International Journal of Research and Development in Pharmacy and Life Sciences
Available online at http//www.ijrdpl.com
April - May, 2016, Vol. 5, No.3, pp 2107-2116
ISSN (P): 2393-932X, ISSN (E): 2278-0238

Research Article

CLINICAL EFFICACY OF VARIOUS MEDICAMENTS USED FOR PULPOTOMY IN PRIMARY MOLARS – A COMPARATIVE STUDY

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(Received: January 30, 2016; **Accepted:** March 25, 2016**)**

ABSTRACT

Background and objectives: Retention of pulpally involved primary teeth in a healthy state until the time of exfoliation remains to be one of the challenges for pedodontist. The aim of this study was to evaluate and compare the efficacy of Ferric sulphate, glutaraldehyde and Mineral trioxide aggregate as pulpotomy medicaments in primary molars.

Method: A total of forty–five primary molars from thirty two children aged 4-8 years were selected for pulpotomy procedure. Teeth were randomly divided into three equal groups of fifteen teeth in each group. Patients in different groups were intended to be treated with different pulpotomy agents. All the molars were evaluated clinically and radio graphically at regular intervals of 24 hrs, 1, 3 and 6 months.

Results: The observations were statistically analyzed using Chi-square test. MTA exhibited overall best results as pulpotomy agent for primary molars followed by 15.5% Ferric sulphate, whereas 2% buffered glutaraldehyde showed least favourable results both clinically and radio graphically.

Conclusion: All the materials showed varying degrees of success clinically and radio graphically, however further larger sample size and longer observational period should be carried out to reach sound conclusions.

Keywords: Primary molars, Pulpotomy, Ferric sulphate, glutaraldehyde, Mineral trioxide aggregate, clinical, radiographical.

INTRODUCTION

Natural primary teeth are considered as best space maintainers; hence every effort should be directed to preserve these teeth as far as possible. Dental caries still, is the most widespread dental disease seen in children (Ruth Holt et al, 2000) and has been the main threat to the overall integrity of primary dentition[1]. The mere extractions of these carious teeth result in many complications, such as difficulty in chewing, loss of normal occlusion and inappropriate arch space[2]. Hence the restoration and maintenance of carious primary teeth is one of the most important goals in pediatric dentistry. They should be restored such that they are in a functional state until their normal exfoliation. Depending on the extent of inflammation and involvement of pulp, various kinds of pulpal therapies are indicated, that is, pulp capping, indirect pulp therapy, pulpotomy or pulpectomy. If a tooth

with a carious lesion remains untreated or, is inadequately treated, a bacterial invasion of the coronal pulp will occur originating an inflammatory response at that level. At this stage the inflammation is confined to the coronal space, but if the affected tissue is removed and the entrance to the root canals is covered with an appropriate agent, the remaining tissue is capable of recovering (Pallares et al, 2010)[3]. Therefore, removal of coronal pulp is an accepted procedure for treating primary and permanent teeth (McDonalds & Avery, 2004)[4].

According to AAPD guidelines 2009 Pulpotomy is performed in a primary tooth with extensive caries but without evidence of radicular pathology when caries removal results in a carious or mechanical pulp exposure[5]. It is a conservative therapy performed to remove the inflamed coronal pulp tissues followed by application of an effective and compatible bactericidal medicament which encourages the tissue in the root canals to remain vital[6]. Pulpotomy procedure can be categorised according to different treatment approaches for example –devitalization using formocresol and electro surgery, where the intent is to destroy the radicular pulp; preservation where the remaining radicular pulp is preserved with the use of glutaraldehyde and ferric sulphate and regeneration of the radicular pulp by stimulation of a dentinal bridge with the use of calcium hydroxide, Mineral trioxide aggregate and bone morphogenetic protein[7].

