Comparative Evaluation of Lyophilized Freeze Dried Platelet Derived Preparation with Calcium Hydroxide as Pulpotomy Agents in Primary Molars.

Kalaskar R R, Damle S G

ABSTRACT

The aim of this study was to compare the efficacy of lyophilized freeze dried platelet derived preparation with calcium hydroxide as pulpotomy agents in primary molars. Fifty six primary molars in 28 children were treated by a conventional pulpotomy technique. 28 teeth were treated by lyophilized freeze-dried platelet derived preparation and another 28 by calcium hydroxide. Clinical evaluation was carried out at 1, 3, and 6-months interval and the radiographic evaluation was carried out at 1 and 6-months. The success rate of lyophilized freeze-dried platelet derived preparation proved better than calcium hydroxide.

Key Words: Calcium hydroxide, Deciduous teeth, Freeze dried platelet derived preparation, Pulpotomy.

INTRODUCTION

The pulpotomy is a surgical procedure that involves surgical amputation of coronal infected portion of vital pulp followed by application of medicament over the residual radicular pulp tissue to promote healing and also to allow normal tooth physiology to continue. Formocresol, a devitalizing agent has been reported to be carcinogenic and mutagenic. Glutaraldehyde, a preservative agent has been proposed as an alternative to formocresol, that results in inadequate fixation and leaves a deficient barrier to sub base irritation, resulting to internal resorption. Ferric sulfate has received some attention recently as a pulpotomy agent. Although the metal protein clot at the surface of the pulp stump acts as a barrier to the irritating components at the sub base, it functions solely in a passive manner. Calcium hydroxide, a regenerative pulpotomy agent, has been reported to be a failure in primary teeth due to higher incidence of the development of chronic pulpal inflammation and internal resorption. However, recent studies have reported a favorable result for calcium hydroxide by controlling the variables of treatment such as pulpotomy technique, strict selection criteria, etc.

Recent advances in the field of bone and dentin formation have opened new vistas for pulp therapy. Bone Morphogenetic proteins (BMPs) and Growth factor such as transforming growth factor (TGF), platelet derived growth factor (PDGF), insulin growth factor (IGF) derived from platelet have generated considerable interest during the last few years. These compounds act as signaling proteins that could be directly involved in the regulation of cell proliferation, migration and extracellular matrix production in the dental pulp. Hence, these could prove to be feasible alternatives to the materials currently used for pulpotomy. The present study was aimed to evaluate the clinical and radiographic efficacy of lyophilized freeze dried platelet derived preparation and calcium hydroxide as pulpotomy agents in primary molars.

MATERIALS AND METHOD

The study was carried out in the Department of Pediatric and Preventive Dentistry, Nair Hospital Dental College, Mumbai with the aim of comparing lyophilized freeze dried platelet derived preparation and calcium hydroxide as pulpotomy agents in primary molars. The patients were selected from the out patient department with good general health, no history of systemic illness or hospitalization and with no history of antibiotic intake in the past six months. The parents or guardians of the child were informed about the status of the child's dentition. They were explained about the treatment required, the advantages and risks if any. Participation in the study was voluntary, written consent was obtained from the parents or guardians. Fifty six primary molars (first and second) from 28 children in the age group of 4-7 years were selected.

Criteria for case selection [The criteria followed by Hellig J. et al 1984 and Waterhouse et al 2000]:

1. Teeth with deep carious lesion (radiographically the caries should be approximating to the pulp).
2. Teeth should be restorable after completion of the procedure.
3. Absence of symptoms indicative of advanced pulpal inflammation such as spontaneous pain or history of nocturnal pain
4. Absence of clinical signs or symptoms suggesting a non-vital tooth such as suppurating sinus, soft tissue swelling

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5. Absence of clinical radiographic signs of pulpal necrosis i.e. furcation involvement, periapical pathology, internal resorption, calcification in canal.

6. Hemorrhage should stop within five minutes from the amputated pulp stumps using a sterile pledget of moist cotton. After assessment of clinical and radiographical criteria, single visit pulpotomy procedure was performed on the selected molars.

Pre-operative IOPA radiographs were taken (Figs 1, 2) and teeth were then divided in 2 groups, each group containing 28 teeth [Table 1]. In Group I lyophilized freeze dried platelet derived preparation and in Group II calcium hydroxide were used as pulpotomy medicaments.

