Original Article

Evaluation and comparison of mineral trioxide aggregate and cold ceramic in primary tooth pulpotomy: Clinical and radiographic study

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Abstract

Aim: In recent years, many studies have been conducted on different materials for covering the pulp in pulpotomy. Recently, some materials such as Coldceram have been introduced that have the ability to regenerate the pulp. In this study, our aim was to compare the clinical and radiographic success of the pulpotomy of milk molars using MTA and Coldceram over 3-, 6-, and 9-month follow-ups. **Methods:** In this clinical trial, 42 children aged 4-9 years old who fulfilled the inclusion criteria of the study were selected. Finally, pulpotomy was conducted on 42 teeth using MTA and another 42 teeth using Coldceram in these children. Simultaneously, all teeth were permanently repaired using glass ionomer and metal veneers in the same treatment session. Then, clinical and radiographic evaluation was conducted in 3-, 6-, and 9-month follow-up periods. **Results:** None of the teeth showed clinical symptoms at the specified 3-, 6-, and 9-month follow-up times, and clinical success was 100% in both groups. In radiographic evaluation, the numbers of successful treatments were 42/42 (100%) and 41/42 (97%) for the teeth treated with MTA and Coldceram, respectively. **Conclusion:** According to this research, both materials were proven to have a 100% clinical success rate, but in the radiographic evaluation, MTA attained a higher success rate compared with Coldceram; however, this difference was not statistically significant ($P = 0.36$). It is recommended to consider longer follow-ups and larger sample sizes in future studies.

Keywords: Coldceram, MTA, pulpotomy

Introduction

One of the main goals of pediatric dentistry is to maintain the anatomical and functional forms of milk teeth until their exfoliation and the development of permanent teeth.[1] Regarding the structural differences between milk teeth and permanent teeth, such as the presence of a wide pulp chamber, long pulp antenna, and the low thickness of dentin in primary teeth, caries progresses more rapidly in these teeth and reaches the pulp. Therefore, it is necessary to conduct effective and early treatment.[2] If the pulp is involved and exposed to the mouth environment and microorganisms penetrate into the pulp, milk teeth will require pulp therapy. In a sterile environment, the exposed pulp can orchestrate self-repair and also create a dentine bridge. Meanwhile, the involvement and degeneration of the pulp are inevitable in the presence of bacteria. Pulpotomy is a conservative therapeutic method to remove the coronal inflamed tissue of the pulp and cover the noninflamed part of the pulp tissue with biocompatible materials.[1] In this regard, various covering materials are used in the pulp therapy of primary teeth.[3] For a long time, formocresol has been the gold standard for pulpotomy; however, uncertainties about the mutagenic potential and toxicity of this substance urged scientists to seek alternatives, such as calcium hydroxide, glutaraldehyde, and ferric sulfate, to replace formocresol.[4]

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Received: 03-03-2023 **Revised:** 08-05-2023
Accepted: 01-06-2023 **Published:** 21-12-2023

Access this article online

Quick Response Code:

Website: http://journals.lww.com/JFMPC

DOI: 10.4103/jfmpc.jfmpc_412_23

How to cite this article: Rasteh B, Basir L, Taravati S, Khataminia M. Evaluation and comparison of mineral trioxide aggregate and cold ceramic in primary tooth pulpotomy: Clinical and radiographic study. J Family Med Prim Care 2023;12:3068-74.

