Clinical and radiographic outcomes of direct pulp capping therapy in primary molar teeth following haemostasis with various antiseptics: a randomised controlled trial

**ABSTRACT**

**Aim** This was to evaluate the clinical and radiographic outcomes of direct pulp capping (DPC) therapy in primary molar teeth following haemostasis with various antiseptics for 12 months.

**Materials and methods** A total of 70 vital primary molar teeth with deep dentin caries were randomly allocated to different antiseptic groups. After observing the pinpoint exposure, 0.9% saline solution (SS, control), 0.5% sodium hypochlorite (SH), 2% chlorhexidine digluconate (CHX), or 0.1% octenidine dihydrochloride (OCT) was applied with sterile cotton pellets for 3 min before calcium hydroxide (CH) DPC therapy. Statistical evaluation: The intergroup radiographic success criteria were analysed using a Kruskal-Wallis test in each follow-up period at a confidence interval of 95%.

**Results** After 12 months, all groups showed a clinical success rate of 100% (no clinical failures were observed at the time of pulpectomy or extraction), and the overall radiographic success rates were OCT (100%) > SH (94.74%) > CHX (93.3%) > SS (84.21%), respectively (p > 0.05). OCT did not exhibit any failures. The undesirable radiographic failure types (pulpectomy or extraction) were mostly observed in the SS group.

**Conclusion** Compared with SS, the success of conventional CH usage in DPC therapy of primary molar teeth could be enhanced by providing acceptable disinfection features with antiseptic solutions. OCT seems to have relative beneficial effects compared to SH and CHX.

**Keywords** Antiseptic solution; Calcium hydroxide; Direct pulp capping; Primary teeth.

**Introduction**

Direct pulp capping (DPC) therapy has become the preferred means of treating small traumatic and caries-free exposures in primary teeth [Ranly and Garcia-Godoy, 2000; Fuks, 2008]. The site of exposure is commonly capped with calcium hydroxide (CH), which has an antibacterial effect due to its high pH [Ranly and Garcia-Godoy, 2000; Fuks, 2008; Garrocho-Rangel et al., 2009]. As pulp healing and preserving the vitality of the tooth are important, haemorrhagic injury and aseptic conditions should be taken into account for DPC therapy [Garcia-Godoy and Murray, 2005]. The most common means of haemorrhage control is to apply pressure over the exposed site with a sterile cotton pellet until bleeding stops [Pameijer and Stanley, 1998]. The use of sterile saline solution (SS) has also been proposed to prevent clotting [Hafez et al., 2002; Accorinte et al., 2005; Silva et al., 2006].

Sodium hypochlorite (SH) has been used in various concentrations to treat exposed pulpal tissue as it acts as a haemostatic as well as a bacteriostatic and/or bactericidal agent [Horsted-Bindslev et al., 2003; Garcia-Godoy and Murray, 2005; Accorinte et al., 2005; Demir and Cehreli, 2007]. Several studies also used chlorhexidine (CHX) at different concentrations for this purpose [Horsted-Bindslev et al., 2003; Garrocho-Rangel et al., 2009; Silva et al., 2006]. The bipyridine antimicrobial compound octenidine dihydrochloride (OCT) was developed as a potential antimicrobial/antiplaque agent for use in mouthwash formulations at a concentration of 0.1% [Beiswanger et al., 1990]. It also appears to be useful as an endodontic irrigant based on its antimicrobial effects and low cytotoxicity [Dogan et al., 2008; Tirali et al., 2009; Bal et al., 2011].

This study was performed to evaluate the clinical and radiographic outcomes of CH DPC therapy of primary molar teeth following haemostasis with various antiseptics for 12 months.
**Materials and methods**

**Operative procedures**

This randomised, controlled and blind clinical study was conducted in accordance with the ethical standards of the Responsible Committee on Human Experimentation (Institutional and National) and with the 1975 Declaration of Helsinki, as revised in 2000. A total of 70 mandibular primary molar teeth with deep occlusal dentin caries were treated with CH using the DPC technique. The preoperative inclusion criteria were: at least one occlusal deep dentin carious lesion, the removal of which would risk pulp exposure, the availability of at least two thirds of the root length according to radiographic observation. Also, exclusion criteria were presence of: proximal caries, spontaneous pain, tooth tender to percussion, abscess, mobility, root resorption, systemic disease, or specific drug use. Following administration of local anaesthetic, the selected molar was isolated with a rubber dam. Enamel caries were removed. Dentinal caries were removed using low speed carbide round burs. When the accidental pinpoint exposure surrounded by sound dentin was observed, the following solutions were applied using sterile cotton pellets for 3 min before the CH (Dycal; Dentsply, Konstanz, Germany) DPC procedure: 0.9% saline solution (SS, control), 0.5% sodium hypochlorite (SH), 2% chlorhexidine digluconate (CHX) (Klorhex; DrogSan, Istanbul, Turkey), and 1% octenidine dihydrochloride (OCT) (Ocitensept; Schülke & Mayr GmbH, Vienna, Austria). Intermediate Restorative Material (IRM) (Dentsply Caulk, Woodbridge, ON, Canada) was used as a liner base material before placement of an amalgam or stainless steel crown (SSC).

