RANDOMIZED CONTROL TRIAL

Direct Pulp Capping of Primary Molars with Calcium Hydroxide or MTA Following Hemorrhage Control with Different Medicaments: Randomized Clinical Trial

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Abstract: ***Purpose:*** *This study aimed to evaluate the effects of different medicaments (sterile saline [SS]; ferric sulfate [FS]; or sodium hypochlorite [SH]) and pulp capping materials (calcium hydroxide [CH] or mineral trioxide aggregate [MTA]) on the success of direct pulp capping (DPC) in primary molars.* ***Methods:*** *The study was conducted with 55 children aged four to eight years. A total of 118 teeth, in which occlusal caries removal resulted in pulp exposure, were treated with DPC across six groups: SS+CH; FS+CH; SH+CH; SS+MTA; FS+MTA; and SH+MTA. Teeth were restored with Class I composite resin.* ***Results:*** *After two years, the overall clinical and radiographical success for DPC were 94.1 percent (111 out of 118 teeth) and 88.9 percent (105 out of 118 teeth), respectively. The clinical and radiographical success, respectively, for hemorrhage control medicaments were 92.1 percent and 89.5 percent for SS, 92.5 percent and 82.5 percent for FS, 97.5 percent, and 95.0 percent for SH (P>0.05). Internal resorption was significantly higher in the FS+CH group when compared to other groups (P<0.05). MTA had significantly higher success than CH for clinical (98.3 percent versus 89.7 percent) and radiographical success (98.3 percent versus 79.3 percent) (P<0.05, each comparison).* ***Conclusions:*** *For primary molars with occlusal caries and less than one-mm exposure sites, these findings suggest that direct pulp capping with MTA following hemorrhage control with the tested solutions offers a more predictable outcome compared to CH. Further, the findings of this study indicate an increased risk for internal resorption when FS and CH are used for DPC.* *(Pediatr Dent 2022;44(3):167-73) Received August 31, 2021 / Last Revision March 24, 2022 / Accepted March 25, 2022*

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Pulp tissue can often be exposed during restorative procedures in primary teeth that have lesser enamel and dentin thickness, relatively larger pulp chambers, and pulpal horns closer to the occlusal surface than in permanent teeth.[1,2] The American Academy of Pediatric Dentistry (**AAPD**) recommends direct pulp capping (**DPC**) in vital primary teeth where a pinpoint exposure (one millimeter or less)[3] of the pulp is encountered during cavity preparation or following a traumatic injury.[4] Although its success at 24 months was reported as 88.8 percent, DPC has generally been a treatment with limited acceptance.[5]

To be capped, the pulp should not present profuse bleeding or purulent exudate since these have been regarded as the signs of irreversible pulpitis or pulpal necrosis.[1] A capping agent should not be placed against a bleeding pulp.[2,6] The other issue is avoiding a blood clot between the wound surface and the capping material.[7] A better degree of healing was shown to occur when blood clot formation was prevented in exposed primate pulps.[8]

Sterile saline solution (**SS**) is used for wound debridement in pulp therapies, including DPC. Although it has no hemostatic effect, sterile cotton pellets moistened with SS are applied to the pulp using light pressure until hemostasis is achieved.[9,10] Unlike conventional hemostatic solutions, ferric sulfate (**FS**) achieves hemostasis by forming a ferric ion-protein complex on the pulp surface after chemically reacting with blood proteins.[1] The complex mechanically seals the severed blood vessels, which achieves hemostasis and may prevent problems encountered with clot formation.[11] Sodium hypochlorite (**SH**) has also been suggested as a convenient hemostatic agent for vital pulp therapies when used at therapeutic concentrations (1.25 to 2.5 percent).[8,12]

Previously, hard-setting calcium hydroxide (**CH**) pastes have been the material of choice in pulp capping procedures.[13] However, these materials poorly adhere to dentin surfaces, dissolve under restorations, and are unable to prevent microleakage.[1,14,15] Mineral trioxide aggregate (**MTA**) is a biologically active substrate that has been shown to regulate dentinogenic events in pulp cells[16] and be superior to CH in the absence of an inflammatory response as well as a more predictable hard dentin bridge formation.[17] The studies comparing CH to MTA reported a significantly lower failure rate for DPC in permanent teeth with MTA, while no difference was found for primary teeth.[18] However, the small number of good-quality studies have limited comparison and interpretation.[3,19,20]