In 2010, MTA was introduced to the field of dentistry by Torabinejad *et al.* This hydrophilic cement has acquired many applications in dentistry due to its appropriate features.[5] In addition to being insoluble, MTA facilitates sealant properties and enhances the release of cytokines from bony cells, which subsequently enables the formation of hard tissue and increases the sealant ability of the vital pulp. The beneficial features of MTA, such as the high biocompatibility, excellent sealant ability, and the capability of stimulating the formation of the dentine bridge, have also been affirmed in another study.[6] The other advantages of this substance in pulpotomy include pulp coverage via the formation of a calcification barrier and low potential for causing inflammation and necrosis.[5] In addition, MTA has rendered successful outcomes as a regenerative material in the pulpotomy of primary teeth.[1] Based on the latest research findings, MTA has been introduced as a standard material for pulpotomy[4]; nevertheless, it suffers from disadvantages such as poor handling, high cost, the potential for tooth discoloration, and long hardening time. Thus, it is important to clinically investigate the applicability of other calcium silicate-based materials in pulpotomy.[7] In this study, Coldceram was first introduced in Iran in 2000 by Modaresi *et al.*[7] Coldceram is a tri-oxide mineral substance similar to MTA that is used to treat the tooth root and its perforations, open apex teeth, and also as a coverage for the pulp during pulpotomy. Coldceram is based on calcium hydroxide and contains hydrophilic particles in its structure, and its main constituents include calcium oxide, silicon oxide, barium oxide, and sulfur oxide, which make up 93% of its total structure.[7] In a study, Modaresi *et al.* compared the sealing ability of CC and GI using an electrochemical test, and the results showed that the sealing ability of CC was much higher than that of Glass ionomer.[8] Also, in a laboratory environment, the sealing ability of CC was reported to be superior compared to MTA when there is blood contamination;[7] however, the sealing capability of the two materials was comparable in dry or saliva-containing environments.[9] Modaresi *et al.* also evaluated the histocompatibility of CC, and their results indicated the favorable compatibility of this substance.[10,11] According to ISO 6876:2001, the minimum acceptable opacity for endo cement is equivalent to 3-mm-thick aluminum. In their research, Akhawan *et al.* showed that the radiopacity of CC was equal to that of aluminum with a thickness of 4.02 mm. Based on the study of Modaresi *et al.*, the hardening times of MTA and CC were 165 and 15 minutes, respectively, highlighting the superiority of Coldceram,[12] which requires a total time of 24 hours to be complete hardened.[13] Considering the disadvantages of MTA and desirable properties of Coldceram, including a lower cost and shorter hardening time, and the lack of clinical research on the applicability of Coldceram in the pulpotomy of primary teeth, the present study aimed to investigate the clinical and radiographic success rates of pulpotomy for primary molar teeth using Coldceram and MTA over 3-, 6-, and 9-month follow-ups. Table 1 demonstrates the chemical composition of MTA and Coldceram.

Table 1: Chemical composition of white MTA Angelus and coldceramic

Component	MTA Angelus (%)	Coldceramic (%)
Powder		
Calcium silicates	50–65	.
Tricalcium aluminate	5–12	.
Calcium oxide	1–5	48/12
Bismuth oxide	15–30	18/61
potassium oxide	-	0/24
Silicon oxide	-	16/19
Iron oxide	-	0/36
Sulfuric acid	-	10/15
Liquid		
Distilled water	100	100

Methods

Study design and statistical population

This double-blinded parallel clinical trial was designed and conducted in 2020 to evaluate and compare the clinical and radiographic success rate of pulpotomy treatment of primary molars teeth applying two materials, MTA and Coldceram. Before study initiation, an ethical approval code was obtained from Jundishapur Ahvaz University of Medical Sciences (code: IR.AJUMS.REC.1400.589.). In addition, the protocol has been registered in the Iranian Registry for Clinical Trials (IRCT20220426054664N1).

At first, 200 children aged 4-9 years of both sexes referred to the dentistry clinic of Jundishapur Ahvaz University of Medical Sciences were enrolled as the statistical population and examined by trained dentistry students. Children who had at least two teeth meeting the criteria for pulpotomy treatment were considered eligible to participate in the study. The risks and benefits of the study were explained to parents, and after obtaining informed consent, their children entered the study. The participants should have been in perfect health, plausibly cooperated during the treatment process, and had at least two molar teeth requiring repair. Considering a previous report by Carti O *et al.*[14] on the comparison of the clinical and radiographic success of pulpotomy applying MTA and Biodentin, we here included 42 children (25 girls and 17 boys) as the sample population of the research. For each child, two teeth were chosen and repaired using either MTA (i.e., the control group) or Coldceram (i.e., the experimental group).

