



## A Randomized Controlled Clinical Trial Comparing Clinical and Radiographic Success Rates of MTA and rhBMP2 in Pulpotomy of Primary Teeth

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### ABSTRACT

**Objectives:** In an ideal pulpotomy, the radicular pulp remains vital, healthy, and fully encased within an odontoblastic layer. Mineral trioxide aggregate (MTA) and bone morphogenetic proteins (BMPs) have been suggested to facilitate this outcome. We aimed to compare the clinical and radiographic failure and success rates of MTA and rhBMP2 as pulpotomy medicaments.

**Materials and Methods:** Sixty-eight teeth from 3–6-year-old children were randomly assigned to two groups using a split-mouth design. Cervical pulpotomy was performed using MTA in one group and rhBMP2 in the other. Subsequently, the teeth were restored with stainless-steel crowns. Clinical and radiographic assessments were performed at 3, 6, 9, and 12-month follow-up intervals to evaluate success and failure rates. Data were analyzed using Chi-square test and Kaplan-Meier survival analysis ( $P < 0.05$ )

**Results:** At six and nine months, one tooth in the BMP2 group and one tooth in the MTA group showed internal resorption, respectively. After 12 months, one tooth in the BMP2 group exhibited PDL widening. The radiographic success rate was 100% for the MTA- and 97.1% for the BMP2-group at six months, 96.7% for both groups at nine months, and 96.7% and 93.3%, respectively, at 12 months. No clinical failure criteria were observed in any of the teeth. Survival analysis revealed no significant difference between the two groups.

**Conclusion:** The study reveals comparable outcomes between rhBMP2 and MTA, suggesting rhBMP2 as a viable alternative for pulpotomy in primary teeth. With minimal incidences of complications and no significant differences noted, rhBMP2 demonstrates potential for clinical use.

**Keywords:** Pulpotomy; Tooth, Deciduous; Bone Morphogenetic Proteins; Mineral Trioxide Aggregate

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### INTRODUCTION

Rapid progression of dental caries in deciduous teeth affects dental pulp, necessitating effective therapeutic intervention. Considering its

simplicity and high popularity in clinics, pulpotomy is one of the most successful treatments [1]. An ideal pulpotomy treatment aims to preserve the vitality of the pulp,

completely surrounded by a layer of odontoblasts. Many therapeutic agents like mineral trioxide aggregate (MTA) and bone morphogenetic proteins (BMPs) have been used for this purpose [2].

MTA is a bioactive material, with significantly increasing indications and is currently used for a wide variety of purposes. Researchers have also introduced MTA as a favorable therapeutic material for pulpotomy of deciduous teeth and pulp capping procedures [3]. MTA exhibits high biocompatibility and provides a better seal compared to zinc oxide eugenol and has exhibited high tissue regenerating potential in contact with the dental pulp and periradicular tissues [4,5]. Also it has the potential to induce a dentinal barrier in the vicinity of the pulp. However, MTA presents several disadvantages. It can be challenging to handle, as excessive moisture may soften it, impeding its application. Moreover, with a setting time of approximately 4 hours, placement of the permanent restoration typically necessitates an additional treatment session, unless stainless steel crowns (SSCs) are employed [3,6].

BMPs are a family of signaling molecules that take part in the development of bones and teeth [7,8]. They have significant capacity for induction of bone and formation of dentin. BMP2 mRNA seems to be present in the dental papilla and odontoblasts during the development of the tooth bud [9], demonstrating its important role in dentinogenesis. The mature pulp has cells with a capacity to form dentin in response to BMP signals [10,11]. These proteins have been found to induce mesenchymal cell differentiation and promote dentinal bridge formation in animal models, thus yielding promising results [12- 14]. However, to the best of our knowledge, only one human study is available on the clinical success of BMPs [15]. The present study aimed to compare the clinical and radiographic success and failure rates of BMP2 and MTA in pulpotomy procedures of primary molars at 3-, 6-, 9- and 12-month intervals.

## MATERIALS AND METHODS

In this parallel randomized controlled trial the subjects consisted of 3–6-year-old healthy

children referred to Isfahan University of Medical Sciences Faculty of Dentistry for pulpotomy of mandibular deciduous molars on both sides. Fifty patients underwent clinical and parallel periapical radiographic examinations, after which 19 patients (68 tooth samples) were selected. In order to achieve sufficient statistical power with a two-sided type I error at five percent and 80 percent power, 26 teeth in each group were deemed necessary. The sample size was increased by 30 percent, to anticipate any potential loss during follow-up sessions or other attrition factors. Then, a sample size of 34 teeth in each intervention group was planned.

