Clinical Article

A New Haemostatic Agent's Effect on the Success of Calcium Hydroxide Pulpotomy in Primary Molars

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Abstract: ***Purpose:*** *The purpose of this study was to evaluate the effect of the application of a new hemostatic agent, Ankaferd Blood Stopper (ABS), on the clinical and radiographic success of calcium hydroxide (CH) pulpotomies in primary molars.* ***Methods:*** *Patients with bilateral vital mandibular primary molar teeth that required pulpotomies, because of pulpal exposure to caries, were selected for this study. After initial hemorrhage control, complete hemostasis into the canal orifice was achieved by: (1) applying a solution of ABS for 10 to 15 seconds; or (2) placing sterile, saline-wetted cotton pellets. Forty teeth in 2 groups were followed up clinically and radiographic at 1, 3, 6, 9, and 12 months.* ***Results:*** *CH group teeth had a total success rate of 90% at 12 months. CH+ABS group teeth had a total success rate of 95% at 12 months. There were no statistically significant differences between CH and CH+ABS group regarding both clinical and radiographic success rates.* ***Conclusion:*** *Ankaferd Blood Stopper may be a useful product in the management of pulpal bleeding during a calcium hydroxide pulpotomy.* *(Pediatr Dent 2011;33:529-34) Received April 7, 2010 / Last Revision August 7, 2010 / Accepted August 8, 2010*

KEYWORDS: PULPOTOMY, HAEMOSTATIC AGENT, CALCIUM HYDROXIDE

A pulpotomy is still the most common treatment for cariously exposed pulps in symptom-free primary molars.[1] The goal of pulpotomy treatment is to preserve the radicular pulp, avoid pain and swelling, and maintain the integrity of primary teeth.[2] Formocresol (**FC**) is the pulpotomy agent most commonly used in primary teeth, but concerns about FC safety have been published in dental and medical literature for almost 30 years. Even though high clinical success rates have been found using FC in pulpotomy therapy, toxic,[3] mutagenic, and carcinogenic[4] effects of the material have led clinicians to use alternative methods and agents that are more tissue compatible than formocresol.

Calcium hydroxide (**CH**), which is capable of promoting pulp repair and healing, has increased in popularity and represents a significantly more biocompatible alternative to FC. The clinical success rates of CH in the pulpotomy treatment of primary teeth have ranged from 31 to 100%.[5-11] Markovıc et al.,[7] found no statistical differences in overall clinical and radiographic success rates for calcium hydroxide, formocresol, and ferric sulfate pulpotomies in their 18-month follow-up study. Several factors have been cited as influencing the success of calcium hydroxide pulpotomy. One of the factors is control of pulp bleeding, which is a requirement necessary to improve the favorable prognosis of vital pulp therapy.[12] If the pulp bleeding cannot be controlled, a blood clot on the wound surface could prevent intimate contact between the capping material and pulp tissue and provoke a chronic inflammatory response while impairing the healing process.[12-14]

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Many hemostatic agents and procedures have been used to control pulpal bleeding in vital pulp therapy. The most well-known technique is to control pulpal bleeding by applying mechanical pressure to the wound surface with a sterile cotton pellet. The other techniques are to control pulpal bleeding by applying mechanical pressure with pellets soaked in saline, hydrogen peroxide, anesthetic solutions containing epinephrine, or ferric sulphate.[15-21]

Ankaferd Blood Stopper (**ABS**; Ankaferd Sağlık Ürünleri AŞ, İstanbul, Turkey) is an herbal extract obtained from 5 different plants: *Thymus vulgaris*, *Glycyrrhiza glabra*, *Vitis vinifera*, *Alpinia officinarum*, and *Urtica dioica*. Each of these substances has some effects on the endothelium, blood cells, angiogenesis, cellular proliferation, vascular dynamics and cell mediators.[22-26] For centuries, ABS has had a historical role in traditional Turkish medicine as a topical hemostatic.[27] ABS has been approved in the management of dental surgery and external hemorrhage by the Turkish Ministry of Health. The basic mechanism of action of ABS is through the formation of an encapsulated protein network providing focal points for vital erythrocytes to aggregate. The ABS induced protein network formation involves blood cells, particularly erythrocytes, without affecting the physiological individual coagulation systems.[27]

ABS may be used to control pulpal hemorrhaging following the mechanical exposure of pulps. ABS has been safely used in patients to treat epistaxis,[28] after tonsillectomy,[29] or for variceal bleeding.[30] In addition, ABS has been used to control upper gastrointestinal bleeding,[31] life-threatening arterial bleeding of the digestive tract,[32] and bleeding due to solitary rectal ulcer.[33] Moreover, the levels of coagulation factors II, V, VIII, IX, X, XI, and XII were not effected by ABS; therefore, ABS might be used in patients with deficient primary or/and secondary hemostasis, including patients with disseminated intravascular coagulation.[34,35]

The purpose of this study was to evaluate the effect of the application of Ankaferd Blood Stopper, a new hemostatic agent, on the clinical and radiographic success of calcium hydroxide pulpotomies in primary molars.