Statistical analysis

The data were analyzed using SPSS (version 22) statistical software. The Chi-square test was used to compare gender distribution between the two study groups, which showed no significant difference ($P > 0.05$, Table 2).

The independent sample Student *t*-test was used to compare the mean age between the two groups, also showing no difference between the control and experimental groups ($P > 0.05$). In the

present study, the two groups were matched for age and gender [Table 3], which was confirmed by observing no significant difference between the two study groups in terms of these two variables. Some studies, however, have not matched groups and have recruited heterogeneous samples, but, here, this issue was addressed. The ratio of selected teeth between the two groups was also compared using the Chi-square test, indicating no significant difference between the two groups ($P > 0.05$). Table 3 and Figure 1 represent and compare the quantities and percentages of different teeth and gender distribution in the two study groups.

Inclusion/exclusion criteria

The criteria used for including or excluding subjects were according to the guidelines of the American Academy of Pediatric Dentistry.

Research protocol

In this study, pulpotomy treatment was performed by a pediatric dentistry resident, and the outcomes were reviewed and confirmed by a pediatric dentistry specialist with more than 20 years of work experience. For blinding and random allocation, the operator, the evaluator, and the patient were unaware of the type of material used and the purpose of pulpotomy. At the time of operation and during each pulpotomy, an assistant randomly handed over either MTA or Coldceram to the operator to cover the pulp. In the follow-up step, clinical and radiographic evaluations were performed after three, six, and nine months. The study flowchart is shown in Figure 1.

Table 2: Teeth Group Cross-tabulation

			Group		Total
			CC	MTA	
Teeth	1st upper molar	Count	11	7	18
		% within Group	26.2%	16.7%	21.4%
	2nd upper molar	Count	11	10	21
		% within Group	26.2%	23.8%	25.0%
	1st lower molar	Count	8	15	23
		% within Group	19.0%	35.7%	27.4%
	2nd lower molar	Count	12	10	22
		% within Group	28.6%	23.8%	26.2%
Total		Count	42	42	84
		% within Group	100.0%	100.0%	100.0%

Table 3: SEX Group Cross-tabulation

			Group		Total
			CC	MTA	
Sex	Male	Count	17	17	34
		% within sex	50.0%	50.0%	100.0%
	Female	Count	25	25	50
		% within sex	50.0%	50.0%	100.0%
Total		Count	42	42	84
		% within Sex	50.0%	50.0%	100.0%

Post-treatment follow-up

In this step, follow-up calls and contacts were made to monitor the post-treatment success rate [Figure 2].

In the first phase of treatment, periapical radiography was performed for the target tooth. Then, a topical anesthetic gel containing benzocaine 20% (Merowin, Iran) was applied to the target mucosa. The target tooth was anesthetized using lidocaine 2% (xylocaine) containing 100,000 units of epinephrine (Daroupakhsh, Iran), applying the inferior alveolar block technique for mandibular teeth and the infiltration technique for maxillary teeth. Then, the tooth was isolated with a rubber dam. After removing caries using a slow-speed bur (Angle, Tizkavan, Iran), the roof of the pulp chamber was removed using a bur (size No. 329, Tizkavan, Iran) and a high-speed turbine accompanied by water spraying. The pulp of the coronal tooth was removed using a sterile and sharp excavator so that the orifice of the canals was clearly visible without any remnant coronal pulp. The cavity was flushed with normal saline, and pulpal bleeding was stopped by slightly pressing a small sterile cotton swab dampened with normal saline for five minutes. Finally, the pulp covering material (either MTA or Coldceram) was prepared by an assistant according to the manufacturer's instructions and randomly handed over to the dentist to be placed on the pulp, which was then covered by Glass Ionomer Light Cure, and finally, the metal stainless steel crown for primary teeth (3M).

