A Clinical Study of Formocresol Pulpotomy versus Root Canal Therapy of Vital Primary Incisors

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Objectives: *Pulpotomy of primary incisors is a serious challenge due to the lack of a distinct boundary between the coronal and the radicular pulp and the inaccuracy of the clinical indication criteria. The aim of the present study is the clinical and radiographic evaluation of pulpotomy versus root canal therapy (RCT) of vital primary incisors.* ***Study design:*** *A total of 100 incisors in 50 patients (female: 27, male: 23) aged 3-4 years were allocated to formocresol pulpotomy (45 teeth) and RCT (46 teeth) using zinc oxide-eugenol. The radiographic and clinical evaluation of treatment outcomes was performed at 12 and 24 months post-operatively. A history of spontaneous pain, missing restorations, recurrent caries, mobility and percussion sensitivity, parulis or fistula, erythema, and swelling were recorded. Data analysis was performed based on two sample proportional test.* ***Results:*** *The clinical success rate was 86.9% for pulpotomy and 95.6% for RCT (P>0.05). The radiographic assessment exhibited no pathologic signs in 76.08% of pulpotomy group and 91.3% of RCT group and the difference was statistically significant (P<0.05). The most common pathologic finding was periodontal widening followed by external/internal root resorption. Periapical radiolucency and fistula in pulpotomized teeth was significantly higher than in RCT-treated teeth (P<0.05)* ***Conclusions:*** *It may be concluded that the root canal therapy of vital primary incisors may be efficiently substituted for the pulpotomy of these teeth.*

Keywords: *pulpotomy, root canal therapy, primary incisor.*
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INTRODUCTION

Primary dentition is usually affected by dental caries due to a myriad of reasons ranging from anatomical vulnerability to the lack of manual dexterity.[1] For instance, early childhood caries is still considered a serious challenge for clinicians due to the considerable loss of tooth structure. On the other hand, premature loss of the primary dentition may lead to space maintenance problems, phonetic alterations, reduced masticatory force, and development of parafunctional habits.[2,3] Therefore, modern pediatric dentistry seeks to preserve primary teeth maintaining its developmental, esthetic, and functional capabilities.[4,5] Pulp therapy is one such measure performed to prevent extraction of carious or traumatized primary teeth where strict contraindications like the involvement of permanent tooth bud or severe suppuration do not exist.[5-7]

Root canal therapy and pulpotomy may be performed in primary incisors with pulpal involvement. Pulpotomy is indicated for those teeth exhibiting signs of coronal pulp inflammation and viable radicular pulp. However, pulpectomy is usually performed for those teeth with coronal pulp necrosis or chronic inflammation.[8] The choice of the proper technique is based on the histological status of the dental pulp, determined by a clinical and radiographic judgment.[9-11] However, correlating the histological pulpal status with the clinical/radiographic findings can be conflicting as both clinical and radiographic decisions reveal certain limitation and inaccuracies compromising the proper choice of the technique. The inability to delineate the boundary of the coronal and radicular pulp in the primary incisors complicates the pulpotomy of these teeth. Moreover, the tortuous root canals of primary molars are rarely encountered in primary incisors. Further evidence supporting the root canal

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therapy of primary incisors comes from the long-term studies of Spedding.[16] On the other hand, traumatic amputation of the coronal pulp, mechanical pressure on incompletely removed coronal pulp and poor diagnosis have been mentioned as important causes for the clinical failure of a pulpotomy.[17] For these reasons root canal therapy in primary incisors instead of pulpotomy have been suggested by some authors.[9-11, 14]

Only a few studies have investigated the clinical efficacy of formocresol pulpotomy versus root canal therapy of the primary incisors.[11] Considering the importance of the issue and the high success rate of the root canal therapy of primary teeth,[7,9,12] the present study aimed at long-term assessment of clinical and radiographic success of conventional formocresol pulpotomy compared to root canal therapy of vital primary incisors.

