The Comparative Assessment of the use of Formocresol and Calcium Phosphate cement as Pulpotomy agents in primary teeth: An in-vivo study

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ABSTRACT

Introduction: Formocresol (FC) remains to be the medicament of choice in pulpotomy, despite the concerns regarding tissue devitalization and systemic toxicity. Several materials have been used as alternatives, but none proved significant. Recently, calcium phosphate cement (CPC) has been considered as an ideal pulpotomy material considering its tissue compatibility. The aim of the study was to compare clinical and radiographic success of FC and CPC for the treatment of primary molar teeth requiring vital pulp therapy. Materials and Methods: This study included 25 children between 6-7 years of age having a pair of carious primary molar teeth requiring vital pulp therapy. Pulpotomy was performed with either FC or CPC. Clinical parameters were evaluated at 6, 9 and 12 months and radiographic parameters were evaluated at the completion of 12 months. Results: Formocresol group showed 94.7% overall clinical success when compared to 52.6% in CPC group at 12 months. The difference was statistically significant (p<0.05). In the formocresol group, the overall radiographic success was 47.4% when compared to 10.5% in CPC group at 12 months. The difference was statistically significant (p<0.05). Conclusion: Further research is required before considering Calcium Phosphate Cement as a pulpotomy medicament

KEYWORDS: Pulpotomy, Calcium Phosphate Cement, Formocresol

INTRODUCTION

Dental caries is one of the prevalent pathologies that affect pediatric dental health. When pulpal inflammation is confined only to the coronal pulp, the treatment that has attained most clinical and radiographic acceptance is pulpotomy. The purpose of pulpotomy is to retain a functional tooth in the oral cavity until its exfoliation through the preservation of the radicular pulp. An ideal pulpotomy material or drug should be bactericidal, harmless to the pulp, promote healing of the remaining pulp and not interfere with the physiologic root resorption in primary dentition.

Formocresol was first used for pulpotomy in the year 1904 and since then has been the medicament of choice for pulpotomy in primary teeth. Later, in 1930 its use in primary molar endodontics was popularized by Sweet who used Buckley’s Formocresol. It is considered as ‘gold standard’ due to its favorable and consistent results that date back to even more than a century and therefore used as a ‘control’ in several studies till date.

Along with its favorable clinical results, certain concerns have been raised regarding tendency of a formocresol to mummify the entire radicular pulp with the progression of time. Also, few studies suggest that use of the formocresol leads to premature exfoliation of the treated teeth. In the search for newer pulpotomy agents, many studies have been conducted on various materials such as glutaraldehyde, ferric sulfate, MTA, laser, and sodium hypochlorite each with its own advantages and limitations.

A relatively recent alternative medicament for pulpotomy is calcium phosphate cement. It has been considered as a new generation bone substitute with potential clinical applications in orthopedics and dentistry. In dentistry, it has been used as pulp capping agent in animals, as a sealer/filler material in endodontic treatment, for augmenting periodontal defects and as bone filler for implants. It elicits a dentin bridge formation with no evidence of necrosis of tissue or inflammation when compared to calcium hydroxide and has exhibited lower microleakage and higher shear bond strength when used as a pulp capping agent. One study has used calcium phosphate cement as pulpotomy medicament in primary teeth and has reported clinical and histologic success.

Hence, the present study was aimed to determine the clinical and radiographic success of the formocresol and calcium phosphate cement for the treatment of primary molar teeth requiring vital pulp therapy.

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MATERIALS AND METHODS

This study was carried out in the Department of Pedodontics and Preventive Dentistry, Navi Mumbai. The Institutional Ethical Committee clearance was obtained to conduct the study. 25 children between the age group of 6-7 years, having a minimum of two molar teeth requiring vital pulp therapy were selected for the study. The sample size was calculated considering the difference in group means to be 20%, power of the study as 80%, at 95% confidence interval, a ratio of sample size (Group 1/Group 2) as 1 and with the significance level set at 5%, a sample size of 50 was derived (i.e., 25 in each group). Prior to the procedure, informed and written consent was obtained from the parents of children. Restorable teeth with no history of spontaneous pain, tenderness to percussion, swelling, mobility or periodontal problems were selected for the study. Radiographically, it was ensured that there was no radiographic evidence of furcation or periapical involvement and the tooth had at least 2/3rd of its root length. All pulpotomies were performed by the same operator (Diagram 1).

