
2. No history of spontaneous pain in teeth
3. No pathologic tooth mobility
4. Normal gingival and periodontal condition, without signs of pathology such as redness and swelling of the vestibulum, draining sinus tracts or sensitivity to palpation in the vestibule
5. Teeth deemed restorable with a stainless steel crown
6. Absence of furcal/periapical radiolucencies or any pathologic root resorption
7. No pathology of the succedaneous permanent teeth follicles

The study procedure, possible discomforts or risks, as well as possible benefits were explained completely to the parents/legal guardians, and an informed consent form was obtained and recorded. This study was approved by the Ethics Committee and Research Council of the Tabriz University of Medical Sciences.

Study procedure

Primary molars with deep caries and risk of pulp exposure during caries removal were randomly allocated by coin tossing to either of formocresol-premedicated direct pulp capping (PDC) or conventional direct pulp capping (CDC) groups.

After administration of local anesthesia, teeth were isolated with rubber dam and dried with sterile gauze pads. Undermined enamel and peripheral caries were excavated using a high-speed water-cooled air motor and round and fissure diamond burs. Soft, mushy carious tissue was removed manually with an excavator. All remaining caries from the cavity margins and pulpal floor were removed with a steel round bur running at slow speed. Only those teeth were included in the study that a small exposure occurred accidentally during their final preparation (true pinpoint carious exposure surrounded by sound dentin) and showed no bleeding or purulent/serous exudate at the exposure site. Sterile physiological saline was delivered by a syringe and needle to wash away dentin debris.

Once hemostasis was achieved, in the PDC group, a cotton pellet dampened with 20% Buckley's formocresol solution (19% formaldehyde, 35% tricresol, 15% glycerin, 31% water) was placed in contact with the pulp at the exposure site for 5 min. A 2-mm thick paste of zinc oxide-eugenol base (Kalzinol DeTrey®, Onstanz, Germany) was placed to seal the coronal pulp, and allowed to set.

In the CDC group, calcium hydroxide powder[14] was delivered to the exposure site using small endodontic amalgam carrier (PD Messing root canal Gun®; Produits Dentaires SA., Vevey, Switzerland). The powder was gently packed over the pulp at the exposure site with an amalgam condenser and small pellets of cotton wool. Excess agent was meticulously removed from cavity walls with an excavator. Teeth in this group were also sealed with a 2-mm thick zinc oxide-eugenol base.

A preformed stainless steel primary molar crown (Ion 3M Dental Products®; Loughborough, Leicestershire, UK) was fitted and cemented in place using glass-ionomer cement (GIC®; Ketac, 3M-ESPE AG, Seefeld, Germany). Occlusal contacts were checked and adjusted.

Follow-up

Patients were recalled at six-month intervals for a two-year period. The clinical examination was accomplished at each recall. The radiographic evaluation was performed two times at intervals of 12 months for both groups with a size 0 periapical film using the bisecting angle technique. Objectivity was maximized during both clinical and radiographic assessments by not having direct access to records detailing which pulp therapy agent was used. Teeth in both groups were evaluated by one examiner (NAA) for the presence or absence of the following findings:

- Clinical criteria including symptoms of the treated tooth reported by the child or their parents: spontaneous pain, or pain initiated by stimuli; signs of a defective restoration or recurrent caries; signs of mobility, sinus formation, tenderness to percussion, or soft tissue swelling; and signs of exfoliation, mobility or signs/symptoms of the successor tooth erupting.
- Radiographic criteria including defective restoration or recurrent caries; periradicular pathology such as periapical or furcal radiolucency; and pathological internal resorption, replacement resorption, intracanal calcifications, or physiological resorption

The authors evaluated a set of radiographs separately to calculate the inter-examiner reliability of radiographic assessments. In addition, at regular time intervals some radiographs were re-evaluated by the same observer to examine for intra-examiner reliability of data. The clinical and radiographic signs of failure were documented on the data form. The treatment was deemed successful if any of the clinical/radiographic signs of the failure were not present.

Statistical analysis

Intra- and inter-examiner agreement of data for radi-

ographic assessment was evaluated by Cohen's kappa statistics. The two-sample proportional test was used to compare the study outcomes in the CDC and PDC groups. $P < 0.05$ was considered statistically significant.