MATERIALS AND METHODS

Study population

50 children (27 female and 23 male) aged 3-4 years and without any confounding past medical history were included in the present randomized clinical trial. The selected children were categorized as cooperative (Frankel's class IV). The subjects had two or more carious vital primary maxillary incisors where exposure of the vital pulp following the removal of dental caries was inevitable. The procedure, possible discomforts or risks, as well as possible benefits were explained completely to the parents or legal guardians, and an informed consent form was obtained and recorded. This study was approved by the ethical and research committees of the Tabriz University of Medical Sciences.

Periapical radiographs were taken for the each primary incisor that was likely to have a carious pulp exposure. The inclusion criteria for the selected teeth included:[14]

Vital tooth without any history of spontaneous pain, pain on percussion, fistula, and sinus tract

Lack of suppuration from root canals

The selected teeth did not pose a serious challenge for the restoration of the crown

No physiological and pathological root resorption, periapical radiolucent lesions, or pulpal calcification

For each patient, by coin tossing, if one tooth was randomly assigned for formocresol pulpotomy then root canal therapy (RCT) was performed on the other incisor. The evaluation of the treatment outcomes was performed at 12 and 24 months post-operatively.

Of 50 patients, 4 of them did not return for at least one evaluation session and therefore were ruled out from the study. The final study sample consisted of 46 patients for whom clinical and radiographic data were available for analysis at the 2 year reassessment.

One pediatric dentist completed all the treatments over a 15 weeks period. Two clinicians who did not perform any treatments analyzed the clinical and radiographic outcomes.

Formocresol pulpotomy procedure

The formocresol pulpotomy procedure was performed conventionally. All pulpotomy and RCT treatments were completed in one session. After the induction of local anesthesia (Xylocaine® 2%, Epinephrine 1/100000, (Dentsply), a rubber dam was placed to isolate the operative field. Access to the pulp chamber was achieved using a sterile #56 fissure bur mounted in a high-speed handpiece and then refined with round burs with a low-speed handpiece. During access cavity preparation and prior to pulpal exposure, all remaining dental caries as well as undermined enamel pieces were eliminated. The entire roof of pulp chamber and overhanging dentinal remnants over the pulp horns were removed. After the completion of the access cavity, coronal pulp was extirpated using a sharp excavator. Then, the pulp chamber was irrigated with a light flow of sterile 0.9% NaCl-solution and a sterile saline-impregnated cotton pellet was placed over the amputated pulp for 5 minutes to assist in the clotting procedure. If the bleeding had not stopped after the initial application of the cotton pellet, the incisor was eliminated from the study. Subsequently, a formocresol-impregnated cotton pellet (Buckley's 1.5% solution) was gently applied to the radicular pulp for 5 minutes. If hemostasis was achieved, the pulp chamber was sealed using a fortified ZOE mixture (Caulk®, USA). Thereafter, a glass ionomer base (Dentsply®, USA) was applied and the incisor was immediately restored with a self-cure resin restoration.

Root canal therapy procedure

The RCT technique, used herein, was described by Payne *et al*.[11] After the induction of local anesthesia (Xylocaine® 2%, Epinephrine 1/100000, (Dentsply), a rubber dam was placed to isolate the operative field. Access to the pulp chamber was achieved using a sterile #56 fissure bur mounted in a high-speed handpiece and then refined with round burs in low-speed handpiece. An estimated working length, 2 mm short of the primary diagnostic radiographic length, was measured. After negotiating the root canals, an initial endodontic K-file (MANI®, Japan) was introduced to the estimated working length and a second radiography was taken. The endodontic file, proceeding to the estimated working length while fitting snugly in the canal, was used as the initial endodontic file. Subsequently, the corrected working length (CWL) was determined. Cleaning of the canals was started from the initial file working to the CWL with a filing motion. In most cases, the pulp tissue was removed completely on the first attempt. If the first attempt was unsuccessful, the procedure was repeated and canals were generally enlarged three sizes past the initial file to eliminate the organic remnants. Copious irrigation with a light flow of sterile 0.9% NaCl-solution was used throughout the procedure. At the end, the canals were dried using paper points. Using a pressure syringe and starting at 2 mm from the apex, the canals were filled with ZOE and the orifice areas were packed with a stiffer mix of ZOE (Caulk®, USA). The remainder of pulp chamber was filled with restorative glass ionomer (Dentsply®, USA) and the incisor was immediately restored with a self-cure resin restoration.

