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RESEARCH ARTICLE

CLINICAL AND RADIOGRAPHIC EVALUATION OF MODIFIED 3 MIX PLUS DEXAMETHASONE PASTE AND METAPEX IN PULPALLY INVOLVED PRIMARY MOLARS- AN IN VIVO STUDY

[1,*]Patel Chetanaben B., [2]Choudhari Shantanu R., [3]Goyal Swati, [4]Waghela Sweta A. and [5]Patel Bhargavi, S.

[1]Post-graduate student, Department of Pediatrics and Preventive Dentistry, Government Dental college and hospital Ahmedabad.
[2]Professor and Head, Department of Pediatric and Preventive Dentistry, Government Dental college and hospital Ahmedabad
[3]Assistant Professor, Department of Pediatric and preventive Dentistry, Government Dental college and hospital Ahmedabad
[4]Post-graduate student, Department of Pediatrics and Preventive Dentistry, Government Dental college and hospital Ahmedabad
[5]Post-graduate student, Department of Pediatrics and Preventive Dentistry, Government Dental college and hospital Ahmedabad

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ABSTRACT

Aims: To assess and co-relate the healing efficiency of Modified 3 mix plus Dexamethasone combination paste and metapex in pulpally involved primary molars. **Methods and Material:** This study comprised of 60 Primary mandibular molars, which were divided randomly into Group A and Group B, Each treated case was recalled for Clinical and radiographic evaluation at one week, one month and six month interval. **Group A:** All accessible coronal and radicular pulp was removed, followed by medicational cavity preparation and Modified 3 mix plus Dexamethasone placement in meditational cavity and sealed it in single sitting. **Group B:** Conventional single sitting pulpectomy was performed using metapex as an obturating material. Stainless steel crown cementation was done on the same visit and used as final restoration in both groups. Results: Among 60 molars, Postoperative follow up of clinical examinations at one, and six months was 93.3% and 90% in group A and while in group B was 100%, and 96.7%,so, there was no statistically significant difference in results between Group A and Group B at any follow up, as demonstrated by fisher exact test. (p value=1 at 1 week , p value=0.52 at 1 month and p value=0.35 at 6 months). **Conclusions:** Modified 3 mix plus Dexamethasone in primary teeth has shown good clinical and radiographic success which is comparable to conventional pulpectomy treatment.

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INTRODUCTION

The primary aim of pediatric endodontics is to remove all bacterial infection by endodontic instrumentation and to obturate the root canals with a filling material which will resorb at the same rate as the primary tooth and should be eliminated rapidly, if accidentally extruded through the apex. (AAPD Guidelines on pulp therapy for primary and young permanent teeth 2006–07) Biologic approach of lesion sterilization and tissue repair therapy (LSTR) were introduced at the Cariology Research unit of the School of Dentistry, Niigata University, Niigata, Niigata Prefecture, Japan in 1990 for treatment of carious lesions with pulpal and periapical involvement using a mixture of three broad spectrum antibiotics, namely, metronidazole, ciprofloxacin, and minocycline (3Mix) (Hoshino, 1996). The rationale of LSTR is that mixture of three antibiotics (3Mix) can sterilize necrotic pulps, and infected root dentine of primary teeth, If lesions are completely disinfected, tissue repair can be expected (Trairatvorakul, 2012) Minocycline can cause pigmentation, especially in calcifying teeth. So, here in study minocycline was replaced by cefaclor (Pinky, 2011). Inflammation related to endodontic lesions is dependent on the damage sustained by the tissues and the nature of the damaging agent. It has been suggested that antibiotics must be given in conjunction with steroids to reduce inflammation and prevent

Corresponding author: **Patel Chetanaben, B.,**
Post-graduate student, Department of Pediatrics and Preventive Dentistry, Government Dental college and hospital Ahmedabad.

pulpal tissue destruction by inflammatory reaction (Maged, 2001). So, in present study it was intended to compare the efficacy of Modified 3 mix plus Dexamethasone paste and Single sitting Pulpectomy using Metapex as an obturating material for primary teeth with two different techniques.