The purpose of this study was to compare the clinical and radiographic outcomes of direct pulp capping in primary molars treated with calcium hydroxide or mineral trioxide aggregate after hemorrhage control was obtained with the use of sterile saline (control), ferric sulfate, or sodium hypochlorite. The tested null hypotheses were: (1) there is no statistically significant difference in DPC outcome with the use of SS, SH, or FS; and (2) there is no statistically significant difference in DPC outcome when CH or MTA are used.

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Methods

This single-blinded, randomized, and controlled clinical trial utilized a three-by-two factorial design. The effects of two independent variables on the clinical and radiographical success of DPC in primary molars were evaluated. One of the independent variables, the medicaments used for obtaining hemorrhage control, had three levels: SS, FS, and SH. The second independent variable, pulp capping materials, had two levels: CH and MTA.

The study comprised healthy and cooperative patients presenting to the pediatric dentistry clinic at the Faculty of Dentistry, Hacettepe University, Ankara, Turkey for a routine dental examination. Children with deep occlusal caries on primary molars with no clinical or radiographical pathology (Table 1) were invited to participate in the study. The parents were informed about the treatment plan and the procedures involved. Written consent was obtained for each participating child. The recruitment of the patients started in June 2007 following the approval of its protocol and consent form by the Institutional Human Subject Review Committee of Hacettepe University (FON: 07/22-16).

The power analysis determined that a sample size of 120 would be required to achieve 80 percent power to detect an effect size (W) of 0.256 using a one degree of freedom chi-square test where α equals 0.05. Sequentially numbered opaque-sealed envelopes were used for block randomization of teeth in the study groups.[21] Before each session, a sealed envelope containing the choice of treatment (the hemorrhage control solution and the pulp capping material to be used) was given to the operator by the investigators to provide allocation concealment.

One pediatric dentist carried out all treatments. After topical anesthetic (18 percent benzocaine, Topicale®, Premier Dental, Plymouth Meeting, Pa., USA) application, two percent lidocaine with 1:100,000 epinephrine (New Stetic S.A., Bogota, Colombia) was administered. Using rubber dam isolation, Class I cavity preparations were made using high-speed diamond fissure burs (ISO size 012-018, Diatech-Coltène/Whaledent AG, Altstätten, Switzerland). Slow-speed round steel burs (ISO size 016-018) were used to remove carious dentin on the lateral walls of the cavity to reduce the risk of bacterial contamination. The teeth in which no pulp exposure was encountered during caries excavation (i.e., a candidate for indirect pulp therapy) or requiring a proximal cavity preparation were excluded from the study. Pulp exposures (not exceeding one-mm in diameter)[3] with visible and light red bleeding were first rinsed with 2.5 ml of 0.9 percent SS using a dental syringe with tip.

The teeth were then assigned to the following groups: (1) group one, in which a sterile cotton pellet moistened with 0.9 percent SS was placed over the exposure site for up to five minutes; upon success, a hard-setting CH paste (Dycal®, Denstply, Konstanz, Germany) was placed over the exposure site, as well as two mm of the surrounding dentin; (2) group two, in which a 15.5 percent FS solution (Astringedent™, Ultradent, Utah, USA) was applied to the exposure site for 15 seconds; the cavity was rinsed with saline and dried with sterile cotton pellets, and the exposure was covered with CH paste, as in group one; (3) group three, in which a sterile cotton pellet soaked in 1.25 percent SH solution was applied to the exposure for 60 seconds; the cavity was rinsed with sterile saline and dried with sterile cotton pellets; the exposure was covered with CH paste, as in group