Clinical and radiographic evaluation

The clinical and radiographic examination was performed on all primary incisors during the follow-up visits at 12 and 24 months post-operatively. The subjects were asked to report any post-operative history of spontaneous pain related to the treated incisors. Moreover, the following signs were recorded for the treated teeth: missing restoration, recurrent caries, mobility and percussion sensitivity, parulis or fistula, erythema, and swelling.

The radiographs were taken with a size 0 periapical film using the bisecting angle technique. The quality of radiographs was checked for proper contrast, non-distortion, magnification and clarity of the teeth and adjacent osseous structure. The observers evaluated a set of radiographs separately to calculate the inter-examiner reliability of radiographic assessments. Moreover, at regular time intervals some radiographs were re-evaluated by the same observer to examine for intra-examiner reliability of data. The observers were blind to the method of study and just examined the prepared radiographs with reference to the following criteria:

- Periapical radiolucency;
- Presence of widened periodontal ligament space;
- Pulp canal obliteration;
- Pathologic internal or external root resorption.

Data analysis

Intra- and inter-examiner agreement of data for radiographic assessment was evaluated by Cohen's kappa statistics. The two sample proportional test was used to compare the study outcomes in the pulpotomized and root canal-treated teeth. In the present study $P<0.05$ was considered statistically significant.

RESULTS

At the two-year follow-up 46 subjects (91 incisors) were available. 45 teeth were treated using formocresol pulpotomy and the root canal treatment was performed in 46 incisors. Only one pulpotomized incisor had to be extracted and no similar case was encountered in the RCT group.

Inter- and Intra-examiner reliability

The inter-examiner reliability of data for the radiographic assessment was excellent (Kappa coefficient=0.71). Kappa coefficient for intra-examiner agreement of data was 0.91.

Clinical assessment of treatment outcomes

Table 1 present the results of the clinical examination. Individuals with pulpotomized teeth reported spontaneous and nocturnal pain in two teeth (4.4%). One incisor with spontaneous pain had been extracted previously and was not available. The clinical examination of the pulpotomized teeth revealed that pain on percussion was present in one incisor (2.2%) and fistula in three incisors (6.6%).

Individuals with pulpectomized teeth, reported spontaneous pain in one tooth and pain on percussion was present in another incisor. No fistula or parulis were observed in the RCT group.

Table 1. Clinical and radiographic signs of treatment failure.

	Pulpotomy		RCT	
Pathologic findings	no.	percent	no.	percent
Spontaneous pain	2	4.34	1	2.17
Pain/sensitivity on percussion	1	2.22	1	2.17
Parulis/fistula	3	6.66	0	0
Furcation/periapical radiolucency	5	11.11	1	2.17
External/internal root resorption	6	13.33	2	4.34
Post-operative extraction	1	2.17	0	2.17

Table 2. Clinical outcome of pulpectomy and RCT at two-year follow-up.

	Success		Failure	
Treatment	no.	percent	no.	percent
Pulpotomy	40	86.9	6	13.04
Pulpectomy	44	95.6	2	4.3

Table 3. Radiographic outcome of pulpectomy and RCT at two-year follow-up.

	Success		Failure	
Treatment	no.	percent	no.	percent
Pulpotomy	35	76.08	11	23.9
Pulpectomy	42	91.3	4	8.6

While there was not a significant difference regarding the history of spontaneous pain or pain on percussion, the presence of fistula was significantly higher in the pulpotomized teeth ($P<0.05$). In the radiographic examination, periapical radiolucency in the pulpotomized teeth (11.11%) was significantly higher compared to the pulpectomized teeth (2.17%) ($P<0.05$).

