Versha Kamboj¹, Monika Gupta², I.K. Pandit³, Neeraj Gugnani⁴

¹Postgraduate, ²Professor, ³Principal and HOD, ⁴Professor, DAV (C) Dental College Yamunanagar, Haryana

Corresponding Author: Versha Kamboj

ABSTRACT

Aim: The aim of this study was to evaluate and compare Biodentine and Mineral trioxide aggregate (MTA) as pulpotomy agents by clinical and radiological assessments in primary teeth.

Materials and methods: In this study, 30 decayed primary molars indicated for pulpotomy were randomly assigned to the Biodentine and MTA groups. After coronal pulp removal and hemostasis, the remaining pulp tissue was covered with Biodentine or MTA. All teeth were restored with GIC. Clinical and radiographic successes and failures were recorded at 1 week, 3 month and 6 months follow-ups. Data was statistically analyzed.

Results: The 6-months follow-up evaluations revealed that the clinical success rate was 100 percent for both Biodentine and MTA. The radiographic success rates at 6 months were 93.3 percent for Biodentine and 86.7 percent for MTA. No significant differences were found among the groups at all follow-up appointments (P>0.05).

Conclusion: Biodentine and MTA did not differ significantly in combined clinical and radiographic success after 6 months. Therefore, both can be considered reliable medicaments for pulpotomy treatment in primary teeth.

Key words: Biodentine; Mineral trioxide aggregate; Pulpotomy; Primary teeth

INTRODUCTION

Pulpotomy is one of the most widely accepted clinical procedures in cases of pulp exposure with reversible pulpitis. ^[1] It entails removal of the coronal pulp and maintenance of the radicular pulp. There are three main approaches to this technique: i) preserving the radicular pulp in a healthy state; ii) rendering the radicular pulp inert, or iii) encouraging tissue regeneration and healing at the site of radicular pulp amputation (Rodd HD et al 2006).^[2]

Historically, a wide variety of medicaments have been used in pulpotomy of primary teeth namely, Formocresol, Glutaraldehyde etc (Fouad A. Walid et al 2013). ^[3] Though these materials have shown good success rates but owing to the safety concerns, their use as pulpotomy agent is being forbidden these days. Moreover, in recent years, owing to good success rates and safety in usage, Ferric sulphate has become the preferred medicament for pulpotomy Schroder [4] [1978]. Some other alternative medicaments like Propolis, Enamel matrix derivatives, Platelet rich plasma, Mineral trioxide aggregate (MTA) and other means like Lasers and Electrosurgery have also been used as pulpotomy agents.^[5]

Amongst these newer materials, MTA has attracted considerable attention due to its excellent biocompatibility ^[6] and antimicrobial properties. ^[7] MTA is widely being used in pulp therapy and as it provides better seal over the vital pulp and is nonresorbable. ^[8] MTA is also known to stimulate the formation of dentinal bridge. ^[9] Though there exists some drawbacks of this material such as slow wetting kinetics and complicated handling properties, still the reported success rates for MTA as a pulpotomy medicament in primary teeth range from 94 to100% based upon various

meta-analysis, ^[10] systematic reviews ^[11] and evidence base assessments. ^[12]

Further. various other calcium silicate-based products have been launched into the market recently and one of these namely Biodentine has also been advocated as a pulpotomy agent. Biodentine- a calcium silicate-based product which became commercially available in 2009 (Septodont) was specifically designed as a "dentine replacement" material as it closely mimics the properties of dentine. Biodentine has a wide range of applications including pulp and endodontic capping repair (root perforations, apexification, resorptive lesions, and retrograde filling material in endodontic surgery). ^[13] It has increased physico-chemical properties like short setting time, high mechanical strength etc which makes it an easy to use material for pulpotomy in pediatric patients (Allazzam M et al 2015).

According to a network metaanalysis done by (Po-Yen Lin et al 2014)^[14] MTA has already proved itself to be a good 'alternative to formocresol, when used as a pulpotomy agent. Biodentine, on the other hand is reported to be a promising material that could be used as a pulpotomy agent too. However, there are very few studies comparing the success rates of these two materials. Hence, this study was undertaken to evaluate and compare the success rates of MTA and Biodentine when used as pulpotomy agents in primary molars in terms of clinical and radiographic parameters.

MATERIALS AND METHODS

Ethical clearance

Before the start of the study ethical approvals were sought from the Institutional Review Board of D.A.V(C) Dental College, Yamuna Nagar for conducting the study.

