

Clinical Radiographic Evaluation of 3Mixtatin and MTA in Primary Teeth Pulpotomies: A Randomized Controlled

Rakesh K Chak¹, Rajeev K Singh², Jhansi Mutyala³, Nidesh K Killi⁴

ABSTRACT

Introduction: The present study evaluates the efficiency of 3Mixtatin (a combination of Simvastatin and 3Mix antibiotics) in comparison with Mineral Trioxide Aggregate in primary molars pulpotomy.

Materials and methods: A total of 64 deciduous molar teeth with caries requiring pulpotomy procedure were selected and randomly divided into two treatment groups, Group I- MTA (n = 32), Group II- 3Mixtatin (n = 32). Restoration with Glass Ionomer Cement followed by stainless steel crowns was done after pulpotomy procedure. The clinical and radiographical analysis was done in the subsequent follow-up periods of 3, 6, 9, and 12 months simultaneously.

Result: Both groups showed equal success rates, without any significant difference between the MTA and 3mixtatin groups clinically (success rate of 93.8%) and radiographically higher success rate was seen with 3Mixtatin (78% success rate).

Conclusion: 3mixtatin showed similar clinical and better radiographical success rate to MTA. Therefore, 3mixtatin may be a potential alternate pulpotomy medicament in primary teeth.

Key messages: In the present study based on the radiographic findings, 78% success rate was seen in the teeth treated with 3Mixtatin, which was higher than the radiographic success rate of MTA (75%). Therefore, it is reasonable to assume the use of 3Mix with Simvastatin to treat pulpotomized primary molars by 3Mixtatin.

Keywords: 3Mixtatin, Biodentin, Primary molars, Pulpotomy.

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INTRODUCTION

Maintaining the pulp vitality of the decayed or traumatized primary teeth is utmost important to ensure the integrity and smooth transition from primary to permanent dentition. Pulpotomy technique can be done in primary teeth to preserve the vitality of pulp based on the extent of pulp involvement. Pulpotomy procedure can be conducted in any grossly decayed primary tooth that has either bacterial contamination due to caries or mechanical exposure due to trauma or iatrogenic reasons, where the pulp is free of signs and symptoms, both clinical and radiographical.¹ Traditionally many medicaments have been tried like calcium hydroxide and formocresol as a pulpotomy medicament. Due to their lack of potentiality or carcinogenic nature lead to a path in search of newer materials which are effective, biocompatible, bioactive, and bactericidal to act as a potential pulp medicament which encourages the tissue in root canals to remain vital.²

In this newer era of regenerative pulpotomy procedures, Mineral Trioxide Aggregate and Bone Morphogenetic Proteins and many newer agents like nano-hydroxyapatite crystals and Biodentin are being used.³

Mineral trioxide aggregate (MTA, Angelus, Brazil) is primarily indicated as an endodontic root filling material, considered as gold standards in the field of vital pulp therapies. MTA has an enhanced nonresorbable seal over the vital pulp and the ability to induce hard tissue formation due to the release of cytokine from bone cells. MTA with few drawbacks like handling characteristics, composition, setting time, and cost further lead to the search for newer materials.⁴

We are on a continuous look-out for new approaches and substances that stimulate the regenerative ability of dental

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tissues. Statin components are well known for their regenerative capacity. They enhance the activity of osteoblasts and decrease the osteoclastic function leading to increase the rate of formation of bone.^{5,6} They also improve the function of odontoblasts resulting in the ameliorated formation of dentin and angiogenesis.^{7,8} Statins also exhibit potent anti-inflammatory properties and maintain the levels of pro-inflammatory cytokines.⁹ Assuming these properties might have a role in the regeneration of pulp and dentin, statins are used as a pulpotomy medicament in 3Mixtatin.

3Mix paste in a combination of metronidazole, ciprofloxacin, and cefixime can eliminate bacterial pathogens from infected tissue in permanent and deciduous dentition.¹⁰ It is also used in lesion sterilization and tissue repair (LSTR); proving to have an excellent

prognosis for the treatment of infected periapical lesions and cases of physiological root resorption.^{11,12}

3Mixtatin is an acronym for a mix of 3Mix and Simvastatin. This combination aims at decreasing the bacterial load, eliminating pulp inflammation and results in dental hard tissue formation.

