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EFFICACY OF MINERAL TRIOXIDE AGGREGATE (MTA) AND FERRIC SULFATE (FS) AS PULPOTOMY MEDICAMENTS FOR PRIMARY MOLARS– A RANDOMIZED CONTROLLED TRIAL

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Abstract

Objective: *To Compare the efficacy of Mineral Trioxide Aggregate (MTA) and Ferric Sulfate (Fs) as Pulpotomy Medicaments for Primary Molars*

Study design: *Randomized Controlled Trials*

Place of the study: *Department of Operative Dentistry and endodontics, Nishter Institute of Dentistry, Multan*

Methodology: *A total of 90 Patients were included and were divided into two groups using lottery method. Group-A received FS and Group-B received MTA. All the patients were called at 1, 3 months of post treatment and were further followed up for 6 months postoperatively and will be assessed for efficacy of the treatment. Statistical Package for the Social Sciences (SPSS-26) version was used to analyze that data. Mean and standard deviation was calculated for age. Frequencies and percentages were reported for categorical variables like gender and outcome (efficacy). Chi-square test was applied to compare the outcome between the two groups. P-value ≤ 0.05 will be taken as significant.*

Results: *Mineral trioxide aggregate (MTA) was found to be effective in 45 (100%) cases as compared to FS in 28 (62%) cases with statistically significant difference = 0.000*

Conclusion: *Both FS and MTA had comparable clinical and radiographic performance at one month as pulpotomy medicaments. However, at 6 months, MTA showed higher radiographic and overall success as a pulpotomy medicament in primary molars compared to FS. As a result, MTA can be suggested as an appropriate medication for pulpotomies in primary molars.*

INTRODUCTION

The infectious, communicable condition known as dental caries is brought on by bacteria that generate acid in tooth plaque and destroy teeth. The most crucial thing to keep in mind is that dental caries is a dynamic disease process rather than a fixed issue. Second, the caries infection can actually be reversed before a cavity forms in the tooth.[1]

The ability to evaluate the biologic validity of the various important pulp therapies is made possible by recent advancements in our understanding of the molecular and cellular changes that occur during tooth formation and how these changes are replicated during tissue restoration. Therefore, if the diagnosis is supported by a thorough history, a suitable clinical

and radiographic examination, and the tooth has been sealed with a leak-free restoration, indirect pulp therapy may be a legitimate method for primary teeth with reversible pulp inflammation.[2] It is accepted to directly cap the pulp of carious exposures in young permanent teeth, however it is not recommended for primary teeth.[3]

A form of vital pulp therapy called pulpotomy involves applying an active medication over the remaining vital radicular pulp after the infected coronal pulp is surgically removed at the level of the orifices.[4] Pulpotomy allows the clinician to make an intraoperative diagnosis of the pulp based on the pulp tissue presentation (e.g., necrotic, reversibly inflamed, or irreversibly inflamed) and the ability to achieve hemorrhage control after coronal pulp amputation (e.g., hyperemic, normal). It is recommended for primary teeth diagnosed with reversible pulpitis and for teeth with mechanical pulp exposure during caries excavation.[5] A recent systematic review and meta-analysis estimated that the overall success of pulpotomies is 82.6 percent. However, the properties of the pulpotomy medicament directly affect the success of the procedure.[6]

Ferric sulfate (FS) is a hemostatic substance that has gained popularity for primary molar pulpotomies when used in a solution of 15.5%. It was shown that its total success rate (84.8 percent) was comparable to FC's. It is known that when FS comes into contact with blood, it produces a ferric ion-protein complex that agglutinates into plugs that mechanically occlude the cut blood vessels and achieve hemostasis, however the precise mechanism of action is still up for debate. FS thus causes the residual pulp tissue to be preserved. FS's antibacterial action is similar to that of 0.2 percent chlorhexidine gluconate because of its acidity (pH of 1).[7]

One of the most recent materials to be suggested for primary molar pulpotomies is mineral trioxide aggregate (MTA). It was created in 1993 at Loma Linda University and has numerous applications in dentistry, such as apexification, pulpotomy, direct pulp capping, serving as a barrier during internal whitening of teeth that have had endodontic treatment, and repairing root and furcal perforations.[8] Tri-calcium silicate, tricalcium aluminate, tricalcium oxide, and silicate oxide are all present in the fine hydrophilic particles that make up MTA. For radiopacity, a water-insoluble powder called bismuth oxide is added. MTA's high biocompatibility, superior sealing ability, antibacterial qualities, and capacity to trigger the generation of pro-inflammatory mediators have propelled it to the forefront of dentistry. MTA has shown promising results in recent studies when used as a main molar pulpotomy medication, with high success rates of 92.2%.[9]