Study design

Children in the age group of 4-9 years visiting the Out-Patient Clinics in the Department of Paedodontics and Preventive Dentistry at D.A.V. (C) Dental College,

Yamuna Nagar were screened for teeth indicated for pulpotomy. 30 Primary molars were finally selected according to the following inclusion criteria: a carious exposure of the vital coronal pulp, absence of symptoms indicative of advanced pulpal inflammation (spontaneous pain or history of nocturnal pain, sinus, soft tissue swelling). The absence of radiographic signs of pulpal necrosis (furcation involvement, periapical pathology). Teeth should be restorable after completion of the procedure. And the exclusion criteria included: nonconsent of the parents to participate in the study, children with any systemic diseases, teeth that showed excessive bleeding during the amputation of coronal pulp tissue which is difficult to control. Teeth with any signs of internal or external resorption were excluded from the study.

The parents of the children were provided detailed information about the treatment procedure, benefits, and possible risk involved in the study. Written consent was sought from parents prior to treatment. Assent was also sought from the children participating in the study before their inclusion.

Randomization and division of samples

All selected primary teeth were randomly divided into two equal groups of 15 teeth each i.e. Group I in which MTA (ProRoot MTA, Dentsply) was used as pulpotomy medicament and Group II in which Biodentine (Septodont) was used as pulpotomy medicament. For the purpose of randomization, the randomization codes were generated by using computer software (www.random.org). Permuted block randomization scheme was used with block size of 4 and allocation concealment was ensured by using sealed opaque envelope. Neither the investigators nor the patients could be blinded to the type of material placed in the pulp chamber due to the difference in handling characteristics and the nature of the two materials. However, the assessor who was responsible for all the

post- operative recall assessment was blinded of the material used.

CLINICAL PROCEDURE

Standard procedure was followed to prepare the access cavity in both Group I and Group II. Local anesthesia was administered using 2% Lignocaine Hydrochloride with Adrenaline 1:80000. Rubber dam isolation of the tooth was carried out. The pulp chamber was opened with a sterile high-speed diamond bur no. 7, and the coronal pulp was removed by a slow-speed round sterile bur under Complete water irrigation. continuous removal of the coronal pulp tissue was done using a sterile hand spoon excavator. Normal saline was used to irrigate the pulp chamber. The hemorrhage was controlled by placing a sterile, saline-wetted cotton wool pellets on the pulp stumps under slight pressure to achieve the primary hemostasis for 2-3 minutes (Grewal et al 2016). ^[15] Once hemostasis was achieved, remnant blood clots were removed, and the cavity was dried.

GROUP I

The MTA (ProRoot MTA, Dentsply) paste was obtained by mixing powder and distilled water in the ratio 3:1 to obtain a putty like consistency. 2-3 mm thick layer of MTA was placed inside the pulp chamber with a spatula and was condensed with saline moistened cotton pellet.

GROUP II

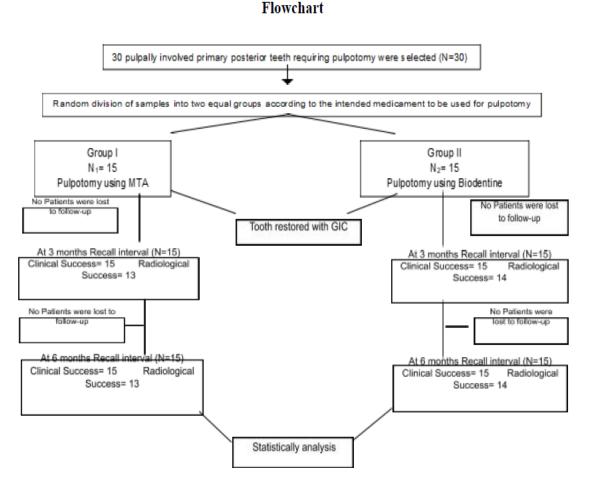
Biodentine (Septodont) paste was prepared by squeezing out the liquid of a single-dose container into the capsule containing powder capsule. The capsule was then placed in a triturator and mixed for 30 seconds at 4,200 rpm. A putty-like consistency was obtained. It was then carried with an amalgam carrier to the pulp stumps and condensed lightly with a metal condenser, in a thickness of 2 - 3 mm. In both the groups, a layer of thick mixture of zinc oxide eugenol (ZOE) cement was applied over the medicaments followed by glass ionomer cement (GC Gold Label 2) restoration. Clinical photographs and intra oral periapical radiograph were taken for the clinical and radiographic assessment of treated tooth.