Methods

The participants were selected from the patient population at the Department of Pediatric Dentistry, Faculty of Dentistry, University of Gazi, Ankara, Turkey. The children were healthy and cooperative. The procedure, possible discomfort, or risks as well as possible benefits were explained fully to parents of the children involved. This study was approved by the Ethics Committee of the Faculty of Dentistry, University of Gazi. A randomized, single-blind, split-mouth study was used with a sample of 20 children (10 boys and 10 girls) 4- to 8-years-old (mean age=6.1±0.99 years old). The patients were selected based on certain criteria. The clinical criteria were:

1. patients with bilateral vital mandibular primary molar teeth that required pulpotomy, because of pulpal exposure to caries;
2. teeth showed no clinical evidence of mobility;
3. teeth had no tenderness to percussion, no swelling, or fistulation; and
4. teeth were deemed restorable.

Radiographic criteria were:

1. absence of external or internal root resorption;
2. absence of furcal, periapical radiolucencies, or widened periodontal ligament spaces;
3. teeth had no more than one third physiologic root resorption.

Forty-eight teeth were selected and randomly divided into 2 treatment groups of 24 teeth (11 first and 13 primary second molars) each. The control group had the pulpotomized teeth treated with CH (Produits Dentaires, Vevey, Switzerland) on one side of the mandible. The experimental group had the pulpotomized teeth treated with CH+ABS (Ankaferd Sağlık Ürünleri AŞ) on the contralateral side of the mandible. Each subject's information was documented on a paper form, including the patient's name, age, date of treatment, and clinical and radiographic successive records.

All the treated teeth were anesthetized by using 4% articaine with 1:200,000 epinephrine (Ultracain D-S, Aventis Pharma San ve Tic, İstanbul), with 1.5 mL being the maximum total dose used, and were then isolated with a rubber dam. After caries removal, the pulp chamber was opened with a sterile high-speed diamond bur, and the coronal pulp was removed by a sterile sharp spoon excavator (Figure 1a). After removing the coronal pulp tissue, the chamber was irrigated with sterile physiologic saline. Hemorrhage was controlled by placing sterile, saline-wetted cotton wool pellets on the radicular pulp stumps under slight pressure,[36] waiting 5 minutes for primary hemostasis, followed by removal of blood clot remnants and drying the cavity. The hemorrhage was re-evaluated to determine whether or not the radicular pulp was free from inflammation. If bleeding continued afterward, the patient was excluded from the study. In the experimental group, ABS solution was applied on the pulp stumps with a dental syringe for 10 to 15 seconds for complete hemostasis and then the ABS was flushed away from the pulp chamber with sterile saline (Figure 1b). In the control group, only sterile, saline-wetted cotton pellets were used for complete hemostasis. Four patients were excluded from the study because of uncontrolled pulpal bleeding.

Pulpotomies were performed in both the control and experimental group by delivering a mixture of calcium hydroxide powder and physiologic saline to the pulp chamber. The mixture was gently packed over the pulp stumps using small cotton pellets (Figure 1c). Then, intermediate restorative material paste (Dentsply Caulk, Milford, Del) was placed over the CH and the teeth were restored with stainless steel crowns.

A total of 40 primary teeth of 20 patients were followed up clinically and radiographic at 1, 3, 6, 9, and 12 months. The outcome in terms of success or failure was determined by the following clinical and radiographic criteria:

1. no tenderness to percussion; teeth remained asymptomatic;
2. absence of a sinus tract;
3. absence of furcal or periapical radiolucencies;
4. absence of external or internal root resorption;
5. absence of widened periodontal ligament spaces; and
6. absence of premature tooth loss.

Clinical outcome assessments were made by the primary investigator at each follow-up visit, whereas radiographic outcome assessments were made by the primary investigator and an independent, experienced clinician, who were both blind to the treatment.

The clinical and radiographic data for the 2 groups were statistically analyzed by using Fisher's exact test.

