Clinical Evaluation of Formocresol and Iodoform-Corticosteroid containing Medicaments used for Pulpotomies of deciduous molars

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ABSTRACT

Introducation: Although clinical guidelines on pulp therapy of primary teeth reflect the cited literature and consensus of experts, more research is needed in the areas of vital and non-vital pulp treatment. The aim of this study is to compare and evaluate clinical outcomes of vital and non-vital pulpotomies of deciduous molars using an iodoform-corticosteroid containing medicament (PT, Pulpotec®) and Formocresol (FC). **Methods:** Pulpotomies of forty two mandibular primary molars in thirty children were available for analysis of success/failure rate. In each vital and non-vital pulpotomy group, eleven primary molars were treated with FC and ten with PT. Signs and symptoms studied were abscess, gingival redness, facial swelling, pain on chewing, spontaneous pain, mobility, sinus tract and others. **Results:** The overall success rate of the study was 95.24% (40 out of 42). Follow-up time of all teeth in both FC and PT groups ranged between 6 and 17 weeks, with a mean of (8.6) weeks. In vital pulpotomies, FC was successful in 90.90% of the cases, one tooth out of eleven was failed clinically and PT had 100% success rate, with no statistical difference between the two materials ($P > 0.05$). The same results were found in non-vital pulpotomy groups. **Conclusion:** High success rate of pulpotomy with PT (100%) both in vital and non-vital groups is impressive but it was only for short follow-up period. Formaldehyde which is one of the contents of PT may potentiate the efficacy of the medicament. It was found that PT can handle inflammation better than FC. It may be due to the corticosteroid content which is well-known for its anti-inflammatory effect. With continued advancement and availability of bioactive pulp medicaments, effective alternatives may replace routine use of Formocresol pulpotomies.

Keywords: Pulpotomy, Deciduous molar, Primary molar, Formocresol, Iodoform

1. Introducton

One of the aims of pediatric dentistry is to keep healthy or restored primary teeth in place on the dental arch until they are replaced by the underlying permanent teeth. Pulp treatment in primary teeth remains one of the most controversial treatments in pediatric dentistry. The goal of pulp therapy in primary teeth is to preserve function and esthetics that would otherwise be lost to extraction. Although clinical guidelines on pulp therapy for primary teeth reflects the cited literature and consensus of experts, more research is needed in the areas of vital and non-vital pulp treatment in primary and young permanent teeth to aid clinicians in the proper technique and medications for use (AAPD ,2004).

Pulpotomy is considered as the treatment of choice for infected coronal pulps in primary teeth (Ranly *et al,* 2000). This procedure involves: (1) coronal pulp tissue removal; (2) fixative agent applied over the radicular pulp tissue; and (3) restoration of the tooth.

This paper will describe a comparative clinical study for evaluation of pulpotomies of deciduous molars using Pulpotec® , an iodoform-dexamethasone containing medicament, and Formocresol , which is still considered as the gold standard medicament (Jabbarifar, 2004), for treatment of infected deciduous molars.

The aim of this study is to compare and evaluate clinical outcomes of vital and non-vital pulpotomies of deciduous molars using an iodoform-corticosteroid containing medicament (PT) Pulpotec®) and Formocresol (FC).

2. Materials and Methods

This clinical study was an observational type and prospective in design. The study involved the clinical procedures and statistical analysis of the results. Ethical

considerations of the study were scrutinized and approved by the research ethics committee of university of dental medicine, Yangon.

An informed courtesy was obtained from a parent or legal guardian. All patients were selected according to the inclusion criteria and registered in a standardized, prepared proforma. Vital or non-vital mandibular deciduous molars which needed endodontic treatment were randomly assigned to either PT or FC group. Acute or chronically infected pulp of mandibular primary molars in 30 children were treated using conventional pulpotomy technique. The teeth were randomly assigned to the PT group (20 teeth) or FC group (22 teeth). Presence or occurrence of any recorded signs and symptoms in four-week review is regarded as failure.