The present research was undertaken to comparatively evaluate the medicaments MTA, 3Mixtatin in primary teeth pulpotomy, after considering their role in pulp repair. MTA belong to the group of calcium-silicate based materials prepared synthetically and 3Mixtatin being an emerging material in regenerative dentistry.

MATERIALS AND METHODS

The proposed outline of the study was assessed and approved by the Institutional Ethics Committee which was removed for blind peer review. The patients in the age group of 3–9 years were included in the study. Written informed consent was taken from the parents or legal guardian prior to the examination of the patient after fully explaining the associated risks and benefits.

Patients with no relevant medical history were ruled out and examined clinically and radiographically for asymptomatic, restorable vital primary molars with deep dentinal carious lesions for inclusion in the study. Clinical evidence of pulp necrosis was ruled out.

Absence of radiographic evidence of pulp degeneration such as widening of periodontal ligament space (PDL widening), internal and external resorption of the root (IRR and ERR), furcal radiolucency or inter radicular bone destruction (FR/IBD) and/or periapical bone destruction (PBD) was ensured for every selected tooth. The presence of at least two-thirds of the root length radiographically, and restorability of selected teeth were also confirmed. The final selection for enrolment in the study was made intraoperatively only when hemostasis was achieved within 5 minutes of the removal of the coronal pulp.

Sample Size Calculation

The enrolment in the study involved the assessment of 70 deciduous molars for eligibility according to the inclusion criteria, and out of them, six teeth were excluded, which does not follow the inclusion criteria. Sixty-four deciduous molar teeth were finalized to include in the study which fulfilled the inclusion criteria. They are randomly allocated into two treatment groups with 32 deciduous molars in each group by Computer-generated random codes with a permuted block randomization scheme generated with Research randomizer form version 4.

- Group I– Mineral trioxide aggregate (MTA)
- Group II– 3Mixtatin

Clinical Procedure

After local anesthesia administration using 2% lignocaine with 1:100,000 epinephrine, isolation was done with a rubber dam. After complete caries excavation access to the pulp chamber and deroofing of the pulp chamber was done with a sterile No. 330 high-speed bur with water spray. Coronal pulp was amputated with a sterile sharp spoon excavator. Sterile cotton pellets that were dampened with saline were put in contact with the amputated pulpal stumps with light pressure for 2–3 minutes was done to aid in hemostasis. After the removal of the cotton pellets, hemostasis was apparent. Based on the medicament used the teeth were divided into three groups.

Group I: MTA

The pulpal stumps of teeth of the patients assigned for group I (Figs. 1A and B) were covered with MTA paste prepared by mixing of MTA

powder with distilled water as per the manufacturer's instructions. After obtaining the recommended putty-like consistency, it was placed on the pulpal stumps using an MTA applicator and condensed slightly with a dampened sterile cotton pellet to make the sure thickness of 2–3 mm (Fig. 1C) was obtained. A thickly mixed zinc oxide eugenol was placed inside the coronal pulp chamber. In the subsequent visit (after one day); the temporary restoration was removed, and final restoration was done with glass ionomer cement.

Group II: 3Mixtatin

The 3Mixtatin was prepared using three commercially available antibiotics metronidazole, ciprofloxacin, cefixime along with simvastatin powder. After removal of the capsules or coating materials that enclosed the drug products, they were pulverized to fine powders using porcelain mortars and pestles. A total of 100 mg metronidazole, 100 mg of ciprofloxacin, 100 mg of cefixime were mixed in 1:1:1 ratio, and 2 mg of simvastatin powder were added to final powdered drug mix, which was kept in a tightly capped porcelain bottle. A clean glass slab and a spatula were used to mix the powder and normal saline into a thick consistency.

After obtaining hemostasis (Figs. 2A and B), the paste was transported to the pulpal orifice with a stainless steel carrier and then pressed lightly. Once a 2–3 mm thickness was ensured (Fig. 2C), the cavity was filled by restorative glass ionomer cement to seal it (Fig. 2D). At the 24-hour follow-up, the pulpotomized teeth in all groups were given stainless-steel crowns which were cemented using luting glass ionomer cement. The treatment of all sixty-four teeth was done by the same operator in this study.