Table 1. SELECTION CRITERIA OF PARTICIPANTS

Clinical/radiogaphical criteria
• Deep occlusal dentin caries on primary first or second molars
• No history of nocturnal/spontaneous pain
• No swelling, fistulae, tenderness to percussion/palpation, pathological mobility
• No evidence of pathological, internal/external root resorption, or periradicular/ furcation radiolucency
Operative criteria
• Pulp exposure (≤1 mm)[3] during excavation with no surrounding caries
• Bleeding stopped within 5 minutes, no need for a second attempt
• No bleeding after the placement of the capping material
• Tooth should be restorable with a Class I composite resin

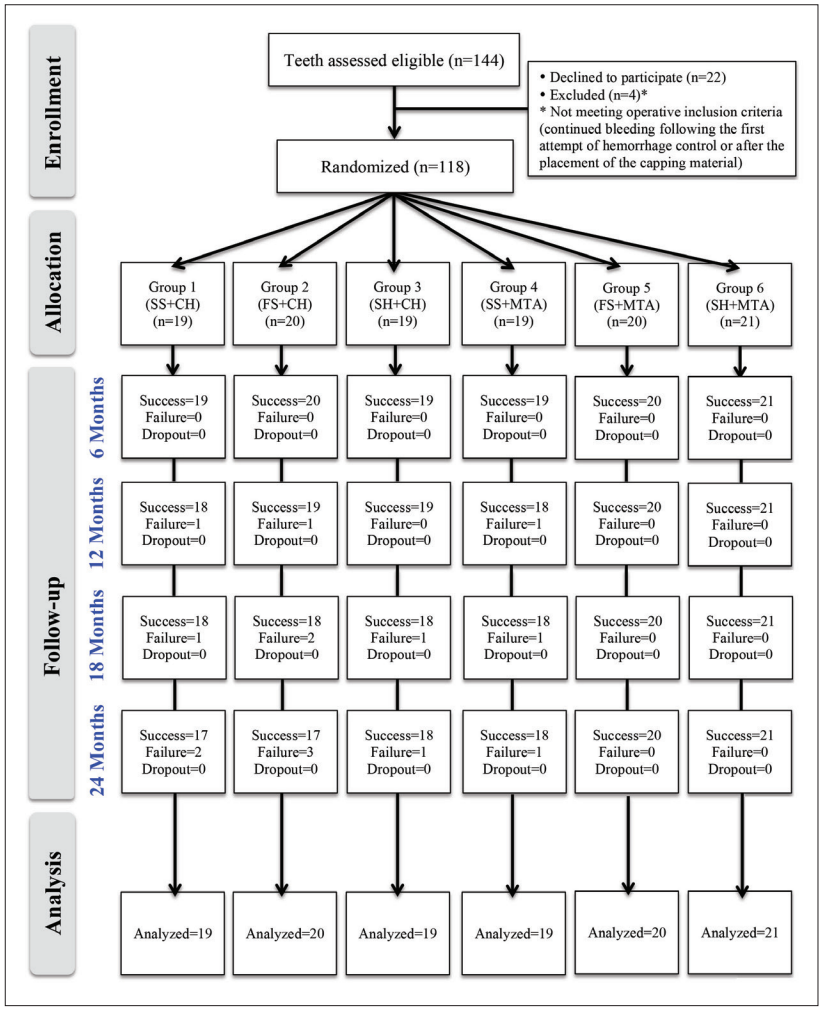

Figure. Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

Abbreviations in this figure: S=sterile saline; FS=ferric sulfate; SH=sodium hypochlorite; CH=calcium hydroxide; MTA=mineral trioxide aggregate.

one; (4) group four, in which 0.9 percent SS was applied, as in group one; it was followed by placement of MTA (ProRoot® MTA, Dentsply, Tulsa Okla., USA) over the exposure as well as two mm of the surrounding dentin; (5) group five, in which, following hemorrhage control with 15.5 percent FS, MTA was placed over the exposure, as in group four; and (6) group six, in which hemorrhage control was obtained with 1.25 percent SH and MTA was placed over the exposure, as in group four.