The success and failure rates of each vital and non-vital pulpotomies were compared in follow-up visits in relation to applied medicaments. The outcomes of different groups were statistically analyzed using (SPSS software) Fisher exact test.

3. Results

Of the 62 pulpotomized teeth, 42 teeth in 30 children (19 boys and 11 girls) were available for analysis of success/failure rate. (Table 1)

3.1 Available follow-up time

Follow-up time of all teeth in both FC and PT groups ranged between 6 and 17 weeks, with a mean of (8.6) weeks. Treatment failure was detected in 2 teeth after a mean period of 10 weeks.

3.2 Evaluated Signs and Symptoms in both vital and non-vital groups

There are altogether 21 mandibular primary molars in each group and the data for each molar was recorded in proforma pre-operatively and post-operatively. Signs and symptoms recorded at first visit and evaluated after pulpotomy treatment

were abscess, gingival redness, facial swelling, pain on chewing, spontaneous pain, mobility, sinus tract and others. (Table 2 & Table 3)

3.3 Outcomes of different treatment

The overall success rate of the pulpotomies of all teeth in this study was 95.24% (40 out of 42). The follow up evaluations revealed two failures (4.76%); one tooth (first primary molar) from vital FC group and one tooth (second primary molar) from non-vital FC group after a follow-up peroid of (10) weeks in both groups.

In vital pulpotomies, FC was successful in 90.90% (10/11) of the cases, and PT had 100% success rate, with no statistical difference between the two materials ($P > 0.05$). One tooth out of 11 treated with Formocresol was failed clinically and all teeth treated with PT get 100% success rate (table 4). Interestingly these same results were found in non-vital pulpotomies (table 5).

Discussion

The aim of pulpotomy in a primary molar is to maintain a symptom-free and functional tooth until its physiologic exfoliation (Holan et al. 2005). Inflammatory changes within the pulp horn region of teeth with carious loss of more than half of the intercuspal marginal ridge would necessitate some invasive pulp treatment (Duggal et al., 2002).

It has been reminded that a throbbing pain associated with an inflamed gingival papilla due to food impaction might simulate an irreversible pulpal infection. These symptoms could be disappeared following restorative treatment (Fuks, 2005). Such condition was noted in one case of vital pulpotomy group of the study.

Concerning with patients visits and follow-ups, one-visit endodontic treatment has clear advantages to both the dentist and patient. It will not only be well-accepted by patients, it also prevents the contamination of the root canal system between

appointments. Ideally vital pulp treatment should be finished in one session provided that the time available, operator's skills and anatomical conditions are all favorable. On the other hand, treatment of necrotic pulps associated with a periradicular lesion will be a great challenge to the dentist (Siqueira, J. F, 2001). A clinical advantage of PT over FC is the fact that less time is needed for the procedure in vital pulpotomy technique. However it should be in mind that although root canal medicaments play a role in outcome of the treatment, it is not the most important factor in the success of pulp therapy. Other factors such as case selection, biomechanical preparation, and parent co-operation especially for a young child will also contribute towards the success of pulp therapy. Patient's co-operation and untoward behaviors are doubtlessly important to the success of the treatment.

As the teeth were randomly assigned to FC or PT groups, it is not feasible that more teeth with undiagnosed, inflamed pulp were assigned to any group. Although signs and symptoms of non-vital molars treated with PT seem to have a more guarded prognosis in this study, there was apparent higher success rate. It is, therefore, reasonable to assume that PT can handle inflammation better than FC. It may be due to the corticosteroid content which is well-known for its anti-inflammatory effect.