A lyophilized freeze dried platelet derived preparation [containing transforming growth factor (TGF), platelet derived growth factor (PDGF), bone morphogenetic proteins (BMPs), insulin growth factor (IGF)] which was obtained from National Plasma Fractionation Center, Mumbai, was allogenic in nature, free of H.I.V. antibodies, Hbs Antigen, HCV antigen and allergic reaction. The product was made available in airtight glass bottles. Before use the material from each glass bottle was divided into 6 equal parts under laminar flow. Each part was dispensed in a separate sterile glass bottle to prevent contamination of the material during use.

Procedure:
Local anaesthesia was achieved using 2% xylocaine with 1:80,000 adrenaline. The teeth were isolated using rubber dam, cavity outline was established with a highspeed round diamond bur with water coolant. Caries was excavated with a spoon excavator. The pulp chamber was entered and the roof was removed with diamond abrasive using high speed air rotor. Sterile, normal saline (Core Pharmaceuticals .9% w/v) was used to wash away the debris. Coronal pulp tissue amputation was achieved using spoon excavator; the chamber was irrigated with normal saline. Hemorrhage was controlled using a sterile pledget of moist cotton under pressure. After control of hemorrhage within five minutes, the lyophilized preparation was placed over the pulp stump in Group I and the preparation was gently packed over the pulp stumps using a sterile pledget of moist cotton. A thick mix of Zinc oxide eugenol cement was placed to seal the coronal pulp chamber. The teeth treated were then restored with glass ionomer cement (GC Fuji GC Corporation Japan). A preformed stainless steel crown was placed after a follow up of one month.

Clinical examination was undertaken at 1,3 and 6 months intervals where as radiographic evaluation of the treated teeth was carried out at the intervals of 1 month (Figs 3, 4) and 6 months (Figs 5,6). Test and control teeth were evaluated for the presence or absence of the following findings for successful treatment.

Clinical findings:
1. Spontaneous pain or pain initiated by stimuli.
2. Signs of sinus formation, tenderness to percussion, soft tissue swelling and mobility.
3. Signs of defective restoration or recurrent caries.

Radiographic findings:
1. Signs of pulpal degeneration such as periapical or furcal radiolucency, canal calcification, internal resorption.
2. Defective restoration or recurrent caries

Treatment failure was said to have occurred if the test tooth showed either clinical signs or radiographical signs of infection.

RESULTS

Pre-operatively, the incidence of pain was present in all patients in Group I and Group II. At one month follow up none of the patients in Group I had reported with pain, swelling and mobility where as 1 patient in Group II reported with pain, swelling and mobility [Tables 2, 3]. Clinical examination after three and six months of treatment, revealed, absence of pain, swelling and mobility in both groups.

Radiographic examination after one month of treatment, revealed, no periapical or furcation involvement in group I where as 1 tooth showed periapical involvement in Group II [Table 3]. The difference between the two groups was insignificant. None of the teeth in Group I and Group II showed internal resorption or calcification at six months follow up. No teeth in Group I show calcific barrier formation at the mesiodistal width of root canal, where as five teeth in Group II confirm calcific barrier formation at the mesiodistal width of root canal after a follow up of six months. The difference between the two groups was not statistically significant. Depending on clinical and radiographical criteria 100% of teeth in Group I and 96.42% of teeth in Group II were considered successful.
A comparative Evaluation of Two Pulpotomy Agents in Primary Molars

Fig. 1: Pre-operative radiograph of 85 (Group I)

Fig. 2: Pre-operative radiograph of 85 (Group II)

Fig. 3: 1 month post operative radiograph of 85 (Group I)

Fig. 4: 1 month post operative radiograph of 85 (Group II)

Fig. 5: 6 months post operative radiograph of 85 (Group I)

Fig. 6: 6 months post operative radiograph of 85 (Group II)
A comparative Evaluation of Two Pulpotomy Agents in Primary Molars

<table>
<thead>
<tr>
<th>Tooth</th>
<th>Pulpotomy with LPDP* [Group I]</th>
<th>Pulpotomy with Ca(OH)$_2$ [Group II]</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>74</td>
<td>4</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>84</td>
<td>5</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>75</td>
<td>3</td>
<td>16</td>
<td>19</td>
</tr>
<tr>
<td>85</td>
<td>16</td>
<td>3</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>28</td>
<td>28</td>
<td>56</td>
</tr>
</tbody>
</table>

* Lyophilized Freeze Dried Platelet Derived Preparation

Table 1. Distribution of samples according to the medicaments used for pulpotomy.