During these procedures, no second attempt was made to control hemorrhage. Any teeth with continued bleeding following the first attempt and/or after the placement of capping material were excluded and treated with advanced procedures (i.e., pulpotomy or pulpectomy). In all groups, following pulp cap, a glass ionomer cement (Fuji Triage®, GC, Tokyo, Japan) was placed and the teeth were restored with Class I resin composite (TPH-Spectrum®, Dentsply, Konstanz, Germany), utilizing an etch-and-rinse adhesive system (Prime&Bond® NT, Dentsply, Konstanz, Germany). Following occlusal adjustment and finishing, restoration margins were etched and sealed with a fissure sealant (Helioseal®, Ivoclar/Vivadent, Schaan, Liechtenstein).

Follow-up. All clinical and radiographical follow-up evaluations were carried out by the two same independent investigators (not the operator), who were blinded to the medicaments used. In each recall, the examiners assessed the clinical status of the teeth, quality of the restorations, and periapical radiographs taken. In cases of disagreement, a consensus was reached by discussion between the examiners. For clinical and radiographic evaluations, Cohen's kappa scores (κ) were performed by re-evaluating entire cases at the same visit and one month after the initial evaluation (only for the radiographs taken), respectively.

Clinical evaluations were made at six, 12, 18, and 24 months. Standardized forms were used to record the following signs and symptoms, any of which were regarded as a failure: (1) history of spontaneous pain; (2) a reliable reporting of tenderness to percussion/palpation; (3) mobility; (4) swelling; and (5) fistula. The intraexaminer kappa scores of examiner one and examiner two for the clinical evaluations were 0.91 and 0.92, respectively. The interexaminer κ equals 0.89.

A standard viewing box was used for radiographical evaluations, which were carried out at six, 12, 18, and 24 months. Success was considered as the absence of: (1) widened periodontal ligament; (2) loss of lamina dura; (3) interradicular/periradicular radiolucency; (4) internal/external root resorption; and (5) pathologic root resorption. For the radiographical evaluations, the intraexaminer kappa scores of examiner one and examiner two were 0.89 and 0.87, respectively. The interexaminer kappa score was 0.84.

The modified U.S. Public Health Service clinical rating system[22] was used to evaluate the marginal quality of the restorations, which were also scored separately by the investigators. The intraexaminer kappa scores of examiner one and examiner two were 0.88 and 0.84, respectively. The interexaminer kappa score was 0.84. At each recall session, after evaluations, all restorations were polished with paste and a rubber cup.

Table 2. DISTRIBUTION OF FAILURES OBSERVED IN THE STUDY GROUPS ACCORDING TO THE EVALUATION PERIODS*

Group	Treatment	Evaluation	Follow-up (months)				
			6	12	18	24	Total
1	SS+CH	Clinical symptoms	0/19 (0)	**1/19 (5.2)****	0/18 (0)	**1/18 (5.5)**	**2/19 (10.5)**
		Interradicular/periradicular lesions	0/19 (0)	**1/19 (5.2)**	0/18 (0)	**2/18 (11.1)**	**3/19 (15.8)**
		Internal/external root resorption	0/19 (0)	0/19 (0)	0/18 (0)	0/18 (0)	0/19 (0)
2	FS+CH	Clinical symptoms	0/20 (0)	**1/20 (5)**	**1/19 (5.2)**	**1/18 (5.5)**	**3/20 (15)**
		Interradicular/periradicular lesions	0/20 (0)	**1/20 (5)**	**1/19 (5.2)**	**2/18 (11.1)**	**4/20 (20)**
		Internal/external root resorption	0/19 (0)	0/19 (0)	**1/19 (5.2)**	**3/18 (16.7)**	**4/20 (20)**
3	SH+CH	Clinical symptoms	0/19 (0)	0/19 (0)	**1/19 (5.2)**	0/18 (0)	**1/19 (5.2)**
		Interradicular/periradicular lesions	0/19 (0)	0/19 (0)	**1/19 (5.2)**	0/18 (0)	**1/19 (5.2)**
		Internal/external root resorption	0/19 (0)	0/19 (0)	**1/19 (5.2)**	**1/18 (5.5)**	**1/19 (5.2)**
4	SS+MTA	Clinical symptoms	0/19 (0)	**1/19 (5.2)**	0/18 (0)	0/18 (0)	**1/19 (5.2)**
		Interradicular/periradicular lesions	0/19 (0)	**1/19 (5.2)**	0/18 (0)	0/18 (0)	**1/19 (5.2)**
		Internal/external root resorption	0/19 (0)	0/19 (0)	0/19 (0)	0/19 (0)	0/19 (0)
5	FS+MTA	Clinical symptoms	0/20 (0)	0/20 (0)	0/20 (0)	0/20 (0)	0/20 (0)
		Interradicular/periradicular lesions	0/20 (0)	0/20 (0)	0/20 (0)	0/20 (0)	0/20 (0)
		Internal/external root resorption	0/20 (0)	0/20 (0)	0/20 (0)	0/20 (0)	0/20 (0)
6	SH+MTA	Clinical symptoms	0/21 (0)	0/21 (0)	0/21 (0)	0/21 (0)	0/21 (0)
		Interradicular/periradicular lesions	0/21 (0)	0/21 (0)	0/21 (0)	0/21 (0)	0/21 (0)
		Internal/external root resorption	0/21 (0)	0/21 (0)	0/21 (0)	0/21 (0)	0/21 (0)