RESULTS

A total of 120 teeth in 84 patients (mean age, 4.35 years old) were allocated to PDC (n = 60) and CDC (n = 60) groups.

Clinical assessment of treatment outcomes

The results of clinical assessments are presented in Table 1. The prevalence of nocturnal and spontaneous pain showed an increasing trend. The between-group difference in spontaneous pain was not statistically significant during the first recall visit ($P > 0.05$). However, at the subsequent follow-ups, the number of teeth in the CDC group with a history of spontaneous pain was significantly more than the PDC group ($P < 0.05$). Two teeth from CDC group had to be extracted due to spontaneous pain history before first and second follow-up visits and were included in the clinical assessment of the treatment outcomes as failures. While the sensitivity to percussion was consistently higher in the CDC group, the significant between-group difference was observed at 18 and 24 months post-operatively ($P < 0.05$). A similar tendency was observed in the prevalence of fistula. The prevalence of fistula at follow-up visits in the CDC group was higher than the PDC group, with statistically significant differences observed only in the third follow-up ($P < 0.05$).

Radiographic assessment of treatment outcomes

Table 2 shows the results of radiographic assessment of treatment outcomes. The inter-examiner reliability of data for the radiographic assessment was 0.82. Kappa coefficient for intra-examiner agreement of data was 0.93. In the CDC group, periapical-furcal radiolucency increased significantly within-group from 12 to 24 months post-operatively ($P < 0.05$). While the between-group difference in the prevalence of periapical-furcal radiolucency was not significant in the first recall ($P > 0.05$), the number of teeth exhibiting radiolucency in the CDC group was substantially higher than the PDC group at the second visit ($P < 0.05$).

Treatment success

The treatment success rate was estimated based on the clinical and radiographic examination results at the final follow-up visit (Table 3). The clinical and radiographic success rates of the CDC were 61.7% and 53.3%, respectively. Regarding PDC, clinical and radiographic success rates were 90% and 85%, respectively. Both the radiographic and the clinical success rates of the PDC were superior to those of the CDC ($P < 0.05$).

DISCUSSION

The aim of the present study was clinical and radiographic assessment of long-term therapeutic outcomes of conventional direct pulp capping (CDC) and formocresol-premedicated direct pulp capping (PDC) of vital primary molars. According to the results, two-year clinical and

Table 1. Clinical assessment of the treatment outcomes in conventional (CDC) and premedicated direct pulp capping (PDC) groups.

Criteria	6 months n (%)	12 months n (%)	18 months n (%)	24 months n (%)
Spontaneous pain				
CDC	8 (13.3)	11 (18.3)	12 (20)	17 (28.3)
PDC	2 (3.3)	3 (5.0)	6 (10.0)	8 (13.3)
Pain/sensitivity on percussion				
CDC	3 (5.2)	4 (6.9)	7 (12.1)	8 (13.8)
PDC	0 (0.0)	0 (0.0)	1 (1.7)	2 (3.3)
Parulis/fistula				
CDC	3 (5.2)	5 (8.62)	8 (13.8)	9 (15.5)
PDC	0 (0.0)	2 (3.3)	3 (5.0)	5 (8.3)

Table 2. Radiographic assessment of the treatment outcomes in conventional (CDC) and premedicated direct pulp capping (PDC) groups.

Criteria	12 months n (%)	24 months n (%)
Furcation/periapical radiolucency		
CDC	4 (6.6)	10 (16.6)
PDC	1 (1.66)	2 (3.30)
External/internal root resorption*		
CDC	10 (16.6)	14 (23.3)
PDC	3 (5.00)	7 (11.6)

*Progressive internal root resorption with no signs of healing process during two years follow-up

Table 3. Clinical and radiographic outcomes of conventional (CDC) and premedicated direct pulp capping (PDC) in the two-year follow-up.

Criteria	Success n (%)	Failure n (%)
Clinical outcome		
CDC	37 (61.7)	23 (38.3)
PDC	54 (90)	6 (10)
Radiographic outcome		
CDC	32 (53.3)	24 (40.0)
PDC	51 (85)	9 (15)

radiographic outcomes of the PDC are superior to those of the CDC in vital primary molars.