**Ethical considerations:** This study (IRCT registration number: IRCT2017062434726N1) was approved by the Institutional Human Subjects Ethics Committee (Ethical approval: IR.MUI.REC.1395.3.753). All procedures are along with the ethical standards established by both the institutional and national research committees. Informed consent was obtained by providing parents or guardians a detailed information sheet about the procedure written in simple, non-professional language. To ensure blindness, patients and parents were not aware to the treatment group assignment.

### ***Inclusion criteria***

To qualify for inclusion in the study, subjects were required to meet the following criteria: 1) cooperation within the ASA I category and absence of systemic conditions; 2) presence of at least two mandibular posterior teeth necessitating vital pulpotomy, symmetrically distributed on both sides; and 3) ability to adhere to the 12-month follow-up schedule.

**Clinical indications for pulpotomy procedures**  
Clinical indications for pulpotomy procedures included pulp exposure resulting from dental caries, a history of mild pain during food intake, potential sensitivity to cold or heat stimuli, lack of tooth mobility, absence of spontaneous or severe pain, no presence of abscesses, fistulae, or swelling, feasibility of restoring the tooth with an SSC, and the ability to achieve hemostasis at the pulp amputation site within five minutes.

### ***Radiographic criteria***

Radiographic criteria for pulpotomy procedures

encompassed pulp exposure due to dental caries, absence of internal or external root resorption, lack of periapical or furcal radiolucency, no degenerative calcification of the pulp, and root resorption not exceeding one-third of the root's length.

### **Procedural steps**

All treatments were performed by a skilled resident in the third year of pediatric dentistry residency under the supervision of senior pediatric dentists. Following administration of inferior alveolar nerve block anesthesia using 2% lidocaine with epinephrine 1/80,000 (Daroopaksh, Iran) and isolation with a rubber dam, carious tissue in the tooth crown was excavated using a round #4 bur in a low-speed handpiece. Subsequently, a #330 bur in a high-speed handpiece was utilized to access the pulp chamber. The pulpal tissue within the crown was then carefully removed using a large round bur (#6) in a low-speed hand piece, followed by irrigation of the pulp chamber with normal saline solution. Hemostasis was successfully achieved at the site of pulp amputation within 5 minutes using sterile cotton pellets saturated with normal saline solution.

The teeth were randomly assigned into two equal groups. Considering the study's split-mouth design, teeth in each patient received their therapy based on the side they resided on. In order to randomize the teeth receiving each therapy under these circumstances, therapies were assigned with a coin flip and patients were assigned randomly with a number from 1 to 19 using an online number generator (Best Random Number Generator by NumberGenerator.org). After being written on identical papers and placed in a tinted container, each number was randomly selected by a blindfolded assistant and reported to another assistant. Using results from an online coin flipper, the second assistant determined the therapy allocated to the right side of each individual, following a Stratified Permuted Block Randomization protocol. Neither assistant was aware of the therapy or patient assignments.

In group 1, the remaining pulp was capped with MTA (ProRoot, Dentsply, Philadelphia, USA),

which was made by mixing powder with sterile saline solution at a ratio of 3:1. In group 2, rhBMP2 (Sigma, Germany, produced in HEK293 cells) was prepared at a concentration of 1µg/µL according to the manufacturer's instructions. Each 10µg pack of lyophilized powder of rhBMP2 was mixed with 100µL of sterile distilled water. The solution was then aliquoted into 10µL Eppendorf vials containing 1µg of BMP2 effective material and stored at 4°C. After complete pulp removal in the pulp chamber and establishing hemostasis, one vial was retrieved, a dental gel foam (Roeko, Germany, measuring 7×7×14) was split in half and completely inserted into the vial so that the whole solution would be absorbed by the sponge, which was gently placed on the root canal orifices. In both groups, IRM (Dentsply, Germany) was used in paste form to completely seal the pulp chamber with an approximate thickness of 2mm. The teeth were prepared for reconstruction with SSC (3M, USA), which was cemented on each tooth with the use of Poly F cement (Dentsply, Germany). Finally, a control radiograph was taken. In cases of non-cooperation, the patient was excluded from the study.

At 3-, 6-, 9- and 12-month follow-up intervals, the clinical and radiographic observations were recorded. All radiographic procedures were carried out with the use of the paralleling technique.

Clinical success was defined as the absence of pain (nocturnal, spontaneous or due to a stimulus), tenderness to percussion, swelling, fistula and pathologic mobility. Radiographic success was defined as the absence of any evidence of periapical radiolucency, furcal area radiolucency, internal resorption, external resorption and PDL widening. Presence of one or more than one of the symptoms and signs mentioned above indicated failure of treatment. Pulp canal obliteration was not considered a sign of failure. Two calibrated pedodontists carried out radiographic and clinical evaluations in a double-blinded manner. In cases of disagreement, evaluations were carried out simultaneously and a consensus was reached.