MATERIAL AND METHODS

The study consisted of patients in the age group of 5 to 9 years in which ethical approval from the Institutional Ethical Committee and consent from the Parents/Guardians was obtained. The criteria for selection of teeth include mandibular first and second primary molars showing signs and symptoms indicating pulpectomy: (a) Spontaneous pain or tenderness on percussion, (b) Deep carious with pulp exposure, (c) Uncontrolled hemorrhage after removal of coronal pulp tissue, (d) Presence of chronic apical abscess or sinus tract (e) and radiographic characteristics: (A) Coronal radiographic evidence of a deep carious lesion involving pulp. (B) Radicular– (i) discontinuity of lamina dura (ii) Furcation involvement less than or equal to half of shortest root in vertical dimension. The teeth were excluded when non restorable or presented with physiologic root resorption more than a third of its length. Patients with any systemic illness or with previous history of allergy to the antibiotics used in the study were also excluded. Clinical and radiographic information before treatment was recorded. The enrolment of teeth to either group was done randomly by envelope draw method. All treatments were performed by single operator.

Group A: All accessible coronal and radicular pulp was removed, followed by medicational cavity preparation and Modified 3 mix plus Dexamethasone placement in meditational cavity and sealed it with glass ionomer cement in single visit.

Group B: Conventional single sitting pulpectomy was performed using metapex as an obturating material.

Clinical procedure: Preparation of Modified 3 mix plus Dexamethasone paste**:** The chemotherapeutic agents used were Metronidazole tablets 400mg (Metronidazole tablets IP 400mg, LA-Chemico Private Ltd), Ciprofloxacin tablets 500mg (Floxip, pharma healthcare Ltd), Cefaclor tablets 250mg (Distaclor^{TM} DT, Baroque pharmaceuticals, India) Dexamethasone 0.5mg (Dexona, zydus health care Ltd). After the removal of enteric coating of tablets with the help of B.P blade, the drugs are pulverized one by one into fine powder using sterilized mortar pestle. Antibiotic paste was freshly prepared for each use before or during treatment. The ratio of the mixture was Metronidazole: Cefaclor: Ciprofloxacin=1: 1: 1 then it mixed with 0.5 mg dexamethasone. Every time we used the fresh tablets from the packets and discarded remained powder. One part of Propylene glycol (P) and the same volume of Macrogol (M) were mixed to make MP. For standard preparation, MP and Dexamethasone plus Modified 3 mix paste were mixed.

Group A: Adequate anesthesia achieved using nerve block or local infiltration for selected tooth as per the age of patient and Rubber dam was placed; Access to the pulp chamber was gained with a round bur and straight fissure bur followed by medicational cavity preparation on root canal orifices using no. 2 round carbide bur (Figure: 1), after preparation of Medicational cavity pulp chamber was cleaned using EDTA and normal saline;Freshly prepared pastewas placed into Medicational cavity (Figure 2). After the placement of prepared paste, the cavity was filled with GIC restoration. Stainless steel crown was given on same visit as a final restoration.

Group B: Adequate anesthesia was achieved using nerve block or local infiltration for selected tooth as per the age of patient and rubber dam was placed. Access to the pulp chamber was gained with a round bur and straight fissure bur followed by working length determination using endodontic hand file. Root canal prepared and obturation done using metapex. Stainless steel crown was given as final restoration.

Criteria for clinical and radiographic scoring: Clinical and radiographic evaluation was done at one week, one month and six month according to criteria laid down by Guttmann JL.[6] clinical and radiographic evaluations were carried out by coinvestigator.

RESULTS

Postoperative, follow up of Clinical examinations at one week, one month, and six months are shown in Tables 1. Postoperative Radiographic follow-up at one week one month and six months are shown in Tables 2. Table 1 shows that at one week Clinical success is 96.7% in Group A(Case) and while it is 100% in Group B(Control). At one month success results of Group A was 93.3% and Group B is similar as one week while at six months success in Group A is 90% while in Group B in it remains higher 96.7% . However, there was no statistically significant difference in results between Group A and Group B at any follow up, as demonstrated by fisher's exact test. (p value=1 at 1 week , p value=0.52 at 1 month and p value=0.35 at 6 months).

Table 2 shows that at one week Radiographic success is 100% in both Group A and Group B. Statistical test demonstrate no significant difference in results of Group A and Group B (p value=1) At one month. 86.7% success is achieved in Group A while it was higher in Group B i.e. 96.7 and at six months again success in Group B remains higher (96.7%) as compared to Group A. How ever there is no statistically significant difference in results in Group A and Group B at 1 month and 6 month (P value=0.48 and 0.35 respectively)

DISCUSSION

The therapeutic goals of pulpectomy are to reduce or eliminate the microbial population and their products, thus obtaining a clean and healthy pulp canal and ensure hermetic seal of the root canals (Aminabadi, 2016). Long term successful outcome of conventional pulpectomy procedure in necrotic or abscessed primary teeth has been reported in literature upto 85%, which is still lesser as compared to substantially higher success percentage in permanent teeth. This may be due to several reasons (Lúcia de Fátima Almeida de Deus Moura, 2016). It is found that even after thorough mechanical and chemical cleaning of the canals in primary teeth, upto 40% of the canals may still exhibit positive bacterial cultures (Doneria, 2017). Which may be due to anatomic complications like curved and torturous shape of root canals and vicinity to permanent tooth buds make the treatment difficult.

