

EFFICACY OF FORMOCRESOL AND MINERAL TRIOXIDE AGGREGATE PULPOTOMY AMONG PRIMARY MOLARS: A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Aim of this study was to evaluate the efficacy of different vital pulp therapy techniques using Formocresol and Mineral Trioxide Aggregate (MTA) as the materials for pulpotomy in cariously exposed primary molars teeth. At the end of one year success was compared both clinically and radiographically. A non randomized convenience sampling method was used as sampling technique.

A retrospective randomized control trial was conducted and completed in one year (February 2015 to January 2016) at the Department of Operative Dentistry, Armed Forces Institute of Dentistry, Rawalpindi. For evaluating the success of the two techniques clinical examination and radiographic evaluation was used as criteria on follow up visits of 290 patients. The sample comprised of patients of age 05 to 08 years with mean age of the patients was 6.35 ± 0.95 and 6.38 ± 0.98 year in group-A and B, respectively. Selected patients were randomly distributed into two groups (group A and group B) using a lottery method. After performing pulpotomy procedure, formocresol was placed in group A patients while Mineral Trioxide Aggregate (MTA) was placed in the group B patients and the patients were called for follow up. 1st visit was at 03 months, 2nd was at 06 months and 3rd visit after a period of 01 year. The results were analyzed and presented as success and failure in the data sheet using SPSS version 17. Efficacy was observed in 104 patients (71.7%) in group-A and 131 patients (90.3%) in group-B with p value of $p < 0.001$. The results show a significant difference in the efficacy of Mineral Trioxide Aggregate (MTA) and Formocresol with higher success rate of MTA.

Key Words: Formocresol, Mineral Trioxide Aggregate, Vital Pulpotomy.

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INTRODUCTION

In pediatric dentistry one of the major aim is to preserve deciduous teeth in an intact state until permanent erupts.¹ It is a unique challenge to treat pulpally

involved primary teeth.² Primary dentition is very essential. It maintains arch length, speech, esthetics and mastication. Trauma to pulp and pulp diseases can result in the loss of vitality of the tooth but this does not mean that tooth should be extracted, instead it should be maintained in the functional state inside oral cavity. There are various procedures to preserve that e.g. pulp capping, partial or complete pulpotomy, complete pulpectomy, apexification, and apexogenesis.³

In deciduous dentition pulpotomy is the procedure of choice to remove infected and inflamed pulp tissue and is usually performed after a pulpal exposure cariously, mechanically or due to trauma.⁴

Different medicament/agents used in pediatric dentistry for pulpotomy are Formocresol, Glutaraldehyde, Mineral Trioxide Aggregate (MTA), Laser therapy, Ferric sulphate, Collagen and Calcium Hydroxide.⁵ In this study we compared the efficacy of formocresol to mineral Trioxide aggregate pulpotomy. After the pulpotomy Formocresol is most widely used medicament

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to maintain the vitality of the underneath pulp, by causing coagulative necrosis of the surface part.⁶ Its causes the mummification of the superficial part of the pulp. The other alternatives to formocresol is Mineral Trioxide Aggregate.²

Biologically Mineral Trioxide Aggregate is more acceptable product. Composition of Mineral Trioxide Aggregate is dicalcium silicate, tricalcium silicate, tricalcium aluminate, gypsum, tetracalciumaluminoferrite and bismuth oxide which makes it radiopaque.⁷ For pulpotomy procedures Mineral Trioxide Aggregate has been suggested as a potential medicament having excellent biocompatibility, ability of dentinal bridge formation, radiopacity, and sealing ability. Different clinical and radiographic studies have showed the clinical success rate of 100% of both the groups after 3, 6, and 12 months. At 06 month the radiographic success rate formocresol and Mineral Trioxide Aggregate were 88% and 96% respectively.⁸

The study was conducted to compare the efficacy of mineral Trioxide aggregate and formocresol so as to help the dental professionals in selecting more efficient material/agent for pulpotomy which will result in higher success rate and will maintain and preserve the teeth in healthy functional condition for long time until permanent successor's erupts.

METHODOLOGY

This study was carried out at Armed forces institute of dentistry Rawalpindi. After patient's selection and pulpotomy procedure the total period of the study was one year. Patient's age range was 5-8 years. Mean age of the patients was 6.35 ± 0.95 and 6.38 ± 0.98 year in group A and B, respectively. In group A, 81 patients and in group B, 75 patients were males while in group A, 64 patients and in group B, 70 patients were females. Sample was selected from the outpatient department

Non-probability, consecutive sampling technique was used. By using lottery method participants were equally divided into two groups, Group A was formocresol and the MTA Group B. It was a randomized control trial. Inclusion criteria was cariously or mechanically exposed vital primary teeth with the history of reversible pulpitis presenting with pain and the lesion extending to the pulp on radiograph which was conformed on cold test.