In the current literature, there is a lack of clinical trials that evaluate the performance of MTA as a pulpotomy medicament in primary teeth. Furthermore, there is a limited number of high-quality studies that directly compare MTA and FS as pulpotomy medicaments in primary molars; further research is needed to determine the cost-effectiveness balance for both materials. Jamali Zahra conducted a study to compare the efficacy of MTA with FS for the pulpotomy of primary molars. The final study sample consisted of 114 children (56 males, 58 females; aged between 3 and 6 years, mean age =5.14±1.12) and found that overall success rate was 78.9% for FC and 88.1% for MTA group.[10] The purpose of this prospective, randomized, controlled trial is to evaluate and compare the clinical and radiographic performance of MTA and FS as pulpotomy medicaments in primary molars over a period 6 months. The dearth of data on the efficacy of mineral trioxide aggregate (MTA) and ferric sulfate (FS) as pulpotomy medicaments for primary molars especially in developing countries inspired us to conduct this study.

Methodology:

The study was conducted after the permission from ethical review committee of hospital. A total of 90 patients attended the dental clinic of the Department of Operative Dentistry and endodontics, Nishter Institute of Dentistry, Multan fulfilling the following eligibility criteria were included in the current study:

Inclusion Criteria:

- Age between 5-12 years of either gender
- Primary molar tooth with deep caries extending into the inner third of dentin, for which the removal of dental caries is likely to produce a pulp exposure

- Tooth with symptoms of provoked pain of short duration and pain relieved upon removal of stimulus
- Tooth with adjacent healthy soft tissues
- Tooth with no radiographic evidence of furcation/apical pathology
- Parent's/guardian who provided written informed consent

Exclusion Criteria:

- Patients with history of systemic diseases, allergic reactions, and special use of local or systemic drugs were excluded.

After taking written informed consent, demographic data like age and gender of the patient was recorded. Patients were divided into groups using lottery method. Group-A received FS and Group-B received MTA.

All patients underwent form for pulpotomy by an expert dentist having experience of atleast five years. FS was administered into Group-A right after pulpotomy and MTA was administered in Group-B. All the patients were called at 3 months of post treatment and were further followed up for 6 months postoperatively and will be assessed for efficacy of the treatment. Efficacy was deemed as positive by the absence of the following clinical and radiographic signs and symptoms: sinus tract, tenderness to palpation and percussion, spontaneous pain or pain of long duration, swelling, and presence of external or internal root resorption, inter-radicular radiolucency and periapical lesion within six months post-operatively.

Statistical Package for the Social Sciences (SPSS-26) version was used to analyze that data. Mean and standard deviation was calculated for age. Frequencies and percentages were reported for categorical variables like gender and outcome (efficacy). Chi-square test was applied to compare the outcome between the two groups. P-value $\leq$ 0.05 will be taken as significant.

Results:

The mean age of the patients in the study sample was 6.86 years (SD+ 1.28) ranging from 5 to 12 years with more than 90% of the patients were above seven (07) years. In both groups, most the patients were female. No statistically significant difference was observed in terms of baseline data, **as shown in table#1.**

At one month follow-up, 100% clinical success was observed in MTA group and same was observed on the subsequent follow-ups at three month and six month. However, in FS group, 100% success was observed at one month follow-up, 41 (91.1%) success rated at three months and 37 (82.2%) at 6 months. Statistically significant difference was observed at three (03) months, p-value = 0.02 and at six months, p-value = 0.003, **as shown in table#2.**

Similarly, radiographic success was observed in 100% cases treated with MTA at one month, 3 months and then six months follow-up. In FS group, radiographic success was observed in 100% cases at one month, 39 (86.6%) at three months and 28 (62%) at six months. Statistically significant difference was observed at three (03) months, p-value = 0.011 and at six months, p-value = 0.000, **as shown in table#3.** Thus, mineral trioxide aggregate (MTA) was found to be effective in 45 9100%) cases as compared to FS in 28 (62%) cases with statistically significant difference = 0.000, as shown in table#4.

