ADA CE Program ARTICLE 2

Clinical and radiographic success of mineral trioxide aggregate compared with formocresol as a pulpotomy treatment in primary molars

A systematic review and meta-analysis

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ABSTRACT

Background. The authors conducted a systematic review and meta-analysis to compare the long-term clinical and radiographic success of using mineral trioxide aggregate (MTA) and formocresol (FC) as a pulp-dressing material in pulpotomy treatment in primary molars.

Types of Studies Reviewed. The authors searched MEDLINE, Thomson Reuters Web of Science and the Cochrane Central Register of Controlled Trials for randomized controlled trials (RCTs) published from Jan. 1, 1990, to May 9, 2013. For an RCT to be included, the authors required that the primary molars treated with a pulpotomy procedure must have received stainless steel crowns as a final restoration and that rubber dam isolation was used during treatment; that the pulp must have been vital as determined clinically by means of hemorrhage control with a cotton pellet; and that the RCT must have included a follow-up period of at least two years. For each included RCT, two authors assessed the risk of bias independently.

Results. The authors identified 20 trials and included five of them. A total of 377 primary molars were treated. The authors judged that none of the included RCTs had a low risk of bias. They noted no significant differences in clinical success (relative risk [RR] = 1.01; 95 percent confidence interval [CI], 0.98-1.05) and radiographic success (RR = 1.09; 95 percent CI, 0.97-1.21) for primary molars treated with MTA versus those treated with FC.

Practical Implications. On the basis of the limited evidence, pulpotomy procedures performed in primary molars involving the use of MTA or FC showed comparable clinical success rates.

Key Words. Formocresol; mineral trioxide aggregate; pulpotomy; primary molar; systematic review; meta-analysis; review literature; evidence-based dentistry; pediatric dentistry.
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The pulpotomy procedure is the most common pulp therapy for severely carious asymptomatic primary molars that have vital pulp. Multiple treatment protocols have been researched and implemented to determine which technique or material is superior. Two treatments of long standing involve the agents formocresol (FC) and mineral trioxide aggregate (MTA).

FC, introduced in 1904,[1] has been the preferred treatment for vital pulpotomies in primary molars since the 1930s.[2] FC is available in two basic formulas, the full-strength Buckley FC (19 percent formaldehyde) and Sultan FC (48.5 percent formaldehyde). FC has demonstrated high success rates—up to 98 percent—within a 36- to 60-month follow-up period.[3,4] Despite the success and popularity of FC, its possible cytotoxicity[5] and evidence of systemic distribution,[6-8] along with the suggested carcinogenicity of formaldehyde,[9,10] have required dentistry to revisit its use and attempt to identify less toxic alternatives. Kahl and colleagues[11] studied the presence of FC in the plasma of children who underwent oral rehabilitation under general anesthetic. They examined the children's formaldehyde and cresol levels before, during and after the procedure; they found that formaldehyde and cresol plasma levels were undetectable above physiologic baseline levels. The researchers concluded that FC is unlikely to pose any risks to children if used in the typical dosage and manner as employed for the vital pulpotomy procedure. The International Agency for Research on Cancer[12] and the National Toxicology

Program,[13] an interagency of the U.S. Department of Health and Human Services, classified formaldehyde as a human carcinogen. Despite that fact, FC still is widely employed, its use still is taught in dental schools,[14,15] and it still is recognized by the American Academy of Pediatric Dentistry[16] (AAPD) as an acceptable pulp-dressing material for use in pulpotomy procedures performed in primary teeth.