All the patients were recalled after 3 months and 6 months from the day of the pulpotomy procedure was done. During these recall visits post-operative clinical evaluation of the teeth was done to check for any spontaneous or nocturnal pain. swelling, sinus formation or pathological mobility using Zurn and Seale criteria [16] (2008).Similarly, radiographic evaluation was also done after 3 months and 6 months to evaluate any sign of periodontal ligament widening, pathological external or internal root resorption and for any periapical or furcation radiolucency using the same criteria.

This scoring criteria was used because this scoring system represents severity of changes but does not define an individual tooth as a 'success' or 'failure', i.e., as the score gets larger, the pathologies get progressively more invasive and requires more frequent follow-up. Teeth scored as 1 or 2 were considered successful. Similar criteria was used in the studies conducted by Bharti Kusum et al 2015, ^[17] Rajasekharan S et al 2016, ^[18] Musale PK and Soni A.S 2016. ^[19]

Statistical analysis

At the end of the study period, the data was collected and subjected to statistical analysis. Statistical analysis was carried out by Chi- square test and McNemar's Chi-square test using SPSS (Version 20.0).



RESULTS

Inter-group comparison between Group I (MTA) and Group II (Biodentine) at 3 months, and 6 months, in terms of clinical evaluation found all (100%) the samples to be asymptomatic as none of the patient reported with pain, gingival swelling, mobility or periodontal pocket. The results were found to be statistically non-significant (p = 1.000).

On radiological evaluation at 3 months interval, 2 (13.3%) patients of Group I (MTA) exhibited signs of periodontal ligament widening, external root resorption and periapical radiolucency. These two 2 patients continued to exhibit the same signs at 6 months recall interval also (13.3%).While in Group Π (Biodentine), at 3 months' time interval, external root resorption, mild PDL widening and periapical radiolucency were seen in 1 patient (6.7%). This patient continued to exhibit the same signs at 6 months recall interval also (6.7%). However, the statistical analysis non-significant showed a difference. (p=0.543)

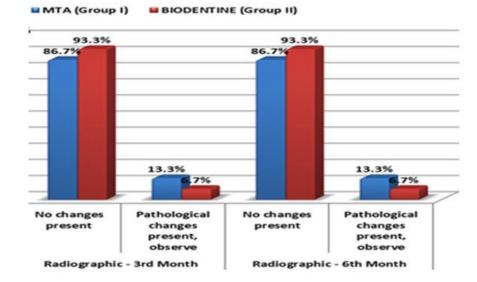
 Table no. 1- Inter-group comparison in terms of clinical parameters as evaluated at 3 months and 6 months time intervals between Group I (MTA) and Group II (Biodentine)

	Groups			Chi-Square value	p-value
Clinical score	MTA (Group I)	BIODENTINE (Group II)	Total		
1	15	15	30		
(Asymptomatic)	100.0%	100.0%	100.0%	0.000	1.000#
1	15	15	30		
(Asymptomatic)	100.0%	100.0%	100.0%	0.000	1.000#
	1 (Asymptomatic) 1	Clinical scoreMTA (Group I)115(Asymptomatic)100.0%115(Asymptomatic)100.0%	Clinical score MTA (Group I) BIODENTINE (Group II) 1 15 15 (Asymptomatic) 100.0% 100.0% 1 15 15 (Asymptomatic) 100.0% 100.0% 1 15 15 (Asymptomatic) 100.0% 100.0%	Clinical score MTA (Group I) BIODENTINE (Group II) Total 1 15 15 30 (Asymptomatic) 100.0% 100.0% 100.0% 1 15 15 30 (Asymptomatic) 100.0% 100.0% 100.0% 1 15 15 30 (Asymptomatic) 100.0% 100.0% 100.0%	Clinical score MTA (Group I) BIODENTINE (Group II) Total 1 15 15 30 (Asymptomatic) 100.0% 100.0% 100.0% 1 15 15 30 (Asymptomatic) 100.0% 100.0% 0.000 1 15 15 30 (Asymptomatic) 100.0% 100.0% 0.000

Chi-square test # non-significant difference

		Groups			Chi-Square value	
Recall	Radiographic score	MTA (Group I)	BIODENTINE (Group II)	Total		p-value
	1 (No changes present)	13	14	27		
		86.7%	93.3%	90.0%		
3rd Month 3	3 (Pathological changes present)	2	1	3	0.370	0.543#
		13.3%	6.7%	10.0%		
	1 (No changes present)	13	14	27		
6th Month 3 (Path		86.7%	93.3%	90.0%		
	3 (Pathological changes present)	2	1	3	0.370	0.543#
		13.3%	6.7%	10.0%]	

 Table no. 2- Inter-group comparison in terms of radiological parameters as evaluated at 3 months and 6 months time intervals between Group I (MTA) and Group II (Biodentine)



DISCUSSION

The choice of medicament used in pulpotomy procedures is influenced by several factors including pulp healing potential. antibacterial properties, biocompatibility, properties, mechanical cytotoxicity, dimensional stability, and handling properties, etc. Evidence reports MTA to be a successful material in this context.^[20] MTA also has some associated drawbacks related to mechanical properties, handling characteristics and cost. ^[21] To overcome these shortcomings, efforts have led to the development of new calcium silicate-based material called Biodentine with active bio-silicate technology.