Formocresol had been a popular pulpotomy medicament based on the principle of devitalization for the past 60 years and was considered as the gold standard in performing vital pulpotomy for primary teeth (Eidelman et al, 2001)[8]. However, in spite of years of success of its use, concerns had been raised about its potential toxicity, mutagenicity and carcinogenicity in humans (Agamy et al, 2004)[9]. In June 2004 the International Agency for Research on Cancer (IARC) of the World Health Organisation classified formaldehyde as a known human carcinogen[10]. In order to avoid these harmful effects of formocresol, alternative agents for vital pulpotomy procedures are being sought like glutaraldehyde, ferric sulphate, bioactive glass, hydroxyapatite, freeze dried bone, laser, electrosurgery, bone morphogenic protein, recombinant protein-1, and mineral trioxide aggregate.

A possible substitute for formocresol is Glutaraldehyde which has been advocated because of its better fixative property and a superior cross linking ability (Prakash C et al, 1989)[11] besides being less volatile causing less apical penetration with less dystrophic pulp calcification and more initial chemical activity than formocresol.

Ferric sulphate, a non-aldehyde chemical has received considerable attention as pulpotomy agent due to its haemostatic action. It seems that agglutination of blood proteins results from the reaction of blood with ferric and sulphate ions with the acidic pH of the solution. The agglutinated proteins form plugs that occlude the capillary orifices (Lemon et al, 1993)[12].

Mineral trioxide aggregate (MTA) a relatively newer material has been introduced to dentistry in 1995 by Torabinejad who had suggested it for endodontic root filling. It is composed of tricalcium silicate, tricalcium aluminate, tricalcium oxide and silicate oxide. It also contains oxides of iron, magnesium and bismuth which is added for radiopacity purpose (Lewis, Salako et al, 2003)[13]. It is biocompatible, has high sealing ability, ability to form dentinal bridge and can cause regeneration of cementum and periodontal ligament. It also has the ability to stimulate cytokine release from bone cells, so it has the capacity to actively promote hard tissue formation (Eidelman et al, 2001). Recently, its use is extended to pulpotomy in primary teeth[14].

Retention of pulpally involved primary teeth in a healthy state until the time of exfoliation remains to be one of the challenges for pedodontist. Though there's availability of various medicaments which can be used for pulpotomy, concerns have been raised about their toxicity and carcinogenicity and alternatives have been proposed to maintain pulp vitality. However, due to lack of comparative studies regarding the efficacy of various pulpotomy medicaments, the present study was undertaken to compare and evaluate the efficacy of ferric sulphate, glutaraldehyde and MTA as pulpotomy medicaments in primary molars.

MATERIALS AND METHODS

Before the start of the study ethical approvals were sought from the parents of the patients and institutional review board of D.A.V(C) Dental College, Yamuna Nagar for conducting the study.

Table 1: Various pulpotomy medicaments used in the study.

S.NO	Pulpotomy agent	Trade name	Manufactures
1.	Ferric sulphate	(Astringedent®)	(Ultradent Products Inc., Salt Lake City, UT, USA)
2.	2% Buffered Glutaraldehyde	Glutaraldehyde solution 25% LR	(SDFCL sd fine-chem limited, Mumbai)
3.	Mineral trioxide aggregate	MTA angelus	Angelus Industria de produtos Odontologicos S/A

Table 2: Distribution of patients in different groups at various recall intervals

	Group I		Group II		Group III	
Time interval	**No. Of patients reported**	**Drop-outs**	**No. Of patients reported**	**Drop-outs**	**No. Of patients reported**	**Drop-outs**
Baseline	15	0	15	0	15	0
After 24 hrs	15	0	15	0	15	0
After 1month	15	0	15	0	15	0
After 3 months	15	0	8	7	14	1
After 6 months	11	4	7	8	11	4

At 24-hr post-operative interval, none of the groups had presence of any clinical or radiological finding.

