Clinical and radiographic outcomes of the use of capping materials in vital pulp therapy of human primary teeth

Resultados clínicos e radiográficos do uso de materiais de capeamento na terapia de polpa vital de dentes decíduos humanos

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ABSTRACT

Objective: The aim of this study was to compare the clinical and radiographic outcomes of Calcium Hydroxide (CH), Calcium Hydroxide preceded by corticosteroid/antibiotic solution (O+CH) and diluted formocresol (FC) in the vital pulp therapy of human primary teeth. Material and methods: Forty-five mandibular primary molars of children aged between 5-9 years were randomly assigned in the three study groups, FC, CH and O+CH and received conventional pulpotomy treatment. Clinical and radiographic follow-up was made at 3, 6 and 12-months. Results: No sign of clinical failure was observed in the three study groups during all the periods of evaluation. Radiographic analysis showed a total of six failures of internal root resorption in CH and O+CH groups after the 12 months follow-up, with statistically significant difference as compared with FC group. FC group did not show hard tissue barrier formation, which was observed in CH and O+CH groups in all the follow-up periods. Conclusion: All employed materials showed acceptable clinical and radiographic success rates. The results showed that the use of an anti-inflammatory solution prior the dressing material has therapeutic properties that help with pulpal healing. Continued clinical investigations using these medicaments as vital pulpotomy treatment in primary molars are recommended.

KEYWORDS
Calcium Hydroxide; Dental pulp; Formocresol; Pulpotomy; Tooth deciduous.

RESUMO

Objetivo: O objetivo deste estudo foi comparar os resultados clínicos e radiográficos de hidróxido de cálcio (CH), hidróxido de cálcio precedido de solução corticosteróide / antibiótico (O + CH) e formocresol diluído (FC) na terapia de polpa vital de dentes decíduos humanos. Material e Métodos: Quarenta e cinco molares decíduos inferiores de crianças com idade entre 5-9 anos foram divididos aleatoriamente em três grupos: FC, CH e O + CH e receberam tratamento convencional de pulpotomia. Acompanhamento clínico e radiográfico foi realizado após 3, 6 e 12 meses. Resultados: Nenhum sinal de falha clínica foi observado nos três grupos de estudo durante todos os períodos de avaliação. A análise radiográfica mostrou um total de seis falhas de reabsorção radicular interna nos grupos CH e O + CH após 12 meses de acompanhamento, com diferença estatisticamente significativa em comparação com o grupo FC. O grupo FC não mostrou formação da barreira de tecido duro, o que foi observado nos grupos CH e O + CH em todos os períodos de acompanhamento. Conclusão: Todos os materiais empregados apresentaram taxas de sucesso clínico e radiográfico aceitáveis. Os resultados mostraram que o uso de uma solução anti-inflamatória antes do material de capeamento tem propriedades terapêuticas que ajudam na cicatrização pulpar. São recomendadas investigações clínicas contínuas utilizando estes medicamentos no tratamento de pulpotomia vital em molares decíduos.

PALAVRAS-CHAVE
Hidróxido de Cálcio; Polpa Dentária; Formocresol; Pulpotomia; Dente Decíduo.
**INTRODUCTION**

Pulpotomy of primary teeth has been the treatment of choice in cases of inflammation of the coronal pulp caused by caries or trauma with no involvement of the radicular pulp, thus avoiding the premature loss of the teeth [1-3]. Not only is the diagnosis of the inflamed dental pulp required for this therapy to succeed, but also the selection of an effective and biocompatible capping material [4-6].

One of the first medicaments used for pulpotomy was the formocresol, and the technique employing it have been practiced widely world over and a sizable literature is available on its different aspects [7-10]. However, nowadays researchers are seeking for alternative materials due to the fact of reports questioning the side effects of the formocresol [11].

Consequently, several capping materials are being studied to identify alternatives that provide better clinical efficacy without secondary effects. Hence calcium hydroxide has been suggested as a biological material, with the potential to maintain the vitality of the remaining radicular pulp, with the formation of a mineralized tissue barrier in the region where the pulp was amputated [1,4,12-13].

Besides the materials employed for pulp capping, it’s important to establish the inflammatory pulp condition, to predict the pulp tissue reparability. In order to control the inflammatory process after the coronal amputation on pulpotomies of cariously exposed teeth, the application of anti-inflammatory medicaments, such as a combination of corticosteroid/antibiotic solution, preceding the dressing material, seems to be a conservative treatment technique [14].

The aim of this study was to compare the clinical and radiographic outcomes of Calcium Hydroxide (CH), Calcium Hydroxide preceded by corticosteroid/antibiotic solution (O+CH) and diluted formocresol (FC) in the vital pulp therapy of human primary teeth.

**METHODS**

Following approval of the protocol of this study by the Ethics Committee of Bauru School of Dentistry, University of São Paulo (process #62/2007), the parents or guardians of the children received detailed information concerning the procedures involved in the study and signed informed consent forms during the treatment screening period.