Inclusion criteria: Children falling within 05 years to 08 years age, both genders, children with good oral hygiene, physical and mental status, absence of symptoms of irreversible pulpitis such as nocturnal pain or history of spontaneous and lingering pain.

Exclusion criteria: Extra oral swelling, intra oral swelling, tenderness to percussion, sinus/fistula, root resorption, periapical radiolucency, pulp obliteration and inter radicular radiolucency.

According to inclusion/exclusion criteria patients were selected. After informed consent of the parents the pulpotomy procedure was initiated and was carried

out in one visit in which the tooth was anesthetized using local anesthesia 2% lidocaine of 1.8mL with epinephrine 1: 100,000 (Medicainer Inj, Huon Co.,Ltd, Korea). Isolation was done using cotton wool rolls and saliva ejection. Cavity outline was formed by high speed round diamond bur. De-roofing of the pulp chamber was done using non-end cutting slow speed bur. Removal of coronal pulp was done with round burs in slow speed not touching the floor of the chamber. With the help of sterile excavators the chamber was excavated for removal of remaining pulp tissue. Physiological saline was used for pulp chamber irrigation. Sterile pellet of wet cotton wool was used with pressure to control bleeding from remaining pulp tissue.

For Group A after the pulpotomy procedure formocresol was applied with cotton pellet for 05 minutes over the radicular pulpal tissue, Cotton pellet was moistened using formocresol blotted and then dried. After application of formocresol to seal the coronal pulp chamber zinc oxide eugenol cement was used and the tooth was restored with glass ionomer cement (3M ESPE Ketac-Molar). Group B was treated with Mineral Trioxide Aggregate (Proroot, Dentsply). Mineral Trioxide Aggregate powder and the distilled water were mixed in manufacturer recommended 3:1 (powder: liquid) ratio and then with the help of plastic instrument the mixed cement was placed over the radicular pulp after which a moist cotton pellet was placed and compressed over Mineral Trioxide Aggregate and to seal the coronal pulp chamber zinc oxide eugenol cement was used. The next day patient was recalled, temporary restoration and a cotton pellet was removed, the tooth was restored with glass ionomer cement (3M ESPE Ketac-Molar).

At follow up the patients were examined clinically for the signs and symptoms such as swelling, inflammation, pain, pus discharge, mobility, and sinus/fistula and radiographically for periapical radiolucency, intra radicular resorption and internal root resorption. The paralleling technique was used to take radiographs for achieving ideal interpretation. Radiographic success and failure were recorded at 03, 06 and 12 months.

Data were entered and analyzed using SPSS version 17. Descriptive statistics was presented for both qualitative and quantitative variables. Frequency of the efficacy of both groups and percentages for gender was calculated. Mean+S.D was calculated for age. The Chi square test was applied to compare efficacy between groups. Effect modifier like gender and age was controlled by stratification. P-value ≤ 0.05 was considered significant.

RESULTS

A total of 290 patients (145 in each group) were included in this study. Using a lottery method the patients were distributed randomly into two equal groups to controlled the factor of bias; the Formocresol (Group A) and the Mineral Trioxide Aggregate (Group B).

Mean age of the patients was 6.35 ± 0.95 and 6.38 ± 0.98 year in group-A and B, respectively (Table-1). In group-A,

81 patients (55.9%) and in group-B, 75 patients (51.7%) were males while in group-A, 64 patients (44.1%) and in group-B, 70 patients (48.3%) were females (Table-1).

At 03 months, in Group A, 03 cases (2.06%) were reported with failure which includes internal resorption in 02 cases and sinus formation in 01 case while in Group B only 01 case (0.68%) reported failure. Failure was due to intra radicular resorption.

At 06 months, in Group A, 17 cases (7.6%) were reported with failure which includes sinus formation in 07 cases, internal resorption in 04 cases, and pain in 06 cases while in Group B only 05 patients (3.4%) reported failure due to sinus formation.