All 42 children underwent clinical and radiographic evaluation by a pediatric dentist with more than 20 years of work experience at 3-, 6-, and 9-month follow-ups. The treatment was clinically regarded as failed when any of the following signs and symptoms were present: unprovoked pain, sensitivity to touch and pathological mobility, and the presence of edema or fistula.

Also, the failure of treatment was decided when any of the following signs and symptoms were observed in radiography: internal or external pathological deterioration, as well as furca or periapical radiolucency.

MTA

In this study, MTA powder was initially mixed with sterile normal saline at a ratio of 3:1, respectively. Then, the resulting paste was used to cover the pulp tissue of the orifice of the canals.

CC

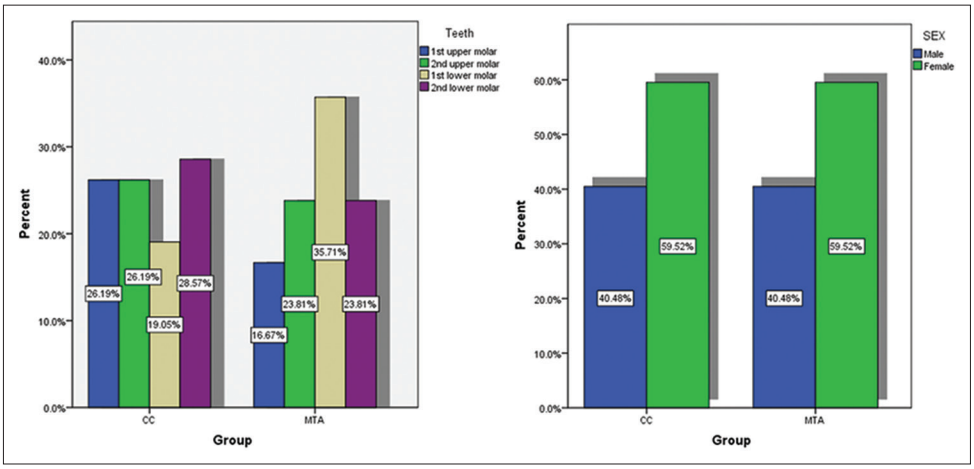
In this study, CC powder was first mixed with sterile normal saline in a ratio of 1:1, respectively. Then, the resulting paste was used to cover the pulp tissue of the orifice of the canals.

Results

The statistical population of the present research consisted of 42 children (25 girls, 17 boys) with a mean age of 6.8 years. At first, 50 children were included in the study, four of whom were excluded due to uncontrollable pulp bleeding. Among the

Table 4: Clinical and radiography result of patients in different follow-up time (3, 6, and 9 months)

	Success and failed field for each follow-up		Success	Failed	Success	Failed	Success	Failed	Success	Failed	Success	Failed	Success	Failed
			c.month3		R.month3		c.month6		R.month6		c.month9		R.month9	
Group	CC	Count	42	0	42	0	42	0	41	1	42	0	41	1
		% within Group	100.0%	0	100.0%	0	100.0%	0	97.6%	2.4%	100.0%	0	97.6%	2.4%
	MTA	Count	42	0	42	0	42	0	42	0	42	0	42	0
		% within Group	100.0%	0	100.0%	0	100.0%	0	100.0%	0.0%	100.0%	0	100.0%	0.0%



remaining 46 children, another child was excluded in the 3-month follow-up due to lack of referral, and three other children were also excluded from the study in the 6-month follow-up due to the relocation of home and lack of access.