SELECTION OF THE PATIENTS

Children in the age group of 4-8 years visiting the Out Patient Clinics in the Department of Paedodontics and Preventive Dentistry at D.A.V. (C) Dental College, Yamuna Nagar with a chief complaint of one or more decayed teeth were screened according to the predetermined inclusion & exclusion criteria. Only those Primary molars that exhibited symptomless exposure of vital pulp with no symptoms or signs [clinical and radiological] of pulpal degeneration or periapical / radicular involvement were selected for the study. Patients with any signs of internal or external resorption were also excluded from the study. Before the start of procedure, the detailed clinical procedure, usage of the different materials, the possible discomfort, risks and benefits of the study were explained to the parents of children and their informed consent was obtained before their final recruitment for the study.

RANDOMIZATION AND DIVISION OF SAMPLES:

The selected patients were randomly divided into 3 equal groups having 15 samples in each group. Patients in different groups were intended to be treated with different pulpotomy agents, that is Ferric sulphate (Astringedent®), 2% Buffered Glutaraldehyde (Glutaraldehyde solution 25% LR) and Mineral trioxide aggregate (MTA angelus)

Before the start of the clinical procedure the patients were assessed using different clinical and radiological parameters which were also used for future post operative evaluations. The absence /presence of all the clinical and radiological signs were recorded. Clinical parameters included Pain, Sinus formation, swelling (Intra Oral) and mobility while the radiological parameters included periodontal ligament widening, internal resorption, external resorption, periapical radiolucency, canal obliteration and furcation radiolucency. The presence of each sign was recorded as a digital score of 1 and the absence was recorded as a digital score of "2".

CLINICAL PROCEDURE

Pulpotomy procedure was performed for the selected patients in the following sequence:

- The tooth was anesthetized.
- Rubber dam isolation was carried out.
- Caries was removed and coronal access was obtained with high speed bur with water spray to expose the pulp chamber.

a. Removal of the coronal pulp was carried out with a spoon excavator.
b. Haemostasis was obtained (a moistened cotton pellet was gently pressed against the amputated pulp stumps in all the groups)

Group I (Ferric Sulphate) - A cotton pellet moistened with 15.5% Astringedent ferric sulphate (Ultradent, USA) was placed in contact with the radicular pulp for 15 seconds. After irrigation with normal saline and observation of haemostasis, Zinc Oxide eugenol paste was applied on the pulp tissue[15].

Group II (2% Buffered Glutaraldehyde) - After coronal pulp amputation, a dry cotton pellet moistened in 2% buffered glutaraldehyde solution was placed on amputated pulp stumps for 5 min. Cotton pellet was removed and zinc oxide eugenol paste was placed over the pulp stumps[16].

Group III (Mineral Trioxide Aggregate) - Sterile cotton pellets moistened with normal saline were placed on to the pulp canal orifices under a light pressure in order to obtain haemostasis. These pellets were then removed and pulp stumps were covered with a thin layer of MTA paste, which was prepared by mixing MTA powder with sterile saline at a 3:1 powder/saline ratio to obtain a thick, creamy consistency. The MTA base was placed on the floor of the pulp chamber and condensed against the pulp orifices with a moist cotton pellet. The cavity was then filled with zinc oxide eugenol[17].

Following pulpotomy all the teeth were restored with stainless steel crown/ light cure glass ionomer cement after 24 hours. Children were recalled post operatively after 24 hours, 1month, 3 months and 6 months respectively for clinical and radio graphical evaluation. The data was collected and subjected to statistical analysis

RESULTS

Statistical analysis was carried out by Chi- square test using SPSS Version 15.0 statistical Analysis Software. After 3 months, 8 samples were lost to follow up. This number increased to a total of 16 after 6 months.

DISCUSSION

Pulpotomy is one of the most frequently used treatments for retaining cariously involved primary molars that would otherwise be extracted. Its objective is to preserve radicular pulp, avoid pain, inflammation and maintain the tooth (AAPD, 2004)[18].

Patients treated with Mineral trioxide aggregate showed 100% clinical success. These findings were in accordance with various studies conducted by Agamy et al 2004[8], Naik and Hegde 2005[19], Holan et al 2005[20].

Table: Post-operative Evaluation at 1 month showing number of patients with positive findings along with significance tests in the frequency of patients.