Data were analyzed with chi-square test at 0.05 significance level and survival analysis was performed using the Kaplan-Meier technique.

**RESULTS**

In the present study 68 deciduous molars (36 deciduous first molars and 32 deciduous second molars) in 19 patients (10 boys and 9 girls) were evaluated. The mean ages of the boys and girls were 66 and 60 months, respectively. All 19 subjects (68 tooth samples) returned for the 3-month and 6-month follow-up appointments. Only 16 (60 tooth samples) returned for the 9-month and 12-month follow-up appointments.

Radiographic findings and the clinical and radiographic failure and success rates of the groups are shown in Tables 1 and 2. At 3 month

follow up there isn't any radiographic evidence of failure in both groups. After 6 months only one tooth showed internal resorption in rhBMP2 group and then at 9 months one other tooth in MTA group also showed sign of internal resorption. however, there was no significant difference between two groups in month 6 and 9. After the 12th month, two cases of radiographic failure were observed in the rhBMP2 group, compared to only one case in the MTA group. However, the disparity in failure rates between the two groups did not reach statistical significance (Table 1).

Furthermore, survival analysis conducted using the Kaplan-Meier method indicated no significant difference between the two groups regarding internal resorption (P=0.990) and PDL widening (P=0.317).

**Table 1.** Distribution of radiographic findings in terms of the pulpotomy material

Follow-up (month)	Radiographic examination	Groups		P
		BMP2 N (%)	MTA N (%)	
3	Internal resorption	0	0	-
	External resorption	0	0	
	Radiolucency in furcation	0	0	
	Periapical radiolucency	0	0	
	PDL widening	0	0	
6	Internal resorption	1(2.9%)	0	0.5
	External resorption	0	0	
	Radiolucency in furcation	0	0	
	Periapical radiolucency	0	0	
	PDL widening	0	0	
9	Internal resorption	1(3.3%)	1(3.3%)	0.746
	External resorption	0	0	
	Radiolucency in furcation	0	0	
	Periapical radiolucency	0	0	
	PDL widening	0	0	
12	Internal resorption	1(3.3%)	1(3.3%)	0.487
	External resorption	0	0	
	Radiolucency in furcation	0	0	
	Periapical radiolucency	0	0	
	PDL widening	1(3.3%)	0	

**Table 2.** Distributions of overall clinical and radiographic failure and success in terms of the pulpotomy material and tooth

Follow-up (month)	Group	Tooth type	Failure		Success	
			N	%	N	%
3	MTA	D	0	0	18	100%
		E	0		16	
	BMP2	D	0	0	18	100%
		E	0		16	
6	MTA	D	0	0	18	100%
		E	0		16	
	BMP2	D	1	2.9%	17	97.1%
		E	0		16	
9	MTA	D	1	3.3%	15	96.7%
		E	0		14	
	P2	D	1	3.3%	15	96.7%
		E	0		14	
12	MTA	D	1	3.3%	15	96.7%
		E	0		14	
	BMP2	D	1	6.66%	15	93.3%
		E	1		13	

## DISCUSSION

Pulpotomy is the most common dental procedure in children. The final aim in this procedure is to stimulate the dentinogenesis potential of pulpal cells [16] and the formation of hard tissue in the region beneath the pulpotomy area which is a prerequisite for the long-term survival of the pulp in a vital tooth [17]. Systematic reviews and meta-analyses of article published on MTA have shown that this material yields favorable results in the pulpotomy of deciduous teeth [18]. In addition to anti-bacterial properties and high biocompatibility, MTA can induce formation of hard tissues [19,20,21].

The results of the present study showed that in the MTA group at 3-and 6-month postoperative intervals none of the teeth exhibited any of the clinical failure criteria and radiographic failure criteria, with 100% success rate. At 9-month evaluations, internal resorption was detected in one tooth, which was also observed in the same tooth only, at 12-month intervals.

Therefore, at 9- and 12-month intervals the radiographic success was 96.7%, consistent with the results of a study by Holan et al [22], who reported a clinical and radiographic success rate of 97% and the results of a study by Yildiz and Tosun [23], who reported a clinical success rate of 100% and a radiographic success rate of 96.4% for MTA. However study done by Agamy et al [24] showed a 100% success rate for MTA at 12-month follow-up. One difference between the present study and the study above was the lower age range of the subjects in our study. One possible explanation for higher failure rate might be the wider root canals in young teeth, which facilitates the transfer of stimulating factors into the root canals, resulting in internal resorption.