Evaluation Criteria

The participants were recalled for clinical and radiographic evaluation. The radiographic evaluation was done in comparison with the preoperative radiograph with the radiographs taken at a time interval of 3, 6, 9, and at 12th month. The images from (Figs. 1D to H) depicts the radiographs of pulpotomies done with MTA, images from (Figs. 2E to I) indicates the radiographs of the pulpotomies done with 3Mixtatin. The patients were blinded with respect to the treatment. The teeth were assessed for clinical and radiographical criteria by two observers who were independently blinded to the type of treatment. This scoring system devised the severity of changes but did not define an individual tooth as a "success" or "failure." The detailed description of the scoring criteria used is as follows:

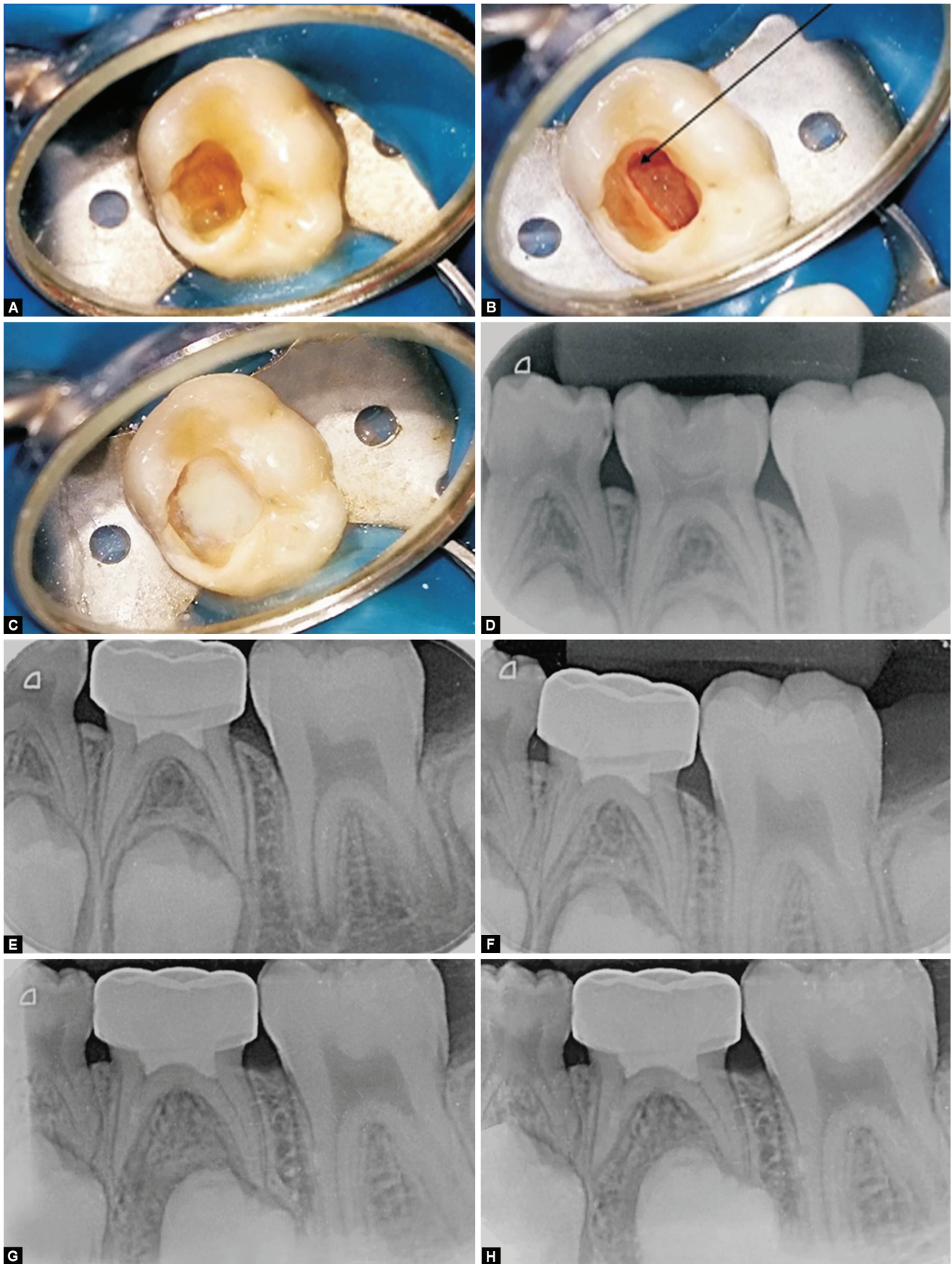
Clinical scoring criteria was based on the clinical signs, including spontaneous pain, swelling, abscess/fistula, abnormal mobility, and tender on percussion, soft tissue redness. The radiographic signs that are included for evaluation are periodontal ligament widening, internal resorption, external resorption, furcal radiolucency/interradicular bone destruction, pulp canal obliteration, and periapical bone destruction.