Table 1. Comparison of clinical results between Group A and Group B

Follow up time	Treatment results	Group A (N=30)		Group B (N=30)		Fisher's exact test
		No.	%	No.	%	
At 1 week	Successful	29	96.7	30	100	P value=1
	Unsuccessful	01	03.3	00	00	
At 1 month	Successful	28	93.3	30	100	P value=0.52
	Unsuccessful	02	06.7	00	00	
At 6 months	Successful	27	90	29	96.7	P value=0.35
	Unsuccessful	03	10	01	3.33	

Table 2. Comparison of radiographic results between Group A and Group B

Follow up time	Radiographic results	Group A (N=30)		Group B (N=30)		Fisher's exact test (between successful and unsuccessful)
		No.	%	No.	%	
At 1 week	Successful	30	100	30	100	P value=1
	Unsuccessful	00	00	00	00	
At 1 month	Successful	26	86.7	29	96.7	
	Unsuccessful	03	10	00	00	P value=0.48
	Questionable	01	03.3	01	03.3	
At 6 months	Successful	26	86.7	29	96.7	
	Unsuccessful	04	13.3	01	03.3	P value=0.35

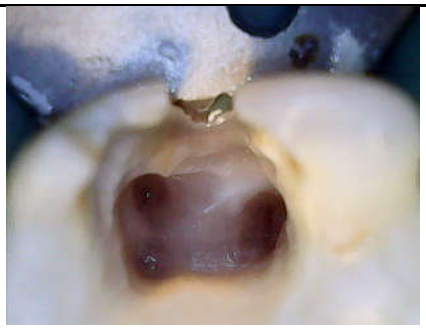

Figure 1. Medicational cavity prepration

Figure 2. Placement of modified 3 mix plus dexamethasone paste into madicational cavity

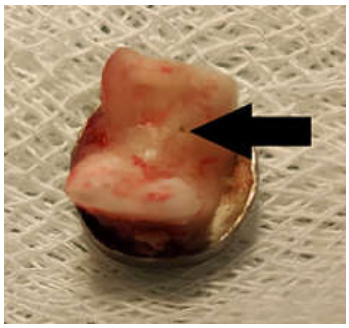

Figure 3. Large accessory canal in furcation area in treated molar of group A

Presence of multiple accessory canals and ramifications, apparent connection between the coronal floor with the intraradicular area and lack of apical closure following physiologic root resorption can lead to failure in obtaining hermetic seal (Abidin Talha Mutluay, 2016). Hence, the use of such procedure in primary teeth should have a convenient alternative with comparable or better success rate. *Enterococcus faecalis* the main endodontic pathogen in canals as well as peri-radicular tissues is highly virulent, hence; Alam et al. studied by in-vitro methods the susceptibility of *E. faecalis* to the triple antibiotic paste. He concluded that the 3-mix, at 100µg/mL, is completely capable of inhibiting the growth of all strain when combinations was used (Alam, 2005). Endodontic pain is associated with inflammation, chemical mediators, especially Bradykinin and Prostaglandin released from injured tissues, are capable of inducing pain. Corticosteroids have the biological ability to inhibit the inflammatory response (Seltzer, 1986; Fauci, 1976; Goldstein, 1975) and therefore can be expected to reduce or eliminate inflammatory process within tissues.

Knowledge of the principles of the anti-inflammatory action of corticosteroids has shown that these agents are capable of controlling the development of inflammatory processes from the irritative phase by inhibiting the production of arachidonic acid and consequently the production of prostaglandins, which have an important role in inducing vasodilatation and increasing vascular permeability. Thus, the vascular inflammatory events tend to diminish.