Forty-five mandibular primary molars of children, aged between 5 and 9 years were selected. The criteria for selection of the sample were as follows: mandibular primary molar tooth compromised by deep caries compromising the pulp and absence of history of pain, thus requiring a pulpotomy therapy; no clinical or radiographic evidence of pulp degeneration, such as internal or external root resorption, inter-radicular and/or furcal bone destruction; no physiological root resorption of more than one-third, as observed in periapical radiographics; and the possibility of proper restoration of the teeth. Exclusion criteria consisted of the presence of systemic pathology and history of allergic reaction to latex, local anesthetics or to the constituents of the pulp dressing agents tested.

Considering a prior study of Moretti et al. [4], the sample size of 15 teeth in each group was calculated to have a power of 80% and 5% significance level, could delect the differences among groups.

A list of random numbers was used to allocate the teeth into the three groups: FC group (diluted formocresol); CH group (calcium hydroxide); O+CH group (calcium hydroxide preceded by corticosteroid/antibiotic solution).

In all groups, the pulpotomy procedure was performed in one single session, by two postgraduate students in pediatric dentistry previously calibrated. After local anesthesia with 4% articaine with 1:100,000 epinephrine and rubber dam isolation, caries removal was accomplished with handpiece with a round bur. The opening of the pulp chambers was
conducted with high speed and round carbide bur under water spray. Complete coronal pulp tissue was removed manually with an excavator, followed by irrigation with saline solution in order to clear off the debris. The wound surface was continuously irrigated with saline solution and a dry sterile cotton pellet was placed on the radicular pulp stumps under slight pressure for 5 minutes until hemostasis was achieved.

In FC group, a sterile cotton pellet dampened with diluted FC - 1:5 Buckley's solution (Biodinâmica Química e Farmacêutica Ltda., Ibiporã, Brazil) was placed on the amputated pulp and removed after 5 minutes, and the pulp stumps were covered with zinc oxide-eugenol paste (ZOE). In CH group, the canal orifices were dressed with powdered calcium hydroxide (Biodinâmica Química e Farmacêutica Ltda., Ibiporã, Brazil) with the aid of a sterile amalgam carrier. In O+CH group, a cotton pellet with two drops of the corticosteroid/antibiotic solution - Polymyxin B sulphate 10.000I.U, neomycin sulphate 5mg ahd hydrocortisone 10 mg (Otosporin® - Farmoquímica, Rio de Janeiro, Brazil) was placed on the amputated pulp and removed after 5 min, than the powder of calcium hydroxide was placed into the pulp chamber with the aid of a sterile amalgam carrier as in CH group. All groups received a layer of reinforced zinc oxide-eugenol - IRM® (Dentsply, Petrópolis, Brazil) prior to restoration with resin modified glass ionomer cement - Vitremer® (3M ESPE, São Paulo, Brazil). Immediate post-operative periapical radiographs were taken in order to serve as the initial parameter for further postoperative evaluations.

At follow-up appointments, clinical success was confirmed in teeth presenting absence of spontaneous pain, mobility, swelling or fistula. Radiographic success was considered as presence of hard tissue barrier formation and pulp calcifications, and absence of internal or external root resorption and furcal radiolucency. Periodic follow-up examinations were carried out 3, 6 and 12-month after the ending of the treatment by two blinded and previously calibrated investigators (kappa values of 0.91 and 0.94 for inter- and intra-examiner reproducibility, respectively), each checkup involved a clinical and periapical radiographic examination of the pulpotomized teeth. Data were submitted to statistical analysis using Ficher's exact test to determine differences among the groups. Statistical significance was established at p < 0.05, using the statistical software Statistica® version 10 (StatSoft Inc., Tulsa, OK, USA).

RESULTS

Forty five teeth were selected and allocated into the three study groups (FC, CH and O+CH). After 12 months, 2 teeth were lost to follow-up due natural exfoliation and one patient dropped out of the study in CH group.

All the groups studied were successful in the clinical evaluation over the follow-up period. No patient reported pain symptomatology or show signs of clinical infection associated with pulpotomy treatment. None of the evaluated teeth show signs of mobility, fistula swelling, or inflammation of the surrounding gingival tissue.

In the present study internal resorption was categorized as radiographic failure, but the teeth were left for follow-up observation. This methodology was adopted because the teeth were asymptomatic and did not show any sign of clinical failure.

The statistical analysis of the radiograph results revealed statistically significant difference among groups (Table 1). The radiographic successes rate for the FC was 100% at all the follow-up periods. At 3 months, the radiographic success rate for CH group was 60% and 80% for O+CH group. After 6 months, the radiographic success rate of 60% was found for both groups CH and O+CH. At 12 months follow-up, the radiographic success rate for CH group was 50% and 60% for O+CH group (Table 1).
The FC group had no internal resorption and hard tissue barrier formation observed in the follow-up periods. Internal resorption was seen in the two other groups, and in O+CH group were found a rise in this finding when compared the 3 and 6 month follow-up (Table 2). The hard tissue barrier was seen in the two other groups, and the O+CH group had the highest number (Table 2). The pulp calcification was seen in all studied groups (Table 2).