Statistical Analysis

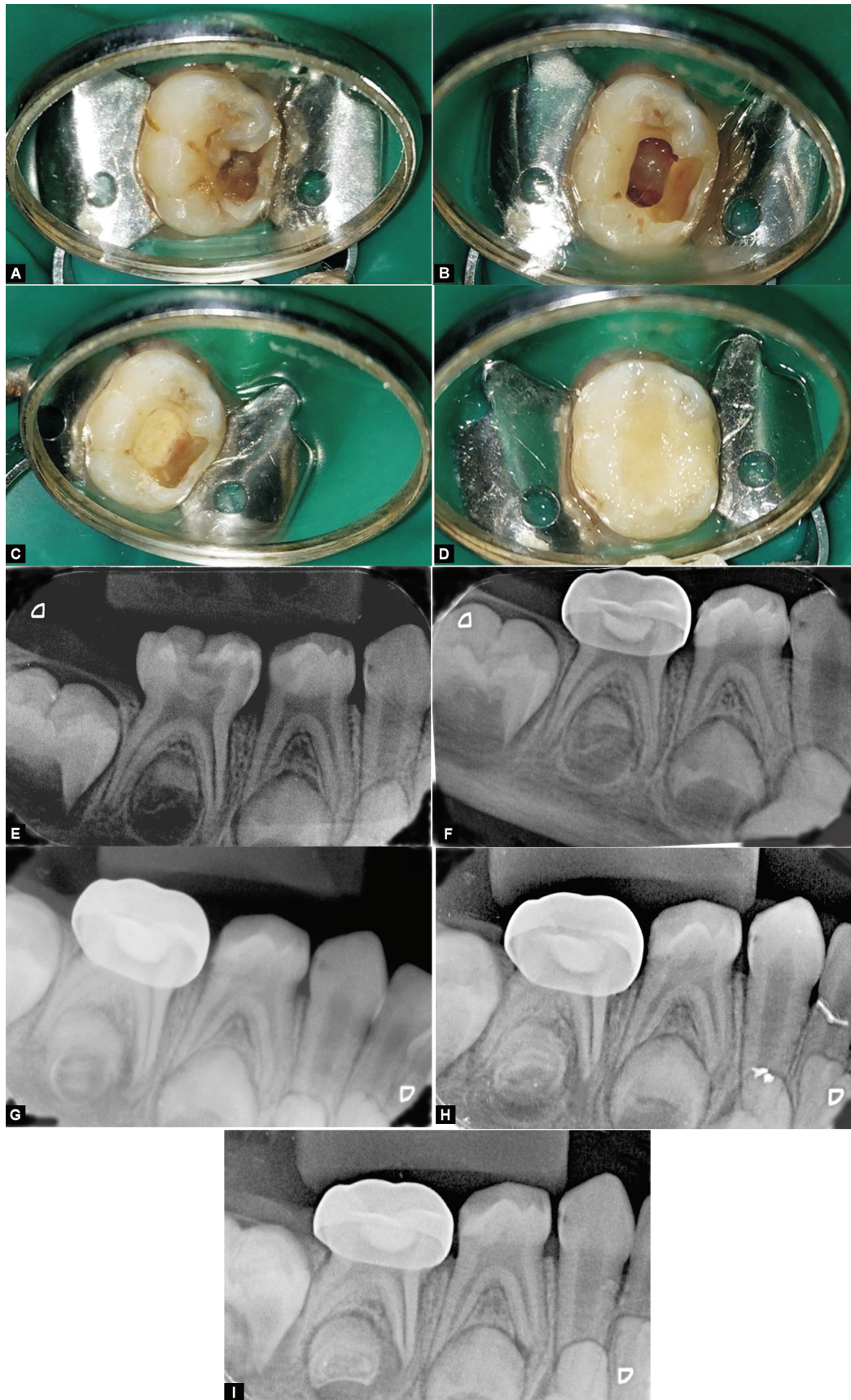
The study data was entered in SPSS (22.0) and the Mann–Whitney *U* test, change in the continuous variables was tested by paired *t*-test. A *p* value <0.5 was considered as significant.