S.N	Parameter	Group I (n=15)		Group II (n=15)		Group III (n=15)		Significance of difference	
		No.	%	No.	%	No.	%	¡²	p
Clinical Parameters									
1.	Pain	0	0	0	0	0	0	–	–
2.	Sinus Formation	0	0	0	0	0	0	–	–
3.	Swelling	0	0	0	0	0	0	–	–
4	Mobility	0	0	0	0	0	0	–	–
Radiological Parameters									
1.	PDL widening	8[c]	53.3	4	26.7	0[a]	0	10.909	0.004
2.	Internal resorption	4	26.7	0	0	0	0	8.780	0.012
3.	External resorption	0	0	0	0	0	0	–	–
4.	Periapical radiolucency	0	0	0	0	0	0	–	–
5	Canal obliteration	0	0	1	6.7	0	0	2.045	0.360
6	Furcation radiolucency	7[c]	46.7	3	20.0	0[a]	0	9.514	0.009

Table: Post-operative Evaluation at 3 months showing number of patients with positive findings along with significance tests in the frequency of patients.

S. No.	Parameter	Group I (n=15)		Group II (n=8)		Group III (n=14)		Significance of difference	
		No.	%	No.	%	No.	%	¡²	p
Clinical Parameters									
1.	Pain	0	0	0	0	0	0	–	–
2.	Sinus Formation	0	0	0	0	0	0	–	–
3.	Swelling	0	0	0	0	0	0	–	–
4.	Mobility	2	13.3	1	12.5	0	0	1.992	0.369
Radiological Parameters									
1.	PDL widening	11[c]	73.3	5[c]	62.5	0[a,b]	0	17.409	<0.001
2.	Internal resorption	6[c]	60.0	1	12.5	0[a]	0	7.927	0.020
3.	External resorption	3	20.0	1	12.5	0	0	3.034	0.219
4.	Periapical radiolucency	2	13.3	1	12.5	0	0	1.992	0.369
5.	Canal obliteration	0	0	1	12.5	0	0	3.726	0.155
6.	Furcation radiolucency	10[c]	66.7	5[c]	62.5	0[a,b]	0	15.393	<0.001

Table: Post-operative Evaluation at 6 months showing number of patients with positive findings along with significance tests in the frequency of patients.

S.N	Parameter	Group I (n=11)		Group II (n=7)		Group III (n=11)		Significance of difference	
		No.	%	No.	%	No.	%	¡²	p
Clinical Parameters									
1.	Pain	1[b]	9.1	4[a,c]	57.1	0[b]	0.0	10.615	0.001
2.	Sinus Formation	1	9.1	3[c]	42.9	0[b]	0	6.937	0.031
3.	Swelling	0	0	0	0	0	0	–	–
4.	Mobility	3	27.3	4[c]	57.1	0[b]	0	7.723	0.021
Radiological Parameters									
1.	PDL widening	7	66.7	6[c]	85.7	0[b]	0	15.242	<0.001
2.	Internal resorption	6	54.5	1	14.3	0[a]	0	9.425	0.009
3.	External resorption	3	27.3	4[c]	57.1	0[b]	0	7.723	0.021
4.	Periapical radiolucency	2	18.2	3[c]	42.9	0[c]	0	5.518	0.063
5.	Canal obliteration	0	0	2	28.6	0	0	6.751	0.034
6.	Furcation radiolucency	8[a]	72.7	7[c]	100	0[a,c]	0	20.262	<0.001

a=Significant as compared to Group I,

b=Significant as compared to Group II,

c=Significant as compared to Group III (Fisher exact test)