Abbreviations used in this table: SS=sterile saline; FS=ferric sulfate; SH=sodium hypochlorite; CH=calcium hydroxide; MTA=mineral trioxide aggregate.

* Teeth requiring extraction were not included in the calculations in subsequent follow-up sessions; values are expressed as "number of failures/total treated teeth (% failure)".

** Failures are highlighted in bold.

Statistical analysis. All data were tabulated and analyzed using SPSS® 11.5 software for Windows (SPSS Inc., Chicago, Ill., USA). Clinical and radiographical data were evaluated by chi-square and Fisher's exact tests. Chi-square and Fisher's exact tests were used to evaluate the restorations according to the groups. Additionally, the main effects of hemorrhage control solutions and pulp capping materials (interaction) were tested with the logistic regression analysis. For all analyses, the level of significance was set as α equals 0.05.

Results

Between June and December of 2007, a total of 71 patients with 144 eligible primary molars were invited to the study. However, only 56 (26 males and 30 females) consented and participated with 122 primary molars. The patients' ages ranged between four and eight years, while the mean age was 66.4±19.5 months. During operative procedures, four teeth were excluded from the study due to continued bleeding following the first attempt at hemorrhage control or after the placement of the capping material. Overall, 118 primary molars were treated with DPC. Of these, 45 (five primary first molars and 40 primary second molars) were in the maxilla and 73 (38 primary first and 35 primary second molars) were in the mandible. A Consolidated Standards of Reporting Trials (CONSORT) flow diagram is shown in the Figure.

In 13 teeth, radiographical failures were observed as interradicular/periradicular radiolucency and internal/external root resorption. Those were noted in nine and five teeth, respectively (one tooth presented both of these findings). Of 13 teeth, only seven required extraction due to accompanying clinical symptoms. For extracted teeth, space maintainers were fabricated and delivered to the patients. The remaining six teeth, presenting internal resorption, continued to recall visits since they were free of clinical symptoms. Clinical and radiographical failure increased between the 12th and 24th months (Table 2).

After two years, the overall clinical and radiographical success for DPC were 94.1 percent (111 out of 118 teeth) and 88.9 percent (105 out of 118 teeth), respectively. Significantly higher internal resorption (seven of 20 teeth) was noted in group two (FS+CH; $P<0.05$). All teeth in group five (FS+MTA) and group six (SH+MTA) completed the two-year period without any clinical or radiographical failures (Table 3).

The clinical and radiographical outcomes according to hemorrhage control solutions and pulp capping materials used are presented in Table 4. The main effects of hemorrhage control solutions and pulp capping materials and the interaction effect of both factors were tested with the logistic regression analysis by placing them into a model. The interaction effect of the two factors was insignificant ($P=0.997$).