RESULTS

In the present study, (Tables 1 and 2; and Fig. 3) depicts the clinical evaluation of both the groups (MTA and 3Mixtatin). There was no statistically significant difference between clinical success rates in months 3, 6, 9, and 12 (*p* < 0.5) (Table 1). In both groups, clinical



Figs. 1A to H: (A) Preoperative photograph; (B) Intraoperative view after removal of coronal pulp tissue; (C) Intraoperative view showing MTA; (D) Preoperative radiograph; (E) 3rd month radiograph; (F) 6th month radiograph; (G) 9th month radiograph; (H) 12th month radiograph



Figs. 2A to I: (A) Preoperative photograph; (B) Intraoperative view after removal of coronal pulp tissue; (C) Intraoperative view showing 3mixtatin; (D) Intraoperative view showing 3mixtatin placement over radicular pulp; (E) Preoperative radiograph; (F) 3rd month radiograph; (G) 6th month radiograph; (H) 9th month radiograph; (I) 12th month radiograph

Table 1: Clinical evaluation MTA and 3Mixtatin as pulpotomy medicament in primary molars at a follow-up period of 3, 6, 9, and 12 months

<i>Clinical evaluation MTA and 3Mixtatin at a follow-up period of 3, 6, 9, and 12 months</i>			
<i>Clinical success</i>	<i>MTA (n = 32)</i>	<i>3Mixtatin (n = 32)</i>	<i>p-value</i>
3rd month	100% (n = 32)	96% (n = 31)	
6th month	96% (n = 31)	93% (n = 30)	0.5
9th month	93% (n = 30)	93% (n = 30)	
12th month	93% (n = 30)	93% (n = 30)	

Table 2: Success rate of MTA and 3Mixtatin as pulpotomy medicament in primary molars at a follow-up period of 3, 6, 9, and 12 months based on clinical evaluation

<i>Clinical evaluation</i>					
<i>Groups (n = 32)</i>	<i>Recall period time (failures in each period)</i>				<i>Success rate (%)</i>
	<i>3rd month</i>	<i>6th month</i>	<i>9th month</i>	<i>12th month</i>	
MTA(n = 32)	0/32	1/32	1/31	0/30	93
3Mixtatin (n = 32)	1/32	1/31	0/30	0/30	93

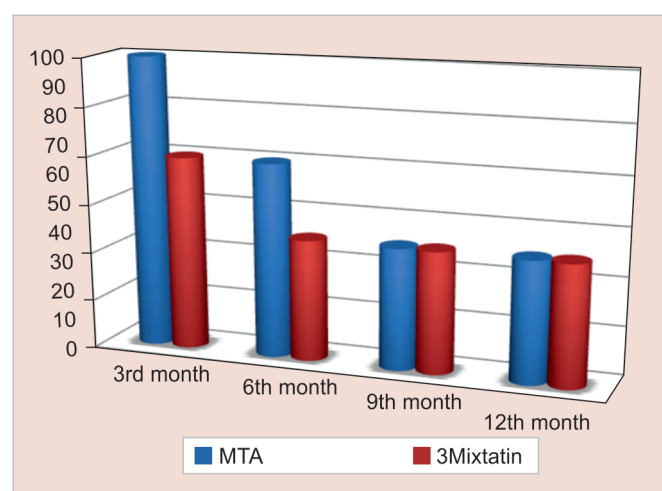


Fig. 3: Success rate of MTA and 3Mixtatin as pulpotomy medicament in primary molars at a follow-up period of 3, 6, 9, and 12 months based on clinical evaluation

signs for failure in one patient each was seen at 6th month follow-up period with tender on percussion. Spontaneous pain in one patient in MTA group at 9th month follow-up period and in one patient in 3Mixtatin group at 3rd month follow-up period was seen. Clinical failures/success signs are presented in (Table 2).