In total, out of 84 pulpotomy performed, half (n = 42) were conducted using MTA, and the other half with Coldceram (n = 42) in a random manner so that each child received both types of pulpotomy. Regarding the types of teeth treated, 20, 11, 23, and 30 were maxillary secondary molars, maxillary primary molars, mandibular primary molars, and mandibular secondary molars, respectively.

Clinical findings

In the 3-, 6-, and 9-month follow-ups, none of the signs of clinical failure were observed, and the success rate was 100% in both MTA (42/42) and Coldceram (42/42) groups [Table 4].

Radiographic findings

None of the teeth demonstrated radiographic evidence of treatment failure in the 3-month follow-up, with a radiographic success rate of 100% in both groups. In the 6-month post-treatment follow-up, the success rate was also 100% in the MTA group (42/42); however, one tooth in the Coldceram group showed evidence of interior deterioration, delivering a success rate of 97% (41/42). At a 9-month post-treatment follow-up, there was no radiographic evidence of treatment failure in the teeth treated with MTA; however, in the Coldceram group, the same tooth deteriorating tooth progressed, so the success rate in this group remained 97% (41/42) [Table 4].

Discussion

This study was the first study that evaluated the clinical and radiographic success of the pulpotomy treatment of primary molars teeth using Coldceram. The therapeutic effects of Coldceram have been previously evaluated in other types of treatments, reporting promising results. In a study, Zare Jahromi *et al.* (2007)[8] reported the comparable histopathological effects of Coldceram and Proroot on periodontal tissue inflammation after sealing perforated furca, suggesting that Coldceram can be a suitable and less expensive alternative for repairing perforations. In another research by Mozayeni *et al.* in 2008,[12] the cytotoxic effects of CC, MTA, and IRM were compared, and the results showed that IRM, MTA, and CC have the highest to lowest cytotoxicity, respectively. Mokhtari *et al.* in 2015[7] performed the marginal concordance of MTA and CC by scanning electron microscopy and reported that although marginal concordance was higher in CC, both materials had plausible marginal concordance.[13] In another study, the radiopacity of CC was reported to be equivalent to 4.02-mm-thick aluminum, which is acceptable according to ISO. 6876:2001 that considers 3-mm aluminum thickness as the minimum acceptable thickness for endo cement. The primary hardening time for Coldceram is 15 minutes, which is shorter than that of MTA (165 minutes), and the complete setting time of Coldcream is 24 hours.

An important criterion for choosing materials is their cost, each gram of Coldceram costs about 20% of the same amount of MTA, which can increase its applicability.[7] It has been shown that MTA has the potential to induce pulp regeneration. Regarding the successful applicability of MTA as a standard material to be used in pulpotomy,