Biodentine attracted attention in the field of dentistry due to its fast setting time, high biocompatibility, high compressive strength, excellent sealing ability, ease of handling as well as its versatile usage without causing any staining of the treated teeth. It has also been proved that biodentine has an excellent antimicrobial property due to its very high pH (pH=12). ^[22] In addition

to that, it is much more cost effective in comparison to MTA. The common underlying mechanism both the medicaments i.e MTA and Biodentine is the stimulation of transforming growth factor TGF- β 1, the key factor which is important for the differentiation of odontoblasts that responsible are for the reparative dentinogenesis.^[23]

In the present study, patients between the age group of 4-9 years were screened and a total of 30 primary molars were selected and randomly divided into two equal groups. Age group 4-9 years was included in the study because caries activity is high during this age group due to increased intake of sugars, starchy foods and greater frequency of eating (Mariri BP et al, 2003).^[24] Moreover, in this age group, patient's responses are also well developed which leads to easy communication between the child and the dentist. Patients in both the were treated with different groups pulpotomy agents i.e. Group I- Mineral trioxide aggregate and Group II-Biodentine.

In both the groups pulpotomy procedure was performed and subsequently all the teeth were evaluated at 3 months and 6 months recall intervals in terms of clinical and radiological parameters. The data obtained was tabulated and statistically analyzed.

In terms of clinical evaluation, all (100%) the samples were found to be asymptomatic as none of the patients in both the groups reported with any clinical symptoms (pain, mobility, sinus formation and swelling). The result could be attributed to the achievement of complete intraoperative aseptic conditions as well as to the antibacterial properties of both Mineral trioxide Aggregate and Biodentine that resist the penetration of micro-organisms. Similar results were obtained by Harshini Togaru et al, 2016, ^[25] Bharti Kusum et al 2015 ^[17] who reported 100% clinical success with both MTA and Biodentine when used as pulpotomy medicaments.

In terms of radiological findings, at 3 months recall interval, 2 (13.3%) patients in Group I (Mineral trioxide Aggregate) mild periodontal showed ligament widening, external root resorption and periapical radiolucency. These two 2 patients continued to exhibit pathological signs at 6 months recall interval also. According to Magnusson 1970^[26] this could be attributed to periapical inflammatory lesion resulting from inflammation of the residual pulp. In a study conducted by O Carti et al 2015, ^[27] radiological signs were seen in 16% of the cases in which Mineral trioxide aggregate pulpotomy was performed over a period of 6 months of follow up.

While in Group II (Biodentine), At 3 months recall interval, 1 (6.7%) patient showed mild periodontal ligament widening, external root resorption and periapical radiolucency. The same patient continued to exhibit pathological signs at 6 months recall interval also. According to Vieira- Andrade R.G et al 2012 ^[28] this could be attributed to diagnostic errors made while assessing pulp condition, or to technical failure while performing the treatment. Similar findings were seen in a study conducted by Bani M et al 2017^[29] in which 6.4% of cases in which Biodentine was used as pulpotomy agent exhibited radiological signs.

However, the statistical analysis showed a non-significant difference. Teeth with radiological signs were not treated, but left for further follow-up observation, because they were asymptomatic and did not show any sign of clinical failure. This was in accordance with a study conducted by Farsi et al, 2005. ^[30]

CONCLUSION

In the present study, both (Mineral trioxide aggregate and Biodentine) were found to be successful pulpotomy medicaments, even though Biodentine outcomes very slightly better than that of MTA. However, the results were found to be statistically non-significant.

Thus, more studies with larger sample size and longer study period are required to validate the result of the present study. As ours was a 6-month long study, we could not include the evaluation of reparative dentinogenesis; but it is recommended to include "reparative dentinogenesis" as one of the outcome measures in future long-term studies. However, the outcome measures used by us do help us to know the success rates of both the medicaments in in-vivo conditions.

Conflicts of interest

There are no conflicts of interest.

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