The radiological evaluation of both groups are presented in (Tables 3 and 4; and Fig. 4). There was no statistically significant difference between clinical success rates in months 3, 6, 9, and 12 ($p < 0.5$) (Table 3). Radiological failure signs presented in MTA group are pulp canal obliteration in one patient each at 6th month follow-up period and at 9th month follow-up period pulp canal obliteration, periodontal length widening, and internal resorption were seen in single patient each. At the end of the 12th month, there were two patients with periodontal length widening, one patient with pulp canal obliteration and one patient with internal resorption.

In 3Mixtatin group radiographical signs of periodontal length widening, internal resorption, and pulp canal obliteration were seen in one patient each at 6th month follow-up period. At 12th month follow-up period signs of periodontal length widening and pulp canal obliteration were seen in one patient each and internal resorption was seen in two patients.

The success rate was 93% in both MTA group and 3Mixtatin group based on clinical evaluation.

Based on radiographical evaluation 75% success rate was seen in the MTA group, and 78% success rate in 3Mixtatin was seen at the end of 12th-month follow-up.

DISCUSSION

Dental caries progression is relatively rapid towards pulpal tissue in primary dentition and leads to pulpal inflammation close to the caries lesion. The inflammatory process can spread throughout the coronal pulp with further advancement of the carious process. If the pulp in the root canals remains unaffected symptom-free in primary teeth, to preserve radicular pulp vitality, a pulpotomy can be the management procedure of such deciduous teeth.¹³

A plethora of medicaments, like formocresol, glutaraldehyde, ferric sulfate, calcium hydroxide, zinc oxide eugenol, paraformaldehyde, mineral trioxide aggregate has been used over the years. Ideal properties for the pulpotomy medicament include nontoxicity, non-mutagenicity, biocompatibility, dimensional stability, antibacterial, and benign to the biological tissues, should promote healing and have no ill effects on the tooth bud.¹⁴

The well-known cytotoxicity, mutagenicity, and carcinogenic potential of formocresol have restricted its use and is a cause of concern in pediatric patients. Calcium hydroxide, a successful pulpal dressing, has also been associated with severe internal root resorption after pulpotomies of primary teeth.¹⁵ All these pulpotomy medicaments have therefore remained unsatisfactory, and thus emphasis of all researchers has moved from an era of "preservation" toward "regeneration." This resulted in the research and synthesis of bioactive material, Mineral Trioxide Aggregate (MTA).

MTA has remained the gold standard material in vital pulp therapy for years, owing to its bioactive potential, biocompatibility, antibacterial properties with exceptional stability and high sealing ability. MTA shared a common mechanism of action with calcium hydroxide. The principal component of the material is calcium oxide which converts into calcium hydroxide when in contact with the humid environment, which has a pH of 12.5, and this exerts a long-term antibacterial effect.¹⁶

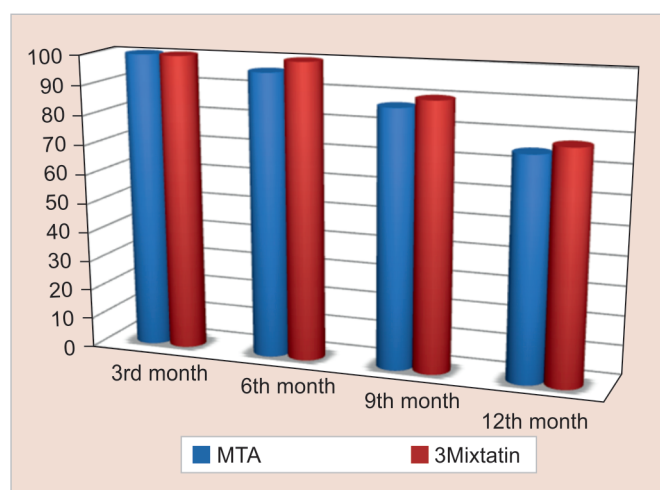
MTA also has certain disadvantages to its credit, such as having certain toxic materials, greater toxicity when newly prepared, higher pH when setting, difficult handling characteristics, long setting time, low flexural strength, greater cost, and discolouration of hard