Regarding hemorrhage control solutions, the clinical success were 92.1 percent (35 of 38 teeth), 92.5 percent (37 of 40 teeth), and 97.5 percent (39 of 40 teeth) for SS, FS, and SH groups, respectively ($P>0.05$). Radiographical success were 89.5 percent (34 of 38 teeth), 82.5 percent (33 of 40 teeth), and 95 percent (38 of 40 teeth) for SH, respectively ($P>0.05$). Concerning the pulp capping materials used, the clinical success of CH (groups one to three) and MTA (groups four to six) were 89.7 percent (52 of 58 teeth) and 98.3 percent (59 of 60 teeth), respectively ($P<0.05$). Radiographical success were also significantly different for these groups, with 79.3

Table 3. CLINICAL AND RADIOGRAPHICAL OUTCOMES IN THE STUDY GROUPS*

Groups			Clinical			Radiographical		
			Success	Failure	Total	Success	Failure	Total
1	SS+CH	N	17	2	19	16	3	19
		%	89.5	10.5	100.0	84.2	15.8	100.0
2	FS+CH	N	17	3	20	13	7	20
		%	85.0	15.0	100.0	65.0	35.0	100.0
3	SH+CH	N	18	1	19	17	2	19
		%	94.7	5.3	100.0	89.5	10.5	100.0
4	SS+MTA	N	18	1	19	18	1	19
		%	94.7	5.3	100.0	94.7	5.3	100.0
5	FS+MTA	N	20	0	20	20	0	20
		%	100.0	0.0	100.0	100.0	0.0	100.0
6	SH+MTA	N	21	0	21	21	0	21
		%	100.0	0.0	100.0	100.0	0.0	100.0
Overall total		N	111	7	118	105	13	118
		%	94.1	5.9	100.0	88.9	11.1	100.0

* Abbreviatons used in this table: SS=sterile saline; FS=ferric sulfate; SH=sodium hypochlorite; CH=calcium hydroxide; MTA=mineral trioxide aggregate.

Table 4. CLINICAL AND RADIOGRAPHICAL OUTCOMES IN THE STUDY ACCORDING TO HEMORRHAGE CONTROL MEDICAMENTS AND PULP CAPPING MATERIALS*

Groups			Clinical				Radiographical			
			Success	Failure	Total	*P*-value	Success	Failure	Total	*P*-value
Hemorrhage control medicaments	SS	N	35	3	38	0.627†	34	4	38	0.197**
		%	92.1	7.9	100.0		89.5	10.5	100.0	
	FS	N	37	3	40		33	7	40	
		%	92.5	7.5	100.0		82.5	17.5	100.0	
	SH	N	39	1	40		38	2	40	
		%	97.5	2.5	100.0		95.0	5.0	100.0	
Total		N	111	7	118		105	13	118	
		%	94.1	5.9	100.0		88.9	11.1	100.0	
Pulp capping materials	CH	N	52	6	58	0.052†	46	12	58	0.001†
		%	89.7	10.3	100.0		79.3	20.7	100.0	
	MTA	N	59	1	60		59	1	60	
		%	98.3	1.7	100.0		98.3	1.7	100.0	
Overall total		N	111	7	118		105	13	118	
		%	94.1	5.9	100.0		88.9	11.1	100.0	

* Abbreviatons used in this table: SS=sterile saline; FS=ferric sulfate; SH=sodium hypochlorite; CH=calcium hydroxide; MTA=mineral trioxide aggregate.

** Fisher's exact test. † Chi-square test.

percent (46 of 58 teeth) and 98.3 percent (59 of 60 teeth) for CH and MTA groups, respectively ($P<0.05$).

When the patients' median ages were grouped as younger or older than 62 months, no statistically significant differences were found in the clinical and radiographical success of the treatment ($P>0.05$). Primary maxillary and mandibular molars also did not differ significantly ($P>0.05$).

At the end of the two-year study period, 'marginal adaptation' and 'marginal discoloration' scores in group five (FS+MTA) and group six (SH+MTA) were significantly lower than for other groups ($P<0.05$). The restorations in group three (SH+CH) and group four (SS+MTA) significantly received worse scores for 'abrasion/anatomic form' ($P<0.05$). However, the groups did not differ significantly regarding 'enamel loss' and 'caries' scores ($P>0.05$), and no significant correlation was found between marginal integrity failure scores and clinical and/or radiographical failure ($P>0.05$).