Results

The agreement between the 2 examiners was good for the radiographic success rates (κ=0.90) using kappa statistics. The CH+ABS group's primary molars had a clinical success rate of 100% at 1, 3, and 6 months. The clinical success rate dropped to 95% at 9 and 12 months (in the 19/20 teeth evaluated). The

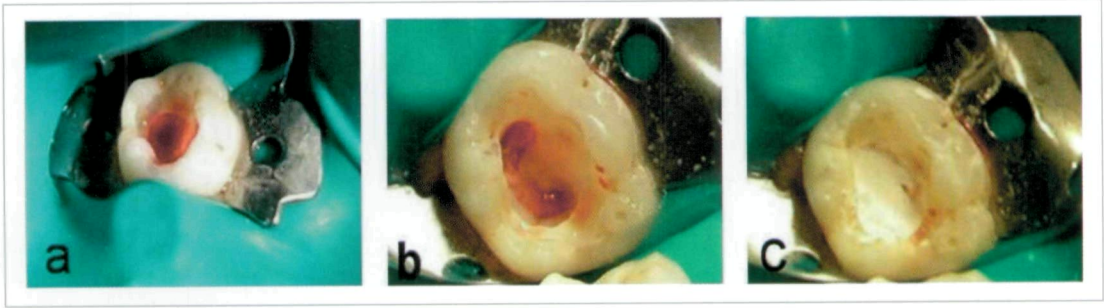

Figure 1. (a) Pulpal bleeding after removal of coronal pulp tissue. (b) Hemorrhage controlled by applying Ankaferd Blood Stopper for 10 to 15 seconds; then, pulp stumps flushed with water using an air-water syringe. (c) Calcium hydroxide packed over pulp stumps using small cotton pellets.

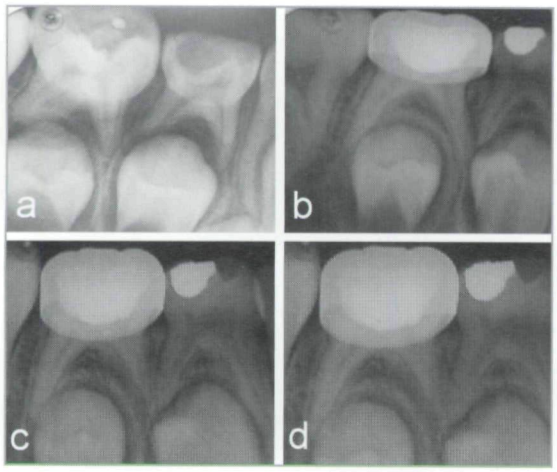

Figure 2. (a) Pretreatment radiograph of tooth #K. Radiographic follow-up of calcium hydroxide and Ankaferd Blood Stopper pulpotomy at (b) 3 months, (c) 6 months, and (d) 12 months.

Table 1. ANALYSIS OF CLINICAL AND RADIOGRAPHIC FINDINGS AFTER 1-, 3-, 6-, 9-, AND 12-MONTH FOLLOW-UP*

Findings	CH+ABS (mos) (N=20)					CH (mos) (N=20)				
Clinical	1	3	6	9	12	1	3	6	9	12
Percussion	0	0	0	1	1	0	0	1	1	1
Swelling	0	0	0	0	0	0	0	0	0	0
Spontaneous pain	0	0	0	0	0	0	0	0	1	0
Fistula	0	0	0	0	1	0	0	0	0	1
Normal	20	20	20	19	19	20	20	19	19	18
Radiographic	1	3	6	9	12	1	3	6	9	12
Internal RR	0	0	0	0	1	0	0	1	2	2
External RR	0	0	0	0	0	0	0	0	0	0
Periapical R	0	0	0	0	0	0	0	0	0	1
Furcal R	0	0	0	0	0	0	0	1	1	1
Widened PL	0	0	0	0	1	0	0	0	0	0
Normal	20	20	20	20	19	20	20	19	18	18

* CH=calcium hydroxide; ABS=Ankaferd Blood Stopper; R=radiolucency; RR=root resorption; PL=periodontal ligament.

CH group's teeth had a clinical success rate of 100% at 1 and 3 months and 95% at 6 and 9 months. The clinical success rate dropped to 90% at 12 months (in the 18/20 teeth evaluated). The clinical success observed for each group was compared at each of the 5 follow-up periods. Statistical analysis of the data, using Fisher's exact test, revealed no statistically significant differences between the 2 groups ($P>.05$).