**Clinical and radiographic evaluation**

The cavities were restored with amalgam or with SSC when required (e.g., for providing occlusal relations). Baseline and recall radiographs were taken. The Modified Ryge Criteria (MRC) [Ryge, 1980] were used for evaluation of the marginal quality of restorations. For the evaluation criteria used to determine the clinical conditions with the presence of: spontaneous pain, tenderness to percussion, mucosal swelling, pathological tooth mobility, and/or radiographic failure, a) periapical and/or furcation radiolucencies, b) internal or pathological external root resorption at 1, 3, 6, and 12 months.

Patients were assigned in a blind random manner to one of the four treatment solution groups. The operative procedures were carried out by a qualified and experienced paediatric dentists blinded to the solution type. Two blinded operators assessed the restorations and clinical symptoms. Two calibrated operators, blind to the solution types and clinical treatment procedures, examined the patients with respect to radiographic examinations. The presence of one or more of the above clinical and/or radiographic symptoms/signs determined the outcome as a failure.

**Statistical evaluation**

SPSS software version 15.0 (SPSS Inc., Chicago, IL, USA) was used for statistical evaluations. Cohen’s kappa statistic was used for interexaminer agreement. The intergroup radiographic success criteria were analysed in each follow-up period with the Kruskal-Wallis test at a confidence interval of 95%.

**Results**

CH DPC therapy was completed for 80 patients. Ten patients dropped out of the study, so recall evaluations were completed in 70 teeth. The mean age was 8.66 ± 1.51 years, and the F/M sex ratio was 51.4/48.6%. No untimely eruption was observed during the study period.

The kappa score values of operators were 0.99 (for evaluating restorations and clinical failures) and 0.82 (for evaluating radiographic failures). Restorations were performed with occlusal amalgams in 66 cases and SSC in 4 cases. The MRC scores were found as 97.14%.

The MRC scores of two patients in SS and OCT groups (occlusal amalgams of two teeth) showed BRAVO scores at 12 months, while the other teeth exhibited ALFA scores. No defective crown, secondary caries, or postoperative sensitivity was observed in teeth treated with SSCs. During the 12-month follow-up period, one tooth was pulpectomised and four teeth were extracted (failures occurred in occlusal amalgam restorations).

No clinical failures (100%) were observed according to the criteria used in this study at the time of pulpectomy/extraction.

The details of radiographic failure/success features are given in Table 1. No significant differences were found among the groups according to the radiographic success criteria (p>0.05).

The overall radiographic success rate was 92.86% (for 12 months). The order of success rates for individual treatment groups was OCT (100%)>SH (94.74%)>CHX (93.3%)>SS (84.21%). Periapical or furcation radioluencies were only observed in the SS group at 6 and 12 months in one patient, and this case was treated with pulpectomy. This was recorded as a case of failure according to the radiographic success criteria at both 6 and 12 months. Internal or pathological external root resorption was observed in the SS group at 6 months in one patient (extracted) and 12 months in one patient (extracted), in the SH group at 12 months in one patient (extracted).
and in the CHX group at 6 months in one patient (extracted). All these radiographic failures occurred without any clinical failure.

Discussion

This study confirmed that the success rate of CH could be enhanced by eliminating clot formation and disinfecting the area of pulp exposure using antiseptic materials in DPC therapy of primary molar teeth.

In DPC therapy, SH is commonly used for disinfecting and controlling haemorrhage in the exposed pulp area [Accorinte et al., 2005; Demir and Cehreli, 2007]. Such studies recommended its use at the lower concentration of 0.5% to obtain acceptable cytotoxic and bactericidal levels [Ayhan et al., 1999; Gomes et al., 2001]. In recent studies, disinfecting the exposed area with 2% CHX solution resulted in beneficial pulp healing following DPC therapy of primary molar teeth [Garrocho-Rangel et al., 2009; Aminabadi et al., 2010]. Additionally, the use of 0.1% OCT solution as a haemostatic and/or an antiseptic agent in the CH DPC procedure was shown to contribute to successful pulp healing in a recent study in rats [Bal et al., 2011]. Therefore, selected concentrations (0.5% SH, 2% CHX and 0.1% OCT) of above solutions were used in the present study.