Discussion

As a vital pulp therapy in the primary dentition, DPC has received limited acceptance from dental profession.[5] Its use has been questioned since the treatment was reported to have a lower success in primary teeth due to the development of internal resorption or acute dentoalveolar abscess.[13] Those arguments were mainly based on the study findings that showed rapid physiological changes in the primary tooth pulp during the period from eruption to exfoliation and the potential transformation of undifferentiated mesenchymal cells into odontoclasts.[2,13] However, a recent systematic review and meta-analysis showed that DPC of primary teeth had a similar success rate to indirect pulp therapy and pulpotomies with MTA or FC.[5] The authors emphasized the very low quality of evidence due to the scarcity of randomized clinical trials.

In this study, the overall clinical and radiographical success of DPC after two years were 94.1 percent and 88.9 percent, respectively. These results were in line with the literature.[5,9,10,23,24] No short-term failure (i.e., postoperative six months) was observed. This could be attributed to the efforts exerted to diagnose and include the teeth. In addition, as per AAPD recommendations,[4] the study was carried out in vital primary teeth with small pulp exposures (one mm or less). Better healing outcomes have been reported when there was no inflammation and infection present due to prior caries process.[2,25,26] However, it would be plausible to suggest that the study teeth had inflammation to some degree since pulp exposures were encountered during caries removal.[3]

It has been stated that not only the diagnostic errors made in the assessment of pulp inflammation before the treatment but microbial contamination, dentinal debris, and lack of proper peripheral seal could also contribute to the failure of pulp capping.[2,6] Stanley[6] has argued that the operator's inability to perform the proper surgical procedures, rather than the inadequacy of the medicament employed, might be another contributing factor. A study by Rodd et al.[27] found that the potential of the primary tooth pulp was similar to that of the permanent tooth in terms of ensuing inflammatory responses to gross caries. Kopel[14] had suggested that DPC could be feasible without the disadvantages of CH, provided that a hermetic seal is achieved at a minimal exposure site in a primary tooth.

The control of pulpal hemorrhage is a critical step in vital pulp therapies.[8] The discouraging results in primary teeth, especially those yielded with CH, have been ascribed to a lack of hemostasis.[6] Without sufficient bleeding control, any excessive serum or plasma would occupy, fill, or create a space between the capping agent and the pulp tissue.[6] Thus, the continuation of bleeding (or oozing) might dislodge the dressing and permit the formation of a blood clot or a thick fibro purulent membrane over the pulp wound, which could compromise the contact between the dressing and the pulp, thereby reducing its effectiveness.[6,7,14,25] The blood clot formation could be subject to secondary infection and lead to complete loss of pulp vitality.[6] Stanley[6] has suggested the use of astringent compounds, which cause contraction or shrinkage of the underlying tissue and produce clot-free hemostasis, to achieve better contact of the CH dressing with the pulp and better healing outcomes.

The main effect of hemorrhage control solutions used in the present study was found to be insignificant. Hence, the study failed to reject the first null hypothesis. SH is a non-specific proteolytic agent with tissue-dissolving ability and hemostatic activity in therapeutic concentrations.[12] It offers advantages such as removing the existing blood clot, infected tissue and cells, and dentine chips from the pulp and providing cavity disinfection.[8,28-30] Hafez et al.[8] have shown healing and dentin formation in CH-pulpotomized permanent primate pulps in which hemorrhage was controlled with three percent SH. Other studies utilizing SH have reported improved success for CH pulpotomy[31] and DPC of primary molars.[32] Tüzüner et al.[32] evaluated the clinical and radiographic outcomes of DPC therapy in primary molars following the use of various antiseptic solutions for hemostasis. They compared 0.9 percent saline solution to 0.5 percent sodium hypochlorite, two percent chlorhexidine digluconate, and 0.1 percent octenidine dihydrochloride. After 12 months, no clinical failures were observed in the groups, and the radiographical success rates were between 84.2 percent and 100 percent with no significant differences. The authors concluded that the tested antiseptic solutions could improve the success of CH in the DPC of primary teeth.