The radiographic success of primary molars in the CH+ABS group was 100% at 1, 3, 6, and 9 months. The radiographic success rate dropped to 95% at 12 months (in the 19/20 teeth evaluated). CH group teeth had a radiographic success rate of 100% at 1 and 3 months and 95% at 6 months. The radiographic success rate dropped to 90% at 9 and 12 months (in the 18/20 teeth evaluated). Internal resorption was the most common radiographic failure in both groups.The success observed for each group was compared at each of the 5 follow-up periods. Statistical analysis of the data, using Fisher's exact test, revealed no statistically significant differences between the 2 groups ($P>.05$). Radiographs of a "normal" case at the last visit are shown in Figure 2a-d. An analysis of clinical and radiographic findings is shown in Table 1.

Discussion

This study evaluated the clinical and radiologic success of calcium hydroxide pulpotomies with and without ABS application in primary molars. A number of studies have examined various hemostatic agents and procedures for the control of pulpal bleeding in vital threrapy.[15-21] This study's results showed that the total success rate of CH+ABS pulpotomies after 12 months was 95%, which was not significantly higher than that of the CH pulpotomy group. CH as the control group in this study showed a total success rate (90%) that was comparable to results from other pulpotomy studies with CH.[5-10]

Formocresol is the pulpotomy agent most commonly used in primary teeth and remained the medicament of choice for pulpotomy in over 75% of dental schools in the United States.[37,38] Recently, teaching protocols for vital pulpotomies of primary teeth in the United Kingdom and Ireland[39] indicate that FC is becoming less popular due to the 2004 report of The International Agency for Research on Cancer,[40] which stated that formaldehyde causes nasopharyngeal cancer. Calcium hydroxide has increased in popularity and may represent a safe alternative to FC. The control of pulpal bleeding after coronal pulp amputation, however, may be a significant factor in the low success rates of pulpotomy treatment.

It has been suggested that pulp capping materials should not be placed against a bleeding pulp or a clinically observed blood clot.[9,13,41] If a bleeding pulp happens, erythrocytes within the pulp tissue would be hemolyzed to hemosiderin by macrophages, and an excess of hemosiderin is detrimental to pulp vitality.[20] The lack of hemostasis can cause embolization and transport of particles from the pulp capping material, delaying pulp healing.[42] Ranly and Garcia-Godoy[43] proposed more extensive debridement and absolute hemostasis for those who are willing to try CH cements on cariously exposed primary teeth in direct pulp capping.

One of the most commonly used hemostatic agents in dentistry is ferric sulfate, which has also been reported to show promising results as a dressing material for primary teeth pulpotomies.[18] The agglutination of blood proteins results from the reaction of blood with ferric and sulfate ions. This ferric ion-protein complex mechanically seals the cut vessel and produces hemostasis. By forming plugs that occlude the capillary orifices, the protein complex also prevents the formation of blood clots and thereby minimizes chances for inflammation and internal resorption in pulp therapy.[13,44] ABS' mechanism involves formation of a protein network that acts as focal points for erythrocyte aggregation without affecting any individual clotting factor.[45]

Although ferric sulfate and MTA have been proposed as the most appropriate alternatives for primary teeth pulpotomies in place of FC,[46-48] routine use of MTA might be limited in developing countries due to economic and commercial reasons. On the other hand, Schröder[49] stated that formocresol as well as other nonbiological medicaments—including glutaraldehyde, Ledermix, and ferric sulfate—should be used in a restricted manner and confined to primary teeth. Schröder suggested using calcium hydroxide instead, which is a well-known wound dressing with biological effects.

The failure of pulpotomy in primary molars has been attributed to several factors, one of which is the leakage of the final restoration of pulpotomized primary molars.[50] Croll and Killian[51] recommended stainless steel crowns as the treatment of choice for teeth that have undergone pulpotomy. In our study, all treated teeth were restored with stainless steel crowns.