DISCUSSION

Pulpotomy therapy is an effective treatment for pulps exposed by dental caries, in symptom-free primary teeth. However, two challenges permeate its indication: the determination of pulp condition and the choice of the dressing material to be employed [3-4,6]. Different capping materials have been investigated to be used as pulpotomy agent, however, Walker et al. [15] reported that there was no common sense in which is the most appropriate agent or technique for pulpally involved primary molars. Also the accurate establishment of the inflammatory process in the pulp is crucial in order to allow the prediction of pulp tissue reparability. In this situation, it is plausible to consider the use of an anti-inflammatory solution prior to the placement of the capping material, thus decreasing the negative consequences of misdiagnosed pulp inflammation [16-19].

In order to control the inflammatory process that might lead to pulp necrosis and pathological resorption resulting in pulpotomy failure, an anti-inflammatory medicament, an otic solution composed of hydrocortisone, a glucocorticoid anti-inflammatory agent, and two broad spectrum antibiotics (neomycin sulphate and polymyxin B sulphate) was topically applied to the pulp stumps for 5 min in the present study, thus allowing the pulpotomy treatment to be concluded in one single appointment, which is more desirable in pediatric dentistry [14,19].

The use of otic solutions prior the capping material are comparable to the studies of Cannon et al. [14], Seow and Thong [20] and Holland et al. [18] using animal teeth and Percinoto et al. [19] in human primary teeth, they use this solutions aiming at reducing or eliminating the inflammatory condition, preventing infection, increasing the repair capacity and preventing irritation to pulp tissue.

According to the results obtained in the present study all the studied groups shows clinical success over the follow-up period, since no pain, mobility, swelling and fistula

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**Table 1** - Radiographic success (S) and failure (F) rates for FC, CH and O+CH pulpotomies at 3, 6 and 12 months of follow-up

<table>
<thead>
<tr>
<th>Treatment</th>
<th>3 months</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>S (100%)</td>
<td>F (0%)</td>
<td>S (100%)</td>
</tr>
<tr>
<td>FC</td>
<td>15</td>
<td>0</td>
<td>15</td>
</tr>
<tr>
<td>CH</td>
<td>9 (60%)</td>
<td>6 (40%)</td>
<td>6 (40%)</td>
</tr>
<tr>
<td>O+CH</td>
<td>12 (80%)</td>
<td>3 (20%)</td>
<td>9 (60%)</td>
</tr>
</tbody>
</table>

**Table 2** - Radiographic findings (number valid percentage) observed in all groups

<table>
<thead>
<tr>
<th>Treatment</th>
<th>3M</th>
<th>6M</th>
<th>12M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal resorption</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pulp calcification</td>
<td>0</td>
<td>3 (20%)</td>
<td>0</td>
</tr>
<tr>
<td>Hard tissue barrier</td>
<td>0</td>
<td>2 (13.3%)</td>
<td>4 (26.7%)</td>
</tr>
</tbody>
</table>

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were detected. Radiographically, internal root resorption and hard tissue barrier were the most common findings in CH and O+CH groups and pulp calcification were observed in all studied groups, corroborating with previous studies on pulpotomy of primary teeth with different capping materials [3-4,8,12-13].

Havale et al. [10] reported that pulpotomy failures were normally detected in the radiographic exams, as the tooth may be asymptomatic clinically. The presence of internal resorption suggests that a silent chronic inflammation on the residual pulp that suggests pulp vitality. However, the exact mechanism accounting for this process remains not properly understood, and factors such as direct contact of the material with blood clot, pulp inflammation, inadequate control of the haemorrhage during the procedure and improper restorations have been related to this alteration [3-4,22-23].

The clinical success rates at 12 month follow-up were 100% for all the studied groups, whereas the radiographic success rates were 100, 50 and 60% for formocresol, calcium hydroxide and calcium hydroxide preceded by corticosteroid/antibiotic solution respectively, the failures did not interfere in the clinical success according to others studies [3-4,10,22].

The presence of root resorption associated to calcium hydroxide is controversial in the literature, Sonmez et al. [21] and Marques et al. [22] shows this alteration when the use of other materials and Waterhouse et al. [23] affirmed that such alteration could be hindered by the direct contact of calcium hydroxide with the remaining pulp tissue. In contrast, other studies reported the dentin bridge formation as a healing and successful characteristic of the use of calcium hydroxide [3-4,12-13].

All employed materials showed acceptable clinical and radiographic success rates. However data show that the use of an anti-inflammatory solution prior the dressing material has therapeutic properties that help with pulpal healing. Continued clinical investigations using these medicaments as vital pulpotomy treatment in primary molars are recommended.

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