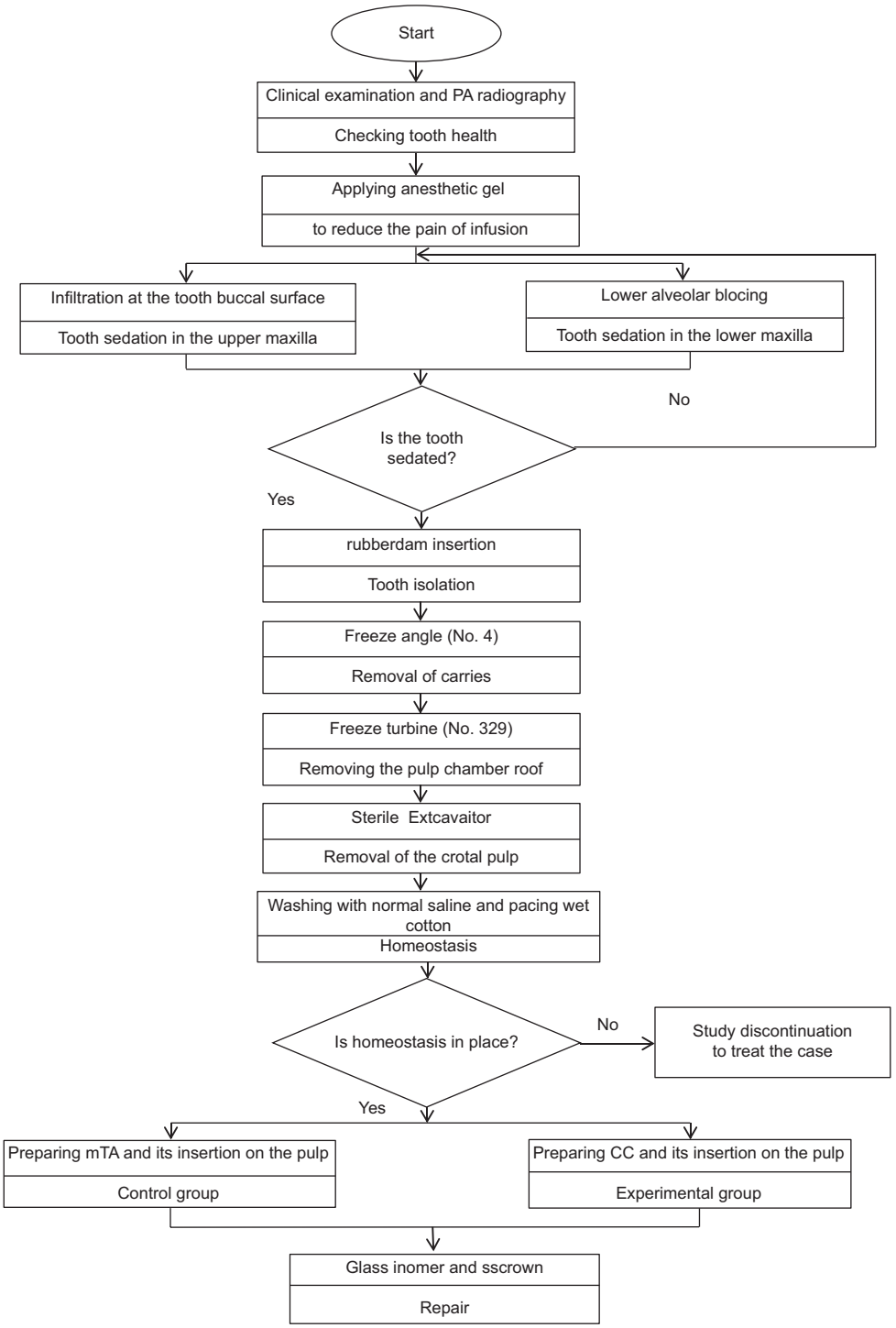


Figure 1: Flowchart of the treatment process

we here employed this substance in the control group. The success of MTA in the present study was obtained 100% in pulpotomy treatment, which was consistent with the results of previous studies employing MTA as a standard material with high histocompatibility.

In the present study, we showed that pulpotomy treatment with MTA and Coldceram delivered a high success rate in maintaining the health of the pulp, with none of the teeth treated showing any evidence of clinical failure. Both of these materials create a nonporous dentine barrier that prevents bacterial leakage, and in the study conducted by Mazini *et al.*,[14] both substances were confirmed to have negligible proinflammatory features and toxicity, maintaining the viability of the adjacent pulp tissue. Regarding radiographic signs of treatment failure, only one case of interior root resorption was observed among the teeth treated with Coldceramic at 6-month post-treatment. Historically, interior tooth deterioration would be left untreated if it was accompanied by no clinical symptoms. In the present