Mineral trioxide aggregate (MTA) was introduced in the dental literature in 1993,[17] and its use as a pulp-dressing material has been the topic of research since its development. MTA has demonstrated high success rates in primary and permanent teeth, perhaps as a result of its biocompatibility,[18] alkanility[19] and sealability,[20,21] as well as its unique ability to form a dentin bridge.[22] Researchers have compared MTA with other pulp-dressing materials, such as FC,[23-25] ferric sulfate[26] and calcium hydroxide.[27,28] However, the number of high-quality randomized controlled trials (RCTs) in which researchers have evaluated these treatments for use in primary teeth is limited. Success of the pulpotomy procedure is not merely a matter of the dressing agent used. Rather, it is success of the entire treatment modality. For instance, a pulpotomy involving the use of FC typically requires placement of a zinc oxide-eugenol mixture on the treated radicular pulp. The pulp's preoperative vitality status and extent of inflammation, as well as the final restoration, may be main indicators for the success of pulpotomy treatment. In 2003, Nadin and colleagues[29] published a Cochrane review regarding pulp treatment for carious primary molars. They could not compare MTA with FC as a pulp-dressing agent owing to an inadequate number of published reports of RCTs. The most recent systematic review and meta-analysis in which investigators compared MTA with FC in pulpotomy treatment of primary molars was published in 2006; its authors concluded that clinical and radiographic outcomes were significantly better for the teeth treated with MTA.[30] Some of the included trials lasted for less than 12 months. Since 2006, reports of several trials with follow-up periods longer than 12 months have been published.[24,31-39]

Our objective in this systematic review and meta-analysis was to evaluate the long-term clinical and radiographic success of two pulp-dressing materials, MTA and FC, in pulpotomy in carious primary molars in children.

METHODS

We used the population, intervention, comparison, outcomes and study design (PICOS) method to develop a search strategy and to establish inclusion and exclusion criteria. We defined the target population as healthy pediatric patients who required pulpotomy treatment for vital and asymptomatic carious primary molars; the intervention group as primary molars treated with MTA as a pulpotomy dressing material; and the comparison group as primary molars treated with FC. We categorized outcomes as clinical and radiographic success rates after an observation period of at least 24 months. We limited study design to RCTs in which investigators compared the two previously mentioned treatments. We did not include systematic reviews.

Included trials for this review were limited to those in which investigators implemented standardized clinical procedures involving the use of a rubber dam for isolation, achievement of complete hemostasis after coronal pulp removal and before application of the dressing material to the vital pulp stumps, and use of stainless steel crowns as a final restoration for the treated primary molars. We used these limits to minimize chances of failure related to inadequate isolation and bacterial contamination, preexisting pulpal pathology or restoration leakage. Therefore, the number of confounders that may affect the success rate of these different treatment modalities was reduced.

We defined the criteria for clinical success as the absence of pain, swelling, pathological mobility, tenderness to palpation or percussion, and abscess of discharge or development of a fistula. For radiographic success, we defined the criteria as the absence of pathological external root resorption, internal root resorption, furcation radiolucency and periapical bone destruction.

We searched three databases: MEDLINE through PubMed, Thomson Reuters Web of Science and Cochrane Central Register of Controlled Trials. We structured the search strategy to involve the following key terms, as Medical Subject Headings terms or free text words, joined by "or": "MTA," "mineral trioxide aggregate," "formocresol," "pulpotomy" and "primary molars." We limited the search to articles published from Jan. 1, 1990, through May 9, 2013. We placed no restriction on language of the searched trials; however, all eligible articles were written in English. We scanned the titles and abstracts of the identified trials for inclusion or exclusion in this systematic review. We also used the citation lists of published reviews for trial identification. When we could not make a decision on the basis of the abstract, we accessed a full report. We contacted one author of a published abstract[40] for further information, but she preferred not to share the data and indicated interest in writing a complete report in the future.

We agreed on the inclusion and exclusion criteria and databases. Two of the authors (A.A.M. and S.O.) conducted the search, study selection, data extraction and risk-of-bias assessment independently. Disagreements were resolved through discussion and through consideration given by the third author (J.-W.C.). We performed the risk-of-bias assessment for the included trials by us-

ABBREVIATION KEY. **AAPD:** American Academy of Pediatric Dentistry. **FC:** Formocresol. **MTA:** Mineral trioxide aggregate. **PCO:** Pulp canal obliteration. **RCT:** Randomized controlled trial.