In this study, 100% success rate of pulpotomies with PT both in vital and non-vital groups is impressive, but it was only for 8.5 weeks of mean follow-up period. It will need to be considered for long-term follow-up period, until shedding time of the treated teeth if possible. It should be noted that formaldehyde is also one of the contents of the evaluated iodoform-corticosteroid containing medicament in this study. The effect of this content on the pulpal remnant together with other contents may have potentiated the efficacy of the medicament. As a paste preparation less

systemic distribution can be expected by use of such medicament than application of liquid FC and so danger of systemic toxicity is quite reduced. Many studies (Cortes *et al* 2007, Boj *et al,* 2003 and Zarzara *et al* (2003)) have questioned the toxic effects of Formocresol, one of which is its systemic distribution. A press release from the International Agency of Research on Cancer (IARC, 2004) considered formaldehyde causes nasopharyngeal cancer in humans but studies (Swenburg et al., 1980) in both humans and animals are based on chronic exposure to formaldehyde at very high doses. In pulpotomy techniques, recent alternatives with proved results such as MTA, Electrocautery and BMP (bone morphogenic proteins) are much more expensive than currently used medicaments.

A zinc oxide eugenol base is usually applied over the radicular pulpal tissue. However, a number of authors have controversial views towards the relation of internal resorption and ZnOE base (Smith et al., 2000; Casas et al., 2003, Smith *et al,* Cotes *et al*). This possible complication warrants further investigations.

It should be realized that, although many studies reported high success rate of pulpotomies, radiographic findings often indicate some pathological changes, which most commonly include calcific metamorphosis and internal resorption (Smith et al., 2000). Hence, regular clinical and radiographic review following any primary molar pulp therapy is strongly recommended. In this study radiographic analysis was excluded as available follow-up time was limited.

Pulpotomy failures in primary teeth with caries exposure can be attributed to pulp contamination due to microleakage of large multi-surface restoration rather than stainless steel crowns (AAPD, 2004). Adhesive restorations have also been shown to provide optimum protection from marginal leakage in pulpotomized primary molars (Guelmann et al., 2004). It is therefore strongly recommended that adhesive

restorations or preformed crowns are employed following any primary molar pulp therapy procedure.

Following a short study period for a limited number of subjects, the effectiveness of the iodoform-corticosteroid containing medicament has been studied and more detailed studies with longer follow-up periods are recommended.

Conclusions

Although the results are not statistically significant PT has showed a higher clinical success rate than FC both in vital and non-vital pulpotomies of deciduous molars. Iodoform-corticosteroid containing medicament can handle pulpal inflammation better than Formocresol alone. Long-term clinical and radiological evaluation will need before saying specific conclusions. With continued advancement and availability of bioactive pulp medicaments, effective alternatives may replace routine use of Formocresol pulpotomies. Until such agent is found, effectiveness of Formocresol cannot be less regarded.

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Table 1. Distribution of Evaluated mandibular primary molars

Materials	pulpotomies	1st molar	2nd molar	Total
Pulpotec	vital	6	4	10
	Non-vital	4	6	10
Formocresol	Vital	6	5	11
	Non-vital	5	6	11
Total		21	21	42

Table (2) Signs and symptoms of pulpotomized vital molars

	Formocresol		Pulpotec®	
	Pre-op	Post-op	Pre-op	Post-op
Abscess	0	0	0	0
Gingival redness	0	0	2	0
Facial swelling	0	0	1	0
Pain on chewing	5	1	4	0
Spontaneous pain	2	0	4	0
Mobility	0	0	0	0
Sinus tract	0	0	0	0
Others				
Total	11 teeth		10 teeth	

Table (3) Signs and symptoms of pulpotomized non-vital molars

	Formocresol		Pulpotec ®	
	Pre-op	Post-op	Pre-op	Post-op
Abscess	1	1	4	0
Gingival redness	2	0	4	0
Facial swelling	0	0	1	0
Pain on chewing	7	0	6	0
Spontaneous pain	2	0	6	0
Mobility	0	0	2	0
Sinus tract	0	0	0	0
Others				
Total	11 teeth		10 teeth	

Table (4) Association between treatment method and outcome of vital pulpotomy

	Success	Failure	No. of teeth	Fisher exact test - p value
Formocresol	10 (90.90%)	1 (9.10%)	11	1.00 (not significant)
Pulpotec	10 (100%)	0	10	

Table (5) Association between treatment method and outcome of non-vital pulpotomy

	Success	Failure	No. of teeth	Fisher exact test – p value
Formocresol	10	1	11	1.00 (not significant)
Pulpotec®	10	0	10	