Table 3: Radiographical evaluation MTA and 3Mixtatin as pulpotomy medicament in primary molars at a follow-up period of 3, 6, 9, and 12 months*Clinical evaluation MTA and 3Mixtatin at a follow-up period of 3,6,9 and 12 months*

Clinical success	MTA (n = 32)	3Mixtatin (n = 32)	p-value
3rd month	100% (n = 32)	100% (n = 32)	
6th month	96% (n = 31)	100% (n = 32)	0.5
9th month	87% (n = 28)	90% (n = 29)	
12th month	75% (n = 24)	78% (n = 25)	

Table 4: Success rate of MTA and 3Mixtatin as pulpotomy medicament in primary molars at a follow-up period of 3, 6, 9, and 12 months based on radiographical evaluation*Radiographic evaluation*

Groups (n = 32)	Recall period time (failures in each period)				Success rate (%)
	3rd month	6th month	9th month	12th month	
MTA (n = 32)	0/32	1/32	3/31	4/28	75
3Mixtatin (n = 32)	0/32	0/32	3/32	4/29	78

**Fig. 4:** Success rate of MTA and 3Mixtatin as pulpotomy medicament in primary molars at a follow-up period of 3, 6, 9, and 12 months based on radiographical evaluation

tissue.^{17,19} Hence, there was a need to develop new material in this category, as efficacious as MTA, but with superior qualities than any other calcium silicate-based materials.

A newer medicament has been introduced through research was 3Mixtatin, an acronym for the new combination of 3Mix antibiotic paste and Simvastatin.

Statins are well known for their antihyperlipidemic action in cardiovascular patients and supported by both experimental and clinical studies for their pleiotropic effects which led the statin components to be used in the field of regenerative dentistry. Statins increase bone formation by improving the function of bone-forming cells while depressing the function of bone-destroying cells. This led the researchers to hypothesize their role in odontogenesis and intricacies of the pathways through which Simvastatin promoted dentin synthesis.²⁰

3Mix antibiotic content which is capable of eliminating bacteria from infected dental tissues *in situ* experiments suggest that this poly mix of drugs acts against bacteria shows their bactericidal effect by penetrating into the lesions and sterilize them. Furthermore, triple antibiotic paste has been used successfully in regenerative endodontic treatment of teeth with large peri-radicular lesions.²¹

In the present study based on the radiographic findings, 78% success rate was seen in the teeth treated with 3Mixtatin, which was higher than the radiographic success rate of MTA (75%). Therefore, it is reasonable to assume the use of 3Mix with Simvastatin to treat pulpotomized primary molars by 3Mixtatin.

The combination of triple antibiotic powder 3Mix with Simvastatin gives 3Mixtatin, which was mixed with normal saline for ease of placement. The amalgamation of these materials reduces bacterial load, lessens pulpal inflammation, and also results in dentinogenesis.

The antibacterial and sterilizing effects along with anti-inflammatory and bioinductive properties of 3Mixtatin and other properties proinflammatory cytokines IL-6 showing no cytotoxic effect on odontoblast, may assist in angiogenesis and reparative dentine formation may lead to the higher success rate of 3Mixtatin.^{22,23}

At the end of the pulpotomy treatment, stainless steel crowns (SSCs) are given to protect the pulpal tissue from microleakage and result in an increased success rate.²⁴

In the present study, based on the evaluated overall clinical score, it was found that 93.8% of the pulpotomized primary molars were successful in all two groups MTA and 3Mixtatin over a 12-months follow-up period. Although minor differences were observed between them at different time intervals, these results were not statistically significant.

CONCLUSION

The present study results help to conclude that the prospective likelihood of 3Mixtatin can be used as a potential alternative to MTA in pulp therapy in deciduous teeth with 12 months follow-up period. 3Mixtatin showed better results than MTA which may need a further follow-up period for a long term effects of the both the medicaments.

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