The selected fifty primary molars were randomly assigned into two groups (n=25) according to the medicament used:

- Group 1: Pulpotomy with the formocresol
- Group 2: Pulpotomy with calcium phosphate cement (CHITRA-CPC)

Following local anesthesia and rubber dam isolation, dental caries was removed with a large slow-speed round bur. On pulp exposure, the roof of the pulp chamber was removed with a high-speed airotor bur. The coronal pulp was then amputated with hand instruments. The hemorrhage was controlled with a moist cotton pellet. A sterile cotton pellet was soaked with a full strength formocresol was compressed between fresh cotton to squeeze out excess. It was then placed on the amputated pulp stumps for five minutes. After 5 minutes, the color change on the opening of the pulp orifices was observed to be brownish black in appearance. Following this, a thick mix of zinc oxide eugenol cement was packed into the pulp chamber up to 2-3 mm thickness.

In CPC group, after the moist cotton was removed and hemostasis was achieved, the calcium phosphate cement was mixed, placed and condensed using a ball burnisher so that the cement sits on the orifices of the pulp. The cement was packed till 2 mm from the orifice of the pulp, and then a thick mixture of zinc oxide eugenol was placed above the calcium phosphate cement.

An immediate post-operative intra-oral periapical radiograph was immediately taken after the completion of the procedure in both the groups. The tooth was then restored with glass ionomer cement, and stainless steel crown was placed in the same appointment. Clinical follow up was done at 6, 9 and 12 months. Radiographic follow up was done after 12 months. Six subjects were lost after 6 months follow-up.

Outcome criteria for success and failure: The clinical criteria evaluated were the presence of spontaneous pain, pain on mastication, tenderness on percussion, palpation, abscess, or pathologic mobility. The degree of mobility was assessed according to Wyman’s index (1975)23. For all other parameters, a negative response was coded as 0, and a positive response was coded as 1.

Radiographic parameters evaluated were a presence of periapical/furcation radiolucency, widened periodontal ligament space (PDL), internal/external root resorption, calcification of canals or bone destruction. Root resorption was measured according to grades reported by Wright (1979)24. Furcation radiolucency was scored according to grades reported by Mendoza AM et al. (2010).25 For bone destruction, calcification of canals and PDL widening, a negative response was coded as 0, and a positive response was coded as 1.

Statistical analysis: All the collected data were subjected to statistical analysis. The Chi-square test was performed to compare the results. In the present study, p < 0.05 was considered to indicate statistical significance.

RESULTS

Clinical assessment: At the end of 12 months, 1 subject in the formocresol group reported with spontaneous pain, gingival inflammation, and mobility. However, subjects in the CPC group exhibited a higher failure rate with maximum failures occurring due to the presence of pathologic mobility (47.4%). Table 1 shows the clinical findings at 6.9 and 12 months.

Radiographic assessment: At the end of 12 months, periodontal ligament widening was observed in 52.6% of
subjects in the formocresol pulpotomy group. The maximum failures in the CPC group occurred due to the presence of external resorption and pathologic/furcation radiolucency (Figure 1.2). All the radiographic parameters comparing the formocresol and CPC showed that Formocresol had better success and this difference was statistically significant. Table 2 shows the radiographic findings at 12 months.

The overall clinical success of Formocresol pulpotomy was 94.7% and 52.6% in CPC group at 12 months (Figure 3.4). The difference was statistically significant (p<0.05). Also the overall radiographic success in formocresol group was 47.4% and 10.5% in CPC group at 12 months. The difference was statistically significant (p<0.05). Table 3 shows the overall clinical and radiographic success.

**DISCUSSION**

The present randomized controlled clinical trial was outlined to determine and compare the clinical and radiographic success of two pulpotomy agents namely, Formocresol and Calcium Phosphate Cement (CPC). Total of fifty primary teeth in twenty-five children aged 6-7 years was selected for this study. In each subject, one molar was treated with CPC and other with the formocresol.

Children below 6 years of were excluded from our study due to possible lack of co-operation which may make the placement of rubber dam difficult. Also, dental anxiety is more pronounced in children between 4-6 years of age and begins to decrease by 6-7 years. Generally, after 6 years the children are expected to understand and cooperate in dental treatment, and it is also possible to create a positive dental attitude in this age group. Children more than 7 years were also excluded due to the
possibility of physiologic root resorption (>3/4 of root). Previous research on assessment of pulpotomy medications has been conducted in the similar age group.

The subject selection was performed according to the clinical and radiographic criteria outlined in various studies. In the present study single sitting 5-minute full strength-formocresol pulpotomy was performed. The success rate of the formocresol pulpotomy ranges from 70% to 90%, and thus it is still considered as 'gold standard' by which all the new modalities are compared.