The other factor of failure is erroneous diagnosis of a chronically inflamed radicular pulp as a noninflamed and noninfected pulp and was also attributed to failure of the pulpotomy treatment.[52] Hobson[53] examined extracted, and exfoliated molars to correlate clinical signs and symptoms with the pulp's histologic status. She suggested that signs and symptoms of painful teeth had a strong correlation with irreversible changes of the dental pulp. In addition to this, she also suggested that the absence of symptoms did not preclude the presence of irreversible pathologic pulp changes. In our study, we selected teeth according to clinical and radiographic criteria, which were used in the other pulpotomy studies. It is possible that the pulpal status is more crucial to a successful pulpotomy procedure when CH and not FC is used, as Huth et al. stated.[6]

The use of CH in pulpotomy treatment frequently results in the development of internal resorption. Moretti et al.,[54] compared MTA, FC, and CH pulpotomies in carious primary teeth. They found 100% success for MTA and FC, but 64% success for CH. They reported that internal resorption was the most common radiographic finding up to 24 month after pulpotomies performed with CH. In this study, we categorized internal resorption as a radiographic failure. Some authors, however, do not consider internal resorption to be a sign of failure.[55-58] Holan et al.,[55] suggested that internal resorption can be left for follow-up appointments, expecting the arrest of the pathology and the development of calcific metamorphosis.

Some authors have suggested that reparative dentin formation is not a sign of success in pulpotomy treatment.[7,43,59] In addition, Cox et al.,[60] reported that 89% of all dentin bridges that were formed following capping procedures with CH had tunnel defects in a primate study, and 41% of the dentin bridges were associated with recurring pulp inflammation. For these reasons, we did not categorize dentin bridge formation as a sign of success.

CH advocates suggest that the sequelae of internal resorption can be prevented by the direct contact of CH with cut pulp tissue.[13]Although this can be technically difficult to achieve and is biologically suspect because an incision into vital tissue produces both hemorrhage and exudation,[61] care was taken to avoid leaving a blood clot between the remaining pulp and CH.[54] Therefore, the CH pulpotomy technique requires more clinical experience than FC pulpotomy. In our study, all observers were specialists, each with approximately 10 years of experience, which may explain the higher total success rates observed in both groups.

The ideal hemostatic agents also should be free of cytotoxicity, but the ability of hemostasis is more important. Bilgili et al.,[62] evaluated short-term hematological and biochemical safety following the oral systemic administration of ABS to rabbits. They found no signs of toxicity were observed in rabbits during a short-term study with oral ABS administration.

Conclusions

1. Total success rate of CH+ABS pulpotomy after 12 months was 95 %, which was not significantly higher than that of CH pulpotomy group.
2. CH as the control group in this study showed a total success rate (90%) that was comparable to results from other pulpotomy studies with CH.
3. Further investigations should be performed, however, to determine ABS' efficacy and safety, and these results should be confirmed in longer follow-ups

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Abstract of the Scientific Literature

Sippy cup usage among preschool aged children in Ontario, Canada

The aim of this study was to compare the prevalence of sippy cup and bottle use by children 1- to 4-years-of-age. Another objective was to determine if there is an association between sippy cup usage and the prevalence of Early Childhood Caries (ECC). Data were collected as part of the cross-sectional Rapid Risk Factor Surveillance System (RRFSS, 2007) telephone-based survey. Random digit dialing was utilized to reach families living in Middlesex County, Ontario, Canada. Those who were at least 18-years-of-age and had a child between 1 and 4-years-of-age were invited to take part. Questions included whether their child used a sippy cup and/or baby bottle with liquids other than water, the types of liquids in sippy cups and bottles, how frequently they were used, and whether the child went to bed with either a sippy cup or bottle. Parents were also asked if their child had experienced caries, as a proxy for ECC. A total of 255 caregivers completed the phone interview; the majority being female (54%), married or living common-law (89%), and well educated. Most respondents (70%) indicated that their child was currently using a sippy cup. Overall sippy cup use, both current and past use was 94%. Younger children were more likely to be current sippy cup users. Meanwhile, 33.3% of children were presently drinking from the bottle. More children were reported to be sippy cup users than baby bottle users. Six percent of parents revealed that their child went to bed with a sippy cup filled with a beverage other than water, with juice being the most common beverage. Unfortunately, nearly half of 4 year olds were still using a sippy cup (46%). It was of interest that 80% indicated that their child was also using a lidless cup. A total of 48.6% of respondents said that their child had experienced ECC. As most children were reported to be both sippy cup and bottle users, the authors could not determine a relationship with ECC. Further, logistic regression analysis for ECC of children who already visited the dentist was unable to support an association between sippy cup use and caries while controlling for other confounders.

Comments: *While this study was unable to demonstrate an association between sippy cup use and ECC, it does suggest that the majority of young children are using such devices. Professional recommendations indicate that children should be transitioned to a regular lidless cup soon after their first birthday. Unfortunately, it appears that children are not being weaned from sippy cups at appropriate ages. If sippy cup use is not limited to meal and snack time, it becomes no different than the baby bottle and thereby increases the risk for caries.* ***RJS***

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