In the present study, the overall clinical success rate (according to the clinical failure criteria, 100%), was found to be acceptable compared with previous studies [Caicedo et al., 2006; Demir and Cehreli, 2007; Tuna and Olmez, 2008]. This may also be related to the restorations completed in the occlusal region with amalgams (IRM used as a liner) or SSCs, which delayed the effects of inevitable postoperative microleakage and eliminated doubts regarding the retention capacity of restorations, particularly during the critical period of healing. Moreover, clinical evaluation according to the clinical failure criteria may not always be sufficient for accurately determining the success rate in pulp therapy of primary teeth [Garrocho-Rangel et al., 2009; Aminabadi et al., 2010]. In previous studies, although the clinical success rates were found mostly higher, different capping materials indicated lower radiographic success rates compared to their own clinical findings, which could decrease the overall treatment success rate [Demir and Cehreli, 2007; Garrocho-Rangel et al., 2009; Aminabadi et al., 2010]. For this purpose, radiographic results may be considered as an indirect method for evaluating the success rates of DPC therapy, since direct evidence of ongoing healing/necrosis can only be determined if the tooth is extracted and investigated at the histological level [Demir and Cehreli, 2007].

The overall radiographic success rate after the 12-month follow-up period was 92.86% in the present study. This result showed that the observed overall healing rate was acceptable and comparable to previous reports [Demir and Cehreli, 2007; Garrocho-Rangel et al., 2009; Aminabadi et al., 2010]. The CH DPC procedure was most successful (according to the radiographic criteria) in primary molar teeth at a level of 97.8% [Garrocho-Rangel et al., 2009] when SS and CHX were performed prior to capping, and 100% enhancement.

TABLE 1 Radiographic evaluation of failure/success rates and failure types of antiseptic materials before CH DPC therapy in primary molar teeth.

<table>
<thead>
<tr>
<th>GROUPS</th>
<th>RECALL PERIODS (MONTHS) (FAILURE/SUCCESS IN EACH PERIOD)</th>
<th>TOTAL FAILURE/SUCCESS (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>0.9% Saline Solution (SS, control) (n = 19)</td>
<td>0/19</td>
<td>0/19</td>
</tr>
<tr>
<td>0.5% Sodium hypochlorite (SH) (n = 19)</td>
<td>0/19</td>
<td>0/19</td>
</tr>
<tr>
<td>2% Chlorhexidine digluconate (CHX) (n = 15)</td>
<td>0/15</td>
<td>0/15</td>
</tr>
<tr>
<td>0.1% Octenidine dihydrochloride (OCT) (n = 17)</td>
<td>0/17</td>
<td>0/17</td>
</tr>
</tbody>
</table>

* Periapical or furcation radiolucencies were only observed in the SS group at 6 and 12 months in one patient. This tooth was recorded as failure according to the radiographic success criteria at both 6 and 12 months.
* Internal or pathological external root resorption was observed in the SS group at 6 and 12 months in two different patients.
* In the SH group at 12 months in one patient.
* In the CHX group at 6 months in one patient without any clinical failures. No failures were observed in the OCT group.
Comparing with previous findings regarding higher SH concentration [Silva et al., 2006; Demir and Cehreli, 2007] the results of the present study also indicated that applying a reduced concentration of SH (0.5%) could have a therapeutic healing effect without risk of cytotoxicity. In addition, the therapeutic concentration of CHX used (2%) resulted in an acceptable healing rate of 93.3%, consistent with previous studies [Caicedo et al., 2006; Garrocho-Rangel et al., 2009].

Recent reports indicated that the success rates of DPC therapy could be explained by comparing the results as percentages [Garrocho-Rangel et al., 2009; Aminabadi et al., 2010]. Furthermore, the failure types were considered valid parameters to explain the actual success of therapeutic approaches in DPC procedures [Demir and Cehreli, 2007; Tuna and Olmez, 2008; Garrocho-Rangel et al., 2009; Aminabadi et al., 2010]. In the present study, radiolucency in the periapical or furcation area was observed only in the SS group at 6 and 12 months in one patient. Internal and pathological external root resorption failures were observed in the SS group at 6 months in one patient (extracted) and 12 months in one patient (extracted), in the SH group at 12 months in one patient (extracted), and in the CHX group at 6 months in one patient (extracted). These results indicated that the use of SS as a haemostatic and/or disinfecting solution would be somewhat problematic, particularly for CH DPC therapy of primary teeth. Also no failures were observed in OCT group. These results also indicate that OCT had relative advantages because of its considerable antiseptic properties, as described previously [Dogan et al., 2008; Tirali et al., 2009; Bal et al., 2011]. Nevertheless, besides providing aseptic conditions in DPC areas, the potential benefits of CH material that preserves the pulp vitality and contributes to the active formation of new hard tissue by induction and upregulation of the differentiation of odontoblast-like cells should not be overlooked [Fukus, 2008; Dammashcke et al., 2011].

This study was conducted over 12 months to avoid untimely exfoliations. Moreover, the availability of at least two thirds of the root length according to radiographic observation could be considered as another reason that the follow-up period would be higher for evaluating the role of antiseptics in CH DPC therapy. Because of the above reasons, the follow-up period may have been relatively short for this type of study [Demir and Cehreli, 2007; Aminabadi et al., 2010].

References