A potential alternative material for pulp capping and pulpotomy is calcium phosphate cement (CPC). The CPC formulation available in India is ‘Chitra-CPC’. The cement used in the present study was manufactured by Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) Trivandrum. Lee et al. (2010) reported that CPC facilitates the growth and differentiation of human dental pulp cells. Only one study till date has evaluated Chita-CPC as pulpotomy agent in human primary teeth.

Clinical Evaluation: In our study the formocresol-pulpotomy showed 94.7 % clinical success as compared to 52.6% success in CPC group at the end of 12 months. This difference was statistically significant (p<0.05). The clinical success of 95% is comparable to various other studies of a formocresol pulpotomy with similar clinical criteria. Agamy et al. (2004), Srinivasan and Jayanthi (2011) and Godhi et al. (2011) reported 90%, 91.3% and 100% clinical success rate respectively at 12 months follow-up period. Ruby et al. (2012), Havale et al. (2013) and Durmus et al. (2014) reported 100%, 86.7% and 97% clinical success rate at 12 months follow-up period. Garcia-Godoy (1983) reported 96% clinical success rate at 18 months follow-up period. Farsi et al. (2005), Huth et al. (2005) and Noorollahian(2008) reported 98.6%, 96% and 100% clinical success rate at 24 months follow-up period. Fuks and Bimstein (1981) reported 94% clinical success rate at 36 months follow-up period.

The overall clinical success for CPC was 52.6%. This was contradictory to the results presented by Jose et al. (2013) who reported 100% success rate at 70 days follow-up period.

Radiographic evaluation: Radiographic evaluation was performed only at 12 months. Radiographs were not taken before 12 months to avoid unnecessary radiographic exposure to children and were taken only if the clinical failure was noticed prior to 12 months. There are no studies done to evaluate the relative radiographic success of CPC as compared to the formocresol till date. Thus, the following radiographic parameters consist only of the formocresol comparative studies. The radiographic success drastically diminished in comparison to the clinical success of both the groups. The radiographic success was 47.4% and 10.5% for a formocresol and CPC respectively at the end of 12 months which showed statistical significance (p<0.05).

Previous studies have reported a varying range of Radiographic success after a formocresol pulpotomy. Durmus et al. (2014) and Olatosi et al. (2016) assessed periapical radiolucency, widened periodontal ligament space (PDL), pathologic internal/external root resorption, or pathologic changes of the alveolar bone in the furcation area and reported 87.5% and 81% radiographic success rate at 12 months follow-up period. In the present study, periapical radiolucency, Periodontal ligament widening, internal resorption, external resorption and bone destruction was seen in 37%, 53%, 5%, 37% and 21% of subjects respectively. Havale et al. (2013) included calcification of canal as an additional parameter reported 56.7% radiographic success rate at 12 months follow-up period. There was no patient with canal calcification in our study.

In the present study, all possible radiographic parameters were evaluated, and the presence of any one parameter was considered as a failure. This may be the reason for the lowered radiographic success with the formocresol in the present study. Previous studies have shown a gradual decrease in radiographic success rate with time, as was noticed in the current study. This could be pertaining to physiological resorption or accelerated root resorption of primary molars.

Histologic evaluation: One tooth which exhibited grade II mobility and intraoral abscess following CPC pulpotomy was extracted and subjected to histological evaluation. The histological report revealed reparative dentin formation and osteo-dentin with resorption bay showing lymphocytes and osteoclasts within the resorption area. Pulp tissue showed dense inflammatory cell response towards the resorbed area and rest of the pulp tissue showed fibrosis which can be due to an injury to the pulp (Figure 5).

Myers et al. (1988) evaluated the histo-pathological findings in teeth with failed formocresol-pulpotomy and reported mixed cellular response. Acute inflammation was also observed which was characterized by the presence of polymorphonuclear leukocytes and chronic proliferative inflammation which included lymphocytes, monocytes, macrophages, and plasma cells. Thus, inflammation appears to be the common factor in the failure of a formocresol group and CPC group.

CONCLUSION

From the present study, it can be concluded that Calcium Phosphate Cement does not fulfill the characteristics of an ideal pulpotomy medicament. However, the merits of CPC in terms of biocompatibility, non-toxicity, reparative dentin formation, reduced microleakage, high compressive strength and mouldability should be considered. Thus further research evaluating the clinical, radiographic and histologic response of primary pulp to...
calcium phosphate cement should be conducted before a definite decision can be established about its use in primary teeth.

REFERENCES


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