<table>
<thead>
<tr>
<th></th>
<th>At 1 month follow up</th>
<th>At 3 months follow up</th>
<th>At 6 months follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>S</td>
<td>F</td>
<td>S</td>
</tr>
<tr>
<td>LPDP*</td>
<td>28</td>
<td>0</td>
<td>28</td>
</tr>
<tr>
<td>Ca(OH)$_2$</td>
<td>27</td>
<td>1</td>
<td>27</td>
</tr>
<tr>
<td>Total</td>
<td>55</td>
<td>1</td>
<td>55</td>
</tr>
</tbody>
</table>

* Lyophilized Freeze Dried Platelet Derived Preparation
S - Number of teeth showing success
F - Number of teeth showing failure

Table 2. Cumulative distribution of success and failure in each group. (LPDP and Calcium hydroxide)

<table>
<thead>
<tr>
<th></th>
<th>At 1 month follow up</th>
<th>At 3 months follow up</th>
<th>At 6 months follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C</td>
<td>R</td>
<td>C</td>
</tr>
<tr>
<td>LPDP*</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ca(OH)$_2$</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

* Lyophilized Freeze Dried Platelet Derived Preparation
C - Clinical and R - Radiographic

Table 3. Number of teeth showing failure, clinically and radiographically in each group. (LPDP and Calcium hydroxide)
DISCUSSION

Vital pulp therapy has been a subject of debate for decades. Cox et al.\textsuperscript{17} stated that healing of exposed pulp is dependent not on the effect of a particular type of a medicament but rather on the capacity of the capping agent. Pulpotomy therapy for the primary dentition can be classified according to the treatment objectives: devitalization, preservation and regeneration.\textsuperscript{18} Devitalization intends to destroy or mummify the vital tissue is represented by the two step and five minute formocresol technique, electrolysis and laser. Preservation - which implies maintaining the maximum vital tissue with no induction of reparative dentin is exemplified by zinc oxide eugenol, Glutaraldehyde and Ferric sulfate pulpotomies. Regeneration and formation of dentin bridge has long been associated with Calcium hydroxide and more recently with Mineral trioxide aggregate, bone morphogenetic proteins, growth factor [such as transforming growth factor(TGF), platelet derived growth factor (PDGF), insulin growth factor (IGF)]. Of the three categories, regeneration is expected to develop most rapidly in the coming years.\textsuperscript{18} In the present study, lyophilized freeze dried platelet derived preparation was used as a pulpotomy agent which contained TGF, PDGF, IGF, BMPs. These are signaling proteins that regulates the key cellular processes such as cell differentiation, mitogenesis, and chemotaxis.\textsuperscript{19} These proteins have been used extensively in oral and maxillofacial reconstruction\textsuperscript{20}, adjunctive procedures related to the placement of osseointegrated implant in humans\textsuperscript{13,21} and periodontal regeneration.\textsuperscript{22} Animal and human invivo and invitro studies have shown that these proteins stimulates differentiated cell of pulp to differentiate into odontoblast to deposit a layer of dentin.\textsuperscript{23,24}

In the present study, lyophilized freeze dried platelet derived preparation showed a 100% success rate, as all these teeth were asymptomatic and not showing any signs of pulpal degeneration clinically and radiographically. None of these teeth showed calcific barrier formation at the mesiodistal width of the root canal, although invitro human and animal studies have shown extracellular matrix formation with these proteins. The exact reason is difficult to explain hence further investigation with histological corroboration in this area is needed. In the reviewed literature we have not come across any invitro study using these proteins as a pulpotomy agent hence cross comparison is difficult. The results obtained using calcium hydroxide showed a greater success rate i.e. 96.42% than previous studies. This may be due to strict selection criteria. Successful outcome in vital pulp therapy procedures may be more dependent upon correct diagnosis of the inflammatory status of the remaining radicular pulp. Once coronal pulp amputation has been achieved the absence of irreversible inflammation in the radicular pulp may dictate the long-term clinical outcome.

REFERENCES

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