The clinical success rate of the PDC in the present study equaled 90%. The findings of our study are in agreement with previous studies reporting a 97% clinical success rate in formocresol premedicated direct pulp capped primary molars after six months.[1] Garcia-Godoy[15] used a paste of one fifth diluted formocresol mixed with a zinc oxide-eugenol paste as a medicament in direct pulp capping of primary molars and reported a 96% clinical and radiographic success rate. An animal study has demonstrated the absence of inflammation when the exposure site is medicated with formocresol and capped with a mixture of formocresol and zinc oxide-eugenol cement.[16]

The success rate of conventional direct pulp capping in primary teeth has been estimated to be 75%.[8] The clinical success rate of CDC was found to be 61.7% in the present study. In line with our findings, Frank *et al* [17] presented convincing proof that direct pulp capping of primary teeth using calcium hydroxide is the least desirable treatment modality.

In the present study, the radiographic evaluation revealed a success rate of 53.3% and 85% for CDC and PDC groups, respectively. These values are significantly lower than those of the clinical evaluations. This implies the clinical evaluation of the therapeutic outcome is not sufficient for determining the success rate in pulp therapy of primary teeth, and that concomitant radiographic evaluation is necessary.

The most common pathologic finding in PDC and CDC groups of the present study was spontaneous pain followed by internal/external root resorption. Contrary to this, many authors have referred to root resorption as the most common pathologic reaction of primary teeth to pulp therapy.[2,3,8,9]

While 3.3% of the teeth in the CDC group were extracted due to pathologic sequel, no similar finding was observed with teeth in the PDC group. Admittedly, all signs and symptoms of failure were more abundant in the CDC group when compared to the PDC group. However, the radiographic findings more clearly highlight the difference in therapeutic outcome compared to clinical evaluation.

It is interesting to note that a similar scenario exists with the use of calcium hydroxide versus formocresol in a pulpotomy procedure. Calcium hydroxide has been proposed as an alternative to formocresol for pulpotomies in primary teeth.[18] Published data report a higher success rate of formocresol pulpotomies compared to the calcium hydroxide pulpotomy methods.[19,20] The use of calcium hydroxide as a pulp dressing material in pulpotomized primary teeth has been discontinued,[9] and it seems the main drawback of this alternative intervention is internal resorption, which is thought to be stimulated by calcium hydroxide.[18]

A number of theories have been proposed to explain the high failure rate of vital pulp treatment using calcium hydroxide in primary teeth. The observed resorption has been attributed to the presence of a blood clot preventing the contact between the capping material and the pulp tissue. Various unsuccessful attempts have been made to prevent the formation of an extrapulpal blood clot; these approaches included minimizing the trauma to major pulp vessels and the resultant clots by performing a partial pulpotomy,[21,22] using a hemostatic agent prior to the placement of calcium hydroxide,[23,24] and pulp amputation by electrocoagulation.[23]

Another explanation for the high failure rate of direct pulp capping relates to the pulp histology and physiology of primary teeth and their response to irritation, infection and trauma. The undifferentiated mesenchymal cells in the primary pulp may differentiate into odontoclasts, leading to internal resorption.[3] One can speculate that the use of formocresol can substantially reduce pulp inflammation,[16] and may prevent the differentiation of mesenchymal cells in the primary pulp through suppression of the inflammatory signaling molecules necessary for differentiation.

It seems the exposed vital primary pulp tissue is capable of healing without resorting to invasive treatment modalities such as pulpotomy. We propose the use of the term "micropulpotomy", as opposed to the conventional pulpotomy, for the procedure of formocresol premedicated direct pulp capping. Future studies may be directed towards the histological and ultrastructural evaluation of these two therapeutic approaches.

It must be kept in mind that, in cases with deep caries, indirect pulp capping should be considered as the preferred treatment modality. Direct pulp capping should be reserved for cases where despite all the efforts to avoid an exposure, an accidental pinpoint opening of the pulp occurs. Considering the unfavorable outcome of direct pulp capping in primary teeth, the present study was designed to evaluate the effectiveness of a modification in the procedure. Based on the results of the present study, it can be concluded that formocresol premedicated direct pulp capping (micropulpotomy) of vital primary molars can safely be used as a substitute for conventional direct pulp capping of these teeth without compromising the final therapeutic outcomes. However, close attention to rigid criteria for case selection and meticulous performance of the procedure appear to be prerequisites for successful treatment.

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