At 01 year, in Group A, 104 cases (71.7%) displayed success and further failure of 21 cases which includes sinus formation in 09 cases, internal resorption in 06 cases, pain in 04 cases and intra radicular resorption in 02 case making the sum of failure to 41 cases (28.3%). Group B reveal success of 131 cases (90.3%) and additional failure of 08 cases due to sinus formation in 05 case and internal resorption in 03 cases, making the sum of failures to 14(9.7%). Efficacy was observed in 104 patients (71.7%) in group-A and 131 patients (90.3%) in group-B at the end of one year with p value of $p < 0.001$ (Table-2). Stratification with regard to age and gender was carried out and presented in (Table 3).

DISCUSSION

In the present study Mineral Trioxide aggregate (MTA), was used as a pulpotomy medicament and its success was assessed clinically and radiographically. Formocresol was compared with MTA. The current study clearly showed that the use of mineral Trioxide aggregate for vital pulp therapy compared to formocresol is more successful (90.3% success rate in MTA Group-B, as compared to formocresol Group-A, having success rate of 71.7%) with a significant difference between the two materials ($p < 0.001$).

Different clinical and radiographic studies have showed the clinical success rate of 100% of both the groups after 3, 6, and 12 months. However, the radiographic success rate at 06 months for formocresol and Mineral

TABLE 1: DESCRIPTIVE STATISTICS

Age (Year)	Group-A (Formo- cresol)	Group-B (MTA)
	n (%)	n (%)
5-6	81(55.9)	75(51.7)
7-8	64(44.1)	70(48.3)
Mean±SD	6.35±0.95	6.38±0.98
Gender		
Male	81(55.9)	75(51.7)
Female	64(44.1)	70(48.3)

TABLE 2: DISTRIBUTION OF PATIENTS BY EFFICACY

Efficacy	Group-A (Formo- cresol)	Group-B (MTA)	P value
Yes	104(71.7%)	131(90.3%)	<0.001
No	41(28.3%)	14(9.7%)	

* Chi Square test

TABLE 3: STRATIFICATION FOR AGE AND GENDER

Age (Year)	Group	Efficacy		P value
		Yes	No	
5-6	Group-A	58	23	0.021
	Group-B	65	10	
7-8	Group-A	46	18	<0.001
	Group-B	66	04	
Gender	Group A	60	21	0.021
	Group B	66	09	
Female	Group A	44	20	<0.001
	Group B	65	05	

Trioxide Aggregate were 88% and 96% respectively.⁸

Pulpotomy is the treatment option to preserve the primary teeth which saves money and time and as compared to pulpectomy procedure which is more time consuming and may affect the cooperativeness of the child due to the long appointments required for completion, it allows treating the child with minimum discomfort.⁹

Pulpotomy will allow the preservation of the teeth that otherwise would be planned for extraction and it will help in maintaining the arch integrity.^{10,11}

Formocresol has been a popular medicament for pulp therapies for decades and is still considered as gold standard due to its easy handling and less technique sensitivity with excellent clinical success.¹² It has been critically evaluated for its toxic effects on pulp tissue. Concerns have been raised about the toxicity and potential carcinogenicity of formocresol in humans and alternatives have been proposed to maintain partial pulp vitality. These alternatives are laser, glutaraldehyde, enriched collagen solution, ferric sulfate, and electrosurgery. Mineral Trioxide Aggregate (MTA) is formulated to have physical properties and characteristics necessary for an ideal repair and medicament materials.¹³ MTA, with an excellent long term prognosis, excellent physical and chemical properties and is found to be biocompatible with good sealing ability.^{14,15} A reason for higher MTA success may be due to

dentinal bridge formation at the orifice entrance and preserving the vitality of the remaining pulp tissue due to its biocompatibility.¹⁶

Instead of using cotton rolls used for isolation in this study Rubber Dam should have been used to eliminate any discrepancy. Placement of Rubber Dam is time taking procedure and it requires the increase cooperation level of the patients which is difficult in this age group so cotton roll was used as an alternative to Rubber Dam. All the teeth were restored with Glass ionomer as a final restoration. No indirect restoration was placed to strengthen the remaining tooth structure and prevent the micro leakage. Stainless steel crown considered as a gold standard should have been used as final indirect restoration to increase the strength of the remaining tooth structure and reduce the chances of micro leakage.

CONCLUSION

MTA was found clinically and radiographically more successful as a dressing material in vital pulpotomy of primary teeth as compared to formocresol. MTA seems to have potential to replace formocresol in primary teeth.

RECOMMENDATIONS

Mineral Trioxide Aggregate, having superior sealing ability, biocompatibility and a higher success rate should be used as a pulpotomy agent in primary teeth.

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