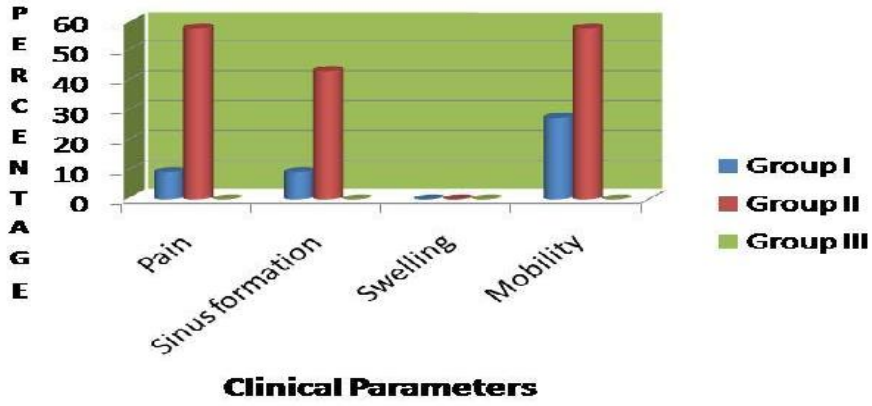

Figure1 - Intergroup comparison for various clinical parameters at 6 months recall visit

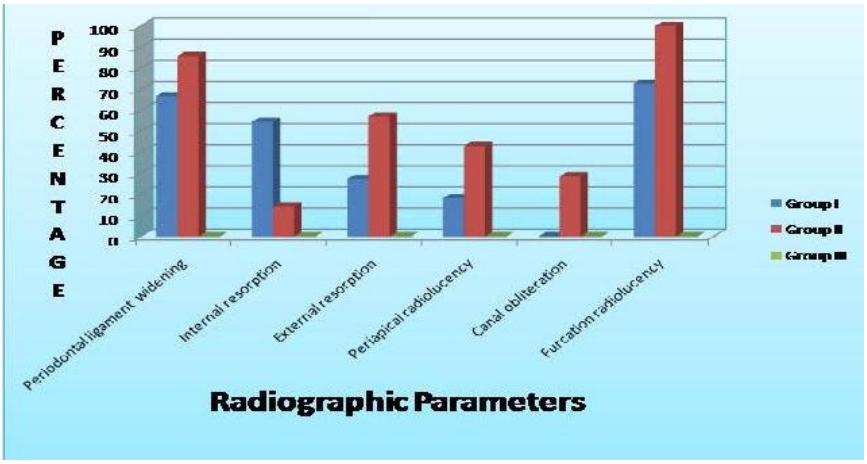

Figure 2 - Intergroup comparison for various radiological parameters at 6 months recall visit

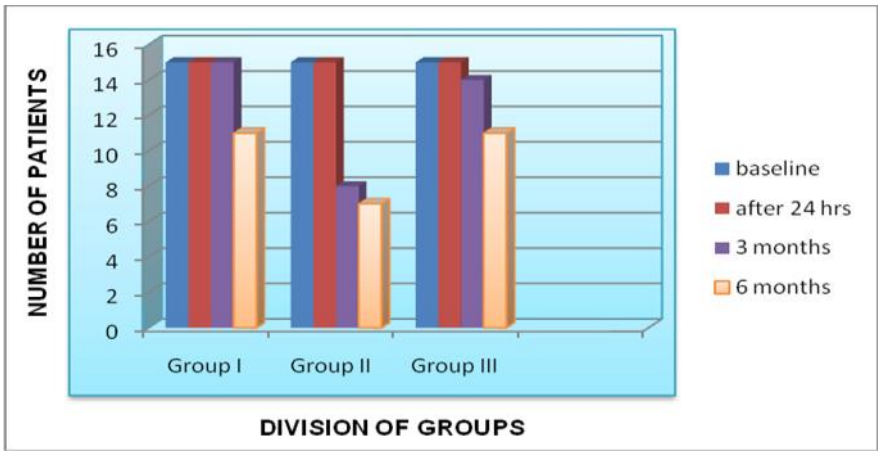

Figure 3 - Intergroup comparison of number of patients who reported for the study at various recall intervals

57.1%patients treated with glutaraldehyde, whereas only 9.1% patients treated with ferric sulphate reported with pain after 6 months. This could be due to the clinical errors in diagnosis and selection of primary teeth or due to iatrogenic factors or could be due to exacerbation of the inflammation following treatment. Similar findings were also seen in a study by Gisoure Elham et al, 2010.