Recent studies on BMPs have shown that these proteins have an important role in the induction and regeneration of bone-like and dentin-like mineralized tissues. Advances in these materials have opened up a new scope in

pulp treatment. Currently, BMPs are available with the use of recombinant technology with osteogenic and dentinogenic properties [25]. It has been shown that the mature pulp has some cells with the potential to produce dentin in response to BMP signals [10,11]. Ranly and Garcia-Godoy [25] conducted a review on dental materials and highlighted that among various materials proposed for pulpotomy, the utilization of BMP molecules in a paste form could potentially yield optimal outcomes if developed into a commercial product.

In the present study, in the BMP2 group at 3-month interval none of the teeth exhibited any evidence for clinical and radiographic failure and the success rate was 100% similar to that in the MTA group. At 6-month interval, one tooth exhibited internal resorption, decreasing the radiologic success rate to 97.1%. At the 12-month interval, one tooth exhibited evidence of PDL widening, decreasing the success rate to 93.3%.

MTA has excellent sealing ability [6]. On the other hand, the BMP2 used in the current investigation was placed on the root canal orifices in the form of an aqueous solution with the use of gel foam as a carrier. To date, numerous animal studies have examined recombinant human BMP, with published results showing promise for pulpal regeneration devoid of inflammation. Investigations have shown that exogenous recombinant BMPs in dogs [13] and human recombinant BMPs in rats [26] and monkeys [14,27] can induce dentinogenesis. It has been suggested that BMP induces formation of a dentinal barrier in pigs, monkeys and dogs [12,13,14]. Holan et al [22] also reported internal resorption as the most frequent radiographic failure when using MTA, consistent with the results of the present study. Internal resorption occurs after chronic inflammation of the pulp. During this process, odontoblasts are destroyed and the predentin and pulp are invaded by macrophage-like cells that are responsible for resorption [28]. In the current investigation, internal resorption was introduced as a criterion for failure. However, the teeth that had internal resorption were not treated because they remained asymptomatic

and did not exhibit further radiographic or clinical failure during the subsequent follow-ups. Smith et al [29] attributed internal resorption to the response of the pulp to the medicaments and techniques used, reporting that internal resorption is not important clinically as long as the tooth is asymptomatic.

In the literature, we encountered only one human study employing BMP2 [15], which administered pulpotomy to five deciduous molars using rhBMP2 (produced in *E. coli*) at a concentration of 1mg/mL in 8–9-year-old children. After a 12-month follow-up, the study reported 100% clinical and radiographic success. However, it's noteworthy that the investigators did not classify internal root resorption as a failure criterion. In the present study, the clinical and radiographic success rates of our 12-month postoperative interval were 100% and 93.3%, respectively, which is a little less than that in the abovementioned study [15]. The discrepancy can be attributed to the larger sample size and the lower age range of the subjects in the present study. Bengtson et al [15] reported histologic evidence of inflammation, necrosis, and internal resorption as well as formation of reactive dentin and calcified islands similar to osteodentin after pulpotomy using rhBMP2. One of the limitations of the present study was a lack of histological evaluations. Rutherford and Gu [26], administered an aqueous solution of Salmonella on the exposed pulps of rat teeth before applying BMP7 and found that BMP7 was unable to induce reparative dentin in the presence of inflammation. In the present study, proper isolation was applied. However, the teeth were carious and had a history of pain during mastication. Therefore, the pulps of these teeth had some degrees of inflammation in the beginning of the study.

Based on our results, the clinical success rate of the MTA and BMP2 groups was similar, and the radiographic success rate in the BMP2 group was a little less than that in the MTA group however it was not statistically significant. Advances in biomedical research have opened up new perspectives for treatment modalities, aiming to regenerate the pulp–dentin complex. The future of pulpal treatments holds promise

in biologic approaches. Given the costliness and challenges associated with handling BMP2, we suggest exploring nano-porous materials capable of achieving comparable outcomes with minimal BMP loading. Additionally, we advocate for human histological studies to assess and compare the quality and quantity of hard tissues formed using BMPs versus MTA, offering valuable insights for future advancements.

## CONCLUSION

Our findings indicate that the clinical and radiographic success rates of both MTA and BMP2 were comparable. However, the radiographic success rate in the BMP2 group was slightly less than that of the MTA group, albeit without a significant difference. Hence, BMP2 emerges as a viable option for pulpotomy procedures in deciduous teeth.

## CONFLICT OF INTEREST STATEMENT

None declared.

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