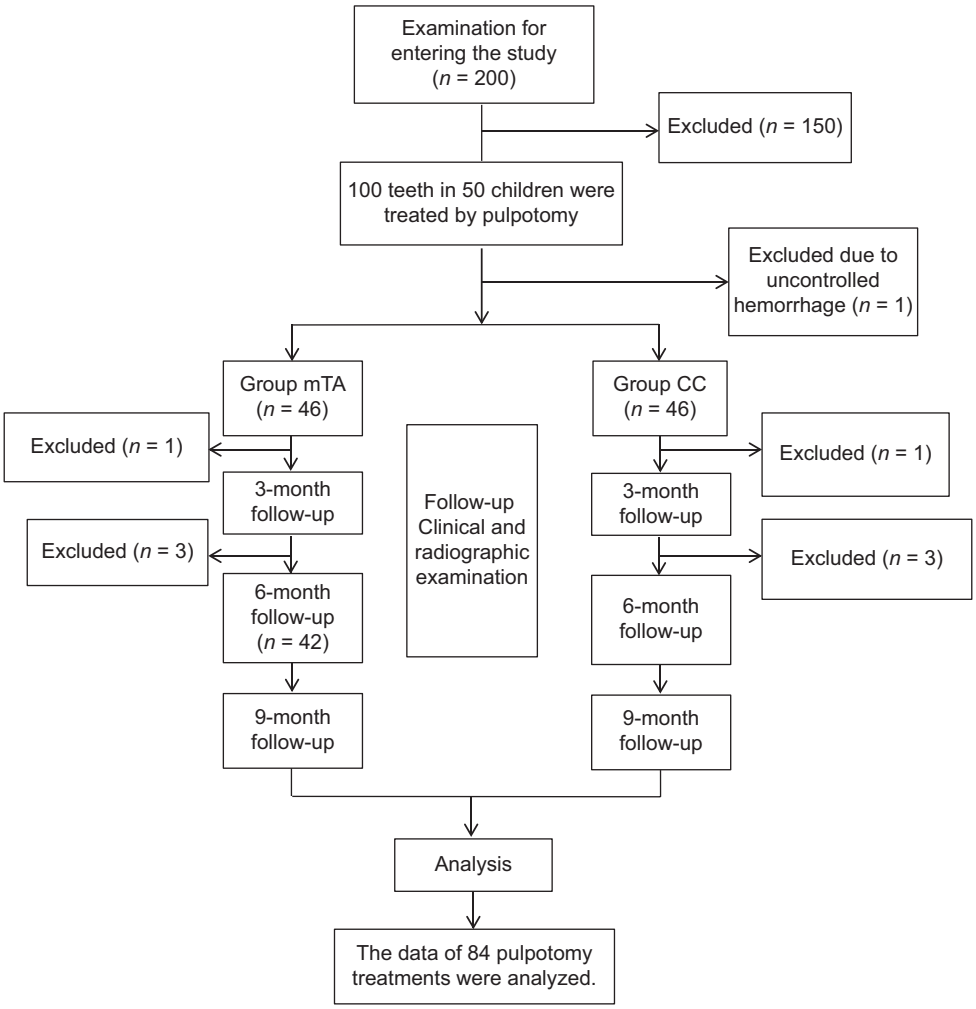


Figure 2: Flow chart of randomization and follow-up of patients according to the standards recommended

study, the tooth showing interior deterioration was associated with no clinical signs and symptoms, so it was solely monitored repeatedly without presenting any treatment. Also, the parents were assured that appropriate treatment would be started if it progressed.

In general, the results of the present study showed that both MTA and Coldceram have appropriate efficiency and effectiveness to be used in pulpotomy therapy. It is suggested to conduct studies with larger sample sizes and longer follow-ups to investigate the long-term success rate of Coldceram in teeth repaired by pulpotomy. The innovation of this study was the simultaneous use of MTA and Coldceram in the same child to eliminate the effects of the potential confounding factors of intraindividual variabilities and the body's response. In addition, the two groups were matched for gender and age. Among the challenges of pulpotomy are the relatively high cost of MTA, which was here obviated by using Coldceram, a substance with a cost of almost one-fifth of MTA. Finally, we recommend conducting studies with larger sample sizes and longer follow-ups in the future to confirm and possibly extend the method used in our research.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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