Mineral trioxide aggregate patients did not show any sinus formation which could be due its antibacterial properties. Similar findings were observed in various other studies (Naik et al, Farsi et al) [19, 21]. Sinus formation was seen in only 9.1% cases of ferric sulphate, which could be due to slow progress of inflammation in the radicular pulp that might have been misdiagnosed as inflammation not limited to coronal pulp only. This finding was in contradiction to the study by Huth et al 2005[22], Casas et al 2004[23]. Whereas, sinus formation seen in 42.9% cases of 2% buffered Glutaraldehyde were similar to the findings of Garcia- Godoy et al 1987[24].

Absence of swelling on postoperative evaluations at all recall intervals in all groups is a clear parameter of success, proper case selection and maintenance of complete intra operative aseptic conditions achieving the proper hermetic seal. Our findings were consistent with the results of other studies conducted by Huth et al, 2005, Ranly et al 1987, Farsi et al 2005.

Tooth mobility was not seen observed in patients treated with Mineral trioxide aggregate, whereas only 27.3% patients treated with ferric sulphate and 57.1% treated with glutaraldehyde showed tooth mobility at 6 months interval. This could be due to widening of periodontal ligament space. Mobility was also seen in a study conducted by Smith et al, 2000[25] using 15.5% Ferric sulphate which could be due to long follow up periods.

Mineral trioxide aggregate did not showed periodontal ligament widening due to its stimulatory effect on the biosynthetic activity of peri radicular cells resulting in stimulation of fibroblasts to lay down a fibrous connective tissue and rapid growth of periodontal ligament due to its high healing capacity. This was in accordance with a study conducted by Torabinejad M et al 1997[26]. Widening of periodontal ligament observed in 66.7% patients treated with ferric sulphate and 85.7%patients treated with glutaraldehyde after 6 months. This could be attributed to occlusal trauma or lack of bone support arising from advanced bone loss. Our findings were consistent with the study conducted by Casas et al 2004[23] using 15.5% ferric sulphate & Garcia-Godoy 1987[24] using 2% Buffered Glutaraldehyde in which most common pathologic finding was periodontal ligament widening.

Histologically, occurrence of internal root resorption after pulpal treatment has been attributed to inflammation of the residual pulp (Magnusson 1970)[27]. It is preceded by chronic pulpal inflammation, disappearance of odontoblasts & predentin and pulpal invasion by macrophage-like resorbing cells (Pindborg 1970, Wedenberg & Lindskoj, 1985). In the current study Mineral trioxide aggregate treated teeth did not showed internal resorption because it was placed directly over the pulp stumps and then a layer of zinc oxide eugenol was placed over it. Similar findings were observed in a study conducted by Mortazavi et al, 2009. Internal resorption in case of Ferric sulphate pulpotomy (54.5%) could be due to the haemostasis produced at the amputated pulp stumps which might leave the vital pulp tissue in contact with Zinc oxide eugenol. Further the irritating properties of eugenol have been shown to result in internal resorption (Casas et al, 2004)[23]. Similar findings were seen in a study conducted by Fuks et al, 1997[28] using ferric sulphate and Ranly et al, 1987[29] using 2% Glutaraldehyde. Internal resorption in case of glutaraldehyde (14.3%) could be due to inadequate fixation which leaves a deficient barrier to sub base irritation, resulting in internal resorption. Teeth with internal resorption were not treated, but left for further follow-up observation, because they were asymptomatic and did not show any sign of clinical failure (Farsi et al, 2005)[21].

External resorption was observed in 27.3% patients treated with ferric sulphate and 57.1% patients treated with glutaraldehyde. This was also a common finding in a study conducted by Somnez et al, 2008[27] using ferric sulphate and Mineral trioxide aggregate and Garcia-Godoy, 1987[24] using 2% Glutaraldehyde. This could be attributed to periapical inflammatory lesion which resulted in the loss of lamina dura around the apex. In our study MTA did not showed any such findings, which could be attributed to its regeneration potential when placed in contact with the dental pulp or periradicular tissues.