Table#1: Demographic Data of the Patients

Demographic Data	Mineral Trioxide Aggregate	Ferric sulfate	P-value
Age (mean $\pm$ sd)	6.82 $\pm$ 0.34	6.9 $\pm$ 0.9	0.578
Gender • Male • Female	15 (33.3%) 30 (66.7%)	13 (28.8%) 32 (71.1%)	0.648

Table#2: Clinical success of mineral trioxide aggregate (MTA) versus ferric sulfate (FS) as pulpotomy medicaments for primary molars

Groups	Clinical Success					
	At one month		At 3 months		At 6 months	
	Yes	No	Yes	No	Yes	No
Mineral Trioxide Aggregate	45 (100%)	0 (0%)	45 (100%)	0 (0%)	45 (100%)	0 (0%)
Ferric sulfate	45 (100%)	0 (0%)	41 (91.1%)	05 (8.9%)	37 (82.2%)	8 (17.7%)
P-value	NA		0.02		0.003	

Table#3: Radiographic Success of mineral trioxide aggregate (MTA) versus ferric sulfate (FS) as pulpotomy medicaments for primary molars

Groups	Radiographic Success					
	At one month		At 3 months		At 6 months	
	Yes	No	Yes	No	Yes	No
Mineral Trioxide Aggregate	45 (100%)	0 (0%)	45 (100%)	0 (0%)	45 (100%)	0 (0%)
Ferric sulfate	45 (100%)	0 (0%)	39 (86.6%)	06 (13.4%)	28 (62%)	17 (38%)
P-value	NA		0.011		0.000	

Table#4: Efficacy of mineral trioxide aggregate (MTA) versus ferric sulfate (FS) as pulpotomy medicaments for primary molars

Efficacy	Mineral Trioxide Aggregate	Ferric Sulfate	P-value
Yes	45 (100%)	28 (62%)	0.000
No	0 (0%)	17 (38%)	

Discussion:

Pediatric dentists have the difficulty of keeping the pulpally affected primary teeth in the oral cavity until their regular exfoliation. When FC is used as a pulpotomy agent, concerns about its toxicity, mutagenicity, and carcinogenicity have caused anxiety.[11,12] Due to its improved biocompatibility, biological seal, and dentinogenic potential, MTA has emerged as a viable substitute for FC in the ongoing search for a better pulpotomy agent.[13] The purpose of the current study was to assess the effectiveness of MTA and FC in terms of clinical and radiographic results at one, three, and six-month follow-up.

The present study showed 100% clinical and radiographic success in 6 months **as pulpotomy medicaments for primary molars.** Similar to the results of the present study, Alsanouni and Bawazir found that NeoMTA Plus® had 100 percent clinical success and 97.5 percent radiographic success in 12 months and recommended it as a primary molar pulpotomy medicament.[9]

Only four randomized controlled studies with samples ranging from 15 to 51 participants per group were suitable for evaluation in Asgary et al.'s systematic review and metaanalysis, which sought to compare the success rates of MTA versus FS pulpotomy in primary molars. While the results of both materials were comparable in one year, the authors discovered that MTA outperformed FS in two years with a statistically significant difference.[14]

In the study, all pulpotomies were completed by PD postgraduate students (residents). While the operators were trained and followed a procedure guide, they had limited PD experience, which is subject to potential diagnostic and procedural errors. However, they were supervised by experienced PD faculty. Nevertheless, the complete success of the MTA group is an indication that MTA may be considered the preferred pulpotomy medicament for novice practitioners. The findings of this study were within the range of FS outcomes reported in the literature.[15-17] Odabas et al.28 examined a sample of pulpotomies performed by dental students and found that, after a year, the FS group had 78.2 percent radiographic success and 84.7 percent clinical success.

In the present study, the sample was relatively small and less follow-up, although it was within the range of the sample sizes of similar trials.27 This clinical setting serves children primarily from lower socioeconomic backgrounds and from ethnic minorities, who often seek dental care based on necessity and have inconsistent recall attendance. This is an example of the inherent challenges of conducting clinical trials in institutional settings. Therefore, this study was conducted on small sample with less follow-up.

Conclusion:

Both FS and MTA had a similar clinical and radiographic performance at one months as pulpotomy medicaments. However, at 6 months, MTA showed superior radiographic and overall success as a pulpotomy medicament in primary molars compared to FS. Thus, MTA can be recommended as a suitable medicament for pulpotomies in primary molars.

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