Pathologic external or internal root resorption was encountered in 13.3% of the pulpotomized incisors and 4.34% of the RCT group. However, the difference was not significant.

Through the clinical and radiographic examination, the treatment success was estimated. The clinical and radiographic success of RCT was 95.6 % and 91.3%, respectively. The clinical success of pulpotomy was 86.9% and the radiographic success equaled 78.07%.

While the difference in clinical success of treatment protocols did not reach statistical significance ($P>0.05\%$), the radiographic success of RCT was superior to that of pulpotomy ($P<0.05$).

DISCUSSION

The aim of the present study was the clinical and radiographic assessment of long-term therapeutic outcomes of formocresol pulpotomy and root canal therapy of vital primary incisors. Our findings indicate that the long-term outcomes of the RCT are superior to that of the pulpotomy with reference to the clinical and radiographic success criteria.

One limitation of the present study is the narrowing of the inclusion criteria, which enhances the internal validity of findings at the expense of decreasing the external validity. Therefore, the conduction of large-scale multi-centered clinical trials with more broad criteria for the selection of study sample seems necessary.

The clinical success rate of the RCT in the present study equaled 95.6%. Casas *et al*.[14] reported a success rate of 82% for the vital primary incisor RCT. The success rate of the primary teeth root canal therapy has been estimated at 90% by Payne *et al*.[11] and 76% by Primosch *et al*.[4] However, the failure rate of 4.4% for the vital primary incisor RCT was substantially less than 20% and 22% failure rates of nonvital primary teeth RCT as demonstrated by Reddy *et al*. and Coll *et al*., respectively.[12]

In the present study, the clinical success rate of 86.9% was estimated for the pulpotomy of the vital primary incisors. This percentage is higher when compared to the study reported by Casas *et al*.[14] reporting a success rate of 78%. Other similar studies showed success rates for the pulpotomy of primary teeth ranging from 67% to 100%.[18]

The radiographic evaluation of the therapeutic outcomes revealed a success rate of 76.08% and 91.3 % for pulpotomy and RCT, respectively. These values are significantly lower than those revealed through clinical approaches. The implication is that the clinical evaluation of therapeutic outcomes of pulpal therapy of the primary teeth is not sufficient for determination of the success rate and concomitant radiographic evaluation is necessary for verification of the results. Previous studies have reported the radiographic success rate ranging from 59% to 100% for the pulpotomy of primary teeth.[18]

The most common pathologic finding for the pulpotomized and pulpectomized teeth was widened periodontal ligament (in 45% of the pulpotomized and 13% of the RCT teeth) followed by internal/external root resorption (in 13.33% of the pulpotomized and 4.34% of the RCT teeth). This finding is in agreement with the findings reported by Casas *et al*.[17] However, some authors mention the internal/external root resorption as the most common pathologic reaction of primary teeth to pulp therapy.

Periapical radiolucency in the pulpotomized teeth appeared more frequently than in the RCT-treated teeth (11.11% versus 2.17%). Moreover, while fistula formation was evident in some of the pulpotomized teeth, no similar finding was observed in the pulpectomized teeth. Admittedly, all signs and symptoms of failure in the pulpotomized teeth were more evident than in the RCT teeth. However, the radiographic findings more clearly highlighted the difference in the therapeutic outcomes compared to the clinical evaluation.

Future studies may be directed towards the evaluation of the histological outcomes of these two therapeutic approaches. Moreover, performing a similar study involving primary molars seems interesting.

Considering the ease of manipulation of the root canal therapy compared to the pulpotomy, it may be concluded that the root canal therapy of the vital primary incisors may be substituted for the pulpotomy of these teeth without compromising the final therapeutic outcomes.

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