The present study is the first in the literature for its utilization of FS in DPC. Significantly more internal resorption was observed in group two, where CH was applied following hemostasis with FS. Therefore, the present study could not suggest the use of FS for hemostasis if CH was the choice of material for DPC. Due to the lack of studies in the field, a comparison with pulpotomy studies could be useful. Although pulpotomy is merely a large pulp capping,[6] the obvious differences in study designs should be acknowledged. In those studies, where CH was placed after hemostasis with FS, internal resorption was also noted.[33,34] However, in those studies, the overall radiographical success of the groups did not differ significantly when compared to other groups. There are other studies with poorer radiographical success in primary tooth pulpotomy where FS was used without CH. Smith et al.[35] have related that finding to the use of zinc oxide and eugenol as the sub-base material.

The AAPD considers both CH and MTA suitable capping materials for DPC in primary teeth.[4] Dhar et al.[3] concluded that the success of DPC was independent of the type of medicament used. The study by Caicedo et al.[36] observed tissue response in 10 primary teeth that had DPC with MTA. The teeth were restored and then clinically reviewed monthly for five months before extraction and histologic evaluation. Although there was no comparison group (e.g., CH), it was reported that the responses of primary teeth pulps to MTA pulp caps were favorable from clinical and radiographic perspectives, with a variety of histological responses. On the other hand, a meta-analysis by Li et al.[17] found higher success for MTA that resulted in less pulpal inflammatory response

and more predictable hard dentin bridge formation than CH. Both studies concluded that MTA appeared to be a suitable replacement for CH in DPC. Schwendicke et al.[18] also stated that the risk of failure significantly decreased if MTA was used instead of CH in permanent teeth, while no difference was found for primary teeth.

There is only one published study that has compared CH to MTA in the DPC of primary teeth.[9] Tuna et al.[9] used cotton pellets moistened with SS and applied light pressure to obtain hemostasis, after which the exposed pulps of one of the symmetric primary molars were capped with CH or MTA. The study comprised 42 teeth with Class I amalgam restorations and reported no clinical or radiographical failures for both groups after two years. The authors concluded that MTA was as successful as CH for use in the DPC of primary teeth. However, the present study findings indicated a significant difference in the main effect of pulp capping materials, favoring MTA over CH. With a larger sample size (118 primary teeth, capped either with CH or MTA) and no dropouts, the study found that the main effect of pulp capping material was significant on the clinical and radiographical outcome of DPC in primary teeth. Accordingly, the second null hypothesis was rejected.

The study was conducted in Class I cavities. This was an attempt to standardize and provide a more rational comparison of the treatment groups in which all teeth were restored with composite resin. Class I restorations and restorations placed using a rubber dam have been shown to present lower annual failure rates.[37] In a systematic review, Chisini et al.[37] reported that composite resin showed the lowest annual failure rates while stainless steel crowns (**SSCs**) had the highest success rate. Hutcheson et al.[38] conducted a study evaluating the success of MTA pulpotomies in primary molars restored with multisurface composites or SSCs. After 12 months, they reported that all teeth were radiographically and clinically successful, regardless of the restoration. All treatments and restorations in the present study were done using a rubber dam. Although 'marginal adaptation', 'marginal discoloration', and 'abrasion/anatomic form' scores were not favorable for some groups of the study, those scores did not contribute to clinical/radiographical failures observed. Maintenance of the restorations carried out at each control session might have contributed to this outcome.

The type of cavity used did not ensure a similar depth of carious lesions among the patients, since a split-mouth study design was not employed. This might also be a study limitation. However, choosing not to do so could substantially limit the number of patients/teeth recruited for the study.

Conclusions

Within the limitations of the study, the following could be stated for direct pulp capping of primary molars where removal of deep occlusal caries resulted in less than one-mm pulp exposures:

1. Hemorrhage control with 0.9 percent sterile saline, 15.5 percent ferric sulfate, or 1.25 percent sodium hypochlorite solutions did not affect the clinical and radiographical success of direct pulp capping with mineral trioxide aggregate or calcium hydroxide.
2. MTA is a suitable alternative to CH in terms of clinical and radiographical outcomes.
3. To prevent internal resorption, FS should not be used for hemorrhage control if CH is chosen for pulp capping.

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