Periapical radiolucency observed in cases of ferric sulphate (18.2%) and glutaraldehyde (42.9%) could be attributed to the release of bacteria and their toxins via the apical foramina (R Caicedo et al) [30]. It was also a common finding in studies conducted by Huth et al, 2005[22], Garcia-Godoy, 1987[29]. In our study, Mineral trioxide aggregate did not showed periapical radiolucency, which could be due to its biocompatibility and the resistance to bacterial penetration in the periapical areas. These findings were in accordance with a study conducted by R Caicedo et al, 2006[30].

Canal obliteration was observed in 28.6% patients treated with glutaraldehyde after 6 months. These findings were consistent with study conducted by Tsai TP et al, 1993[31]. Willard (1976) explained that the calcification was a result of odontoblastic activity following treatment and that the pulp retained some degree of vitality and therefore, was not regarded as failure (Farsi et al, 2005)[21]. Fuks et al (1997)[28] observed that teeth treated with ferric sulphate showed pulp canal obliteration. But we did not come across any such finding in our study. Pulp canal obliteration was a common finding in Mineral trioxide aggregate group in some of the previous studies conducted by Eidelman 2001[12], Holan et al. 2005[20], Maroto et al 2005[32]. But in the present study we did not come across any such findings.

Furcation radiolucency was observed in 72.7% patients treated with ferric sulphate and 100% patients treated with glutaraldehyde. These findings were consistent with other studies conducted by Fei et al, 1991[33] using formocresol & ferric sulphate, Garcia-Godoy, 198729 using 2% glutaraldehyde as pulpotomy agents. It could be attributed to the diffusion of bacteria and their toxins through the accessory canals providing a pathway of communication from the floor of the pulp chamber to the furcation area. In our study MTA did not show any signs of furcation radiolucency which could be explained on the basis of hard tissue bridge formation due to its high sealing ability, biocompatibility, alkalinity and superior seal against bacteria.

The success rate of Mineral trioxide aggregate group in this study has been promising with all 15 teeth being clinically and radio graphically successful. A similar 100% success rate was seen in study by Maroto et al (2007)[34] using White MTA as pulpotomy medicament in primary molar teeth after 6 months follow up period. So to summarize, Mineral trioxide aggregate was found to be a more successful medicament for cariously exposed primary molar as compared to 15.5% Ferric sulphate and 2% Buffered Glutaraldehyde.

CONCLUSION

Following conclusions were drawn from the study:

All the materials exhibited varying degrees of success when evaluated for various clinical / radiological parameters.

Clinical parameters

1. Maximum amount of Pain and sinus formation was observed in patients treated with Glutaraldehyde followed by Ferric sulphate, while no patient treated with MTA reported with pain. The difference was found to be statistically significant ($p < 0.05$).
2. Maximum mobility was observed in patients treated with Ferric sulphate and Glutaraldehyde but the results were found to be non-significant statistically ($p > 0.05$).
3. Radiological parameters.
4. Higher incidence of periodontal ligament widening was seen in patients treated with both Ferric sulphate and glutaraldehyde, and the results were found to be significant ($p < 0.05$) when compared to MTA.
5. Maximum Internal resorption was observed in patients treated with Ferric sulphate followed by Glutaraldehyde, while maximum External resorption was seen in patients treated with Glutaraldehyde followed by Ferric sulphate. While no patient treated with MTA showed any signs of internal and external resorption.
6. Pulp canal obliteration was only observed in patients treated with Glutaraldehyde.
7. Furcation radiolucency was observed in majority of the patients treated with Ferric sulphate and glutaraldehyde while no patient treated with MTA exhibited furcation radiolucency and the differences were found to be significant ($p < 0.001$).

At the end of the study, it was observed that group III (MTA) exhibited overall best results as pulpotomy agent for primary molars followed by 15.5% Ferric sulphate. Whereas, 2% buffered glutaraldehyde showed least favourable results both clinically and radio graphically. However further larger sample size and longer observational period should be carried out to reach sound conclusion.

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