Such aspects were confirmed by the results of the previous studies, which showed a significantly decreased vasodilatation and a significantly smaller number of blood vessels (Lakshmanan, 1972).Topical application of Corticosteroids has been suggested by Schroeder O for control of inflammation in diseases of the pulp ranging from hyperemia to partial suppurative pulpitis (Allan Moskow, 2014). In present study we have used mixture of Ciprofloxacin, Cefaclor, and Metronidazole in 1:1:1 ratio plus Dexamethasone with Macrogol and Propylene glycol as a vehicle in Group A whereas in Group B single sitting Pulpectomy performed using Metapex to evaluate and compare their efficacies in successfully treating pulpally involved primary teeth. The commonly used materials for primary root canal fillings are zinc oxide eugenol, iodoform based pastes and calcium hydroxide (Praveen, 2011). In present study Metapex was used as obturating material in Group B which is combination of Calcium hydroxide and iodoform. A Metapex paste is easily resorbed from the periradicular region, and cause no foreign body reaction like Zinc oxide eugenol. Over filling and resorption of the paste containing Iodoform from the root canals had no effect on the success of the treatment but regarded as having a positive healing effect P. Praveen (2011). stainless steel crown was given immediately after procedure as stainless steel crowns are superior to composite resin with respect to restoration maintenance, marginal integrity and recurrent caries as per study done by K. Chen et al. (2018). Group A of this study showed 93.3% and 90% success at 1 month and at 6 months clinical evaluation.

This result is in accordance and comparable with result obtained by Prabhakar et al. (2008) (93.3%), Pinky et al. (2011) (90%) and Doneria et al[9] (89.5). However, it is lesser than Takushige et al. (2004) (100%) and Nakorchi et al. (2010) (100%) and more than Agarwal et al. (2011) (28%) and Trairatvorakul et al[4](remove this reference) (75%). In our study, Radiographically there was 86.7% success observed at 6 months evaluation, which is comparable with as reported by Pinky et al. (2011) (90%) However, it is higher than that of Nakorchi et al. (2011) (76%) Prabhakar et al. (2008) (63.3%). These reported variations in success rates may be attributed to addition of Dexamethasone in medicament in Group A, differences in sample selection, evaluation criteria and techniques employed. Higher success rate was found compared to available studies; possible reason could be incorporation of dexamethasone in Modified 3 mix paste which has potent anti-inflammatory effect. In Group A, increase in intraradicular radiolucency was found to be the most common cause of radiologic failure. A total of3 teeth were present with increase in radiolucency, PDL enlargement, Discontinuity of lamina dura and 1 teeth showed pathologic resorption with increased in radiolucency. Previous investigations have also reported increase in radiolucency and internal resorption as the most frequent postoperative radiological failures observed in primary molars after LSTR (Prabhakar, 2008; Takushige, 2004; Nakornchai, 2010). Four molars of Group A were given scoring of failure (0); one of the molar was of questionable scoring at the end of 1 month as it had slight increase in peri-radicular radiolucency which was not taken into count. At the 6 months follow up the same molar had tenderness on percussion with mobility and increase in the size of periradicular radiolucency, which led to the clinical and radiographic failure. The molar was extracted and after carefully inspection, it was found that it had a large accessory canal in the furcation area (Figure 3) which could the reason behind failure because we placed Modified 3 mix plus Dexamethasone paste on main canal orifices only. So, it is suggested to cover floor of pulp chamber with thin layer of Modified 3 mix plus Dexamethasone paste to take care of accessory canals before sealing access cavity.

In Group B clinical and radiographic success was 96.7% which is in accordance and comparable with studies reported by Ozalp et al. (2005), Chutima et al. (2012) Martin j roger in literature. The radiological success rate of study done by Nakoechai et al was very less (56%) which can be due to poor prognosis sample selected in their study. However, there is no statistically significant difference in results found in Group A and Group B at 6 months. (P value=0.48 and 0.35 respectively). Concerns of antibiotics in our paste include allergic reactions, the probability for the emergence of antibiotic-resistant bacterial strains, drug side effects, and the risk of developmental anomalies in permanent teeth if used in primary teeth and cyst formation if the focus of chronic infection is left. The positive side to the above-said statement is the volume of these drugs used in LSTR is minimal, and there are no reported side effects till date (Kayalvizhi, 2013). The findings of four investigation indicate that Modified 3 mix plus Dexamethasone therapy hold potential to be used as effective as conventional endodontic treatment of primary teeth. Because of high antibacterial effectiveness and non-instrumentation technique Modified 3 mix plus Dexamethasone paste may be more suitable in cases of poor prognosis. Another clinical advantages of this is less Chair time, easy and simple technique, no instrumentation needed, no need of obturation and more economical. In the present study, although medicament have shown clinically and radiographically comparable and acceptable results yet further studies with a larger sample size with a longer period follow-up is required.

Key Message: Modified 3 Mix plus Dexamethasone therapy hold potential to be used as alternative treatment modality to conventional endodontic treatment of primary teeth.

Conflict of interest: none

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