

COMPARATIVE STUDY OF EFFICACY OF FORMOCRESOL AND CALCIUM HYDROXIDE PULPOTOMY IN PRIMARY MOLARS

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ABSTRACT

Comparative study of formocresol and calcium hydroxide pulpotomy procedure has a particular importance in this part of the subcontinent where low socioeconomic status is debilitating and does not allow many persons to undergo an expensive therapy like Mineral Trioxide Aggregate therapy, laser therapy and electro cauterization modality of pulpotomy. The purpose of this study was to compare the efficacy of two different vital pulp therapy techniques both clinically and radiographically in cariously exposed primary molars, utilizing calcium hydroxide and formocresol as the material for pulpotomy. It was a Quasi-experimental study. The sampling technique was a non-randomized convenience sampling.

Duration: The study was conducted and completed in one year 28, Military Dental Centre, Lahore. The study was carried out using clinical and radiological criteria of follow up for evaluating the success of the two techniques by selecting 60 subjects, all Pakistanis. The sample comprised of subjects within 4 to 6 years age bracket selected alternatively according to gender. Formocresol and Calcium hydroxide pulpotomy was performed after amputation and proper hemostasis of the coronal pulp chamber and the selected patients were divided into two groups. The patients selected for formocresol pulpotomy were placed in Group F and the patients for calcium hydroxide pulpotomy were placed in Group C. Follow up of the cases were performed at 03 months, 06 months and 01 year period and the results in terms of success and failure were recorded in the stipulated data form and analyzed by SPSS version 17 for Windows. Sixty cariously exposed primary molars required vital pulp therapy. Thirty primary molars (50%) in Group F and thirty primary molars (50%) in Group C. 27 teeth (90%) treated with formocresol and 17 teeth (56.7%) with calcium hydroxide were classed as clinically and radiographically successful at the end of one year. The results showed a significant difference in the efficacy of the two groups ($p = 0.004$). It was concluded that there was a significant difference in the efficacy of the two medicaments projecting higher rate of success with formocresol as compared to calcium hydroxide both clinically and radiographically.

Key Words: Formocresol, Calcium hydroxide, Vital Pulpotomy.

INTRODUCTION

The 1996 American Association of Paediatric Dentistry (AAPD) guide lines for pulp therapy for primary and young permanent teeth describes the pulpotomy procedure in primary teeth as the amputation of the

affected or infected teeth, coronal portion of the dental pulp, preserving the vitality and function of all or part of the remaining radicular pulp.^{1,2}

Many Pharmacological agents have been employed to achieve pulpotomy of teeth e.g. Gluteraldehyde, Formocresol, Calcium Hydroxide, Collagen, Ferric sulphate, Mineral trioxide Aggregate (MTA) and non pharmacological agents e.g. Laser therapy, and Electrocauterization.^{3,4} Formocresol and calcium hydroxide are the widely used Pulpotomy materials which are although economically cheaper and easily available in this part of the subcontinent but little has been published regarding the evaluation of the efficacy of these materials in research work.^{3,5}

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Formocresol pulpotomy is the procedure, which utilizes coagulative necrosis of the superficial part of the pulpotomized root stump maintaining the vitality of the pulp underneath.^{6,7} Calcium hydroxide is used because of its predictability in bridge formation and maintenance of vitality of the residual pulp.⁸

There is a variation in different studies related to the determination of the efficacy of formocresol and calcium hydroxide pulpotomy by different authors. Investigators have achieved results with different conclusions that contradict the study of one another. Some authors have deducted 50% success with calcium hydroxide pulpotomy and 92% success with formocresol group, while some authors have found no significant difference between the two procedure which are two extremes that require further evaluation by further prospective studies.^{9,10,11}

Pulpotomy procedure reduces the time consumed on the child patient, alleviating the need of repeated visits making the patient more co-operative. It makes possible the preservation of deciduous teeth to a considerable period as a space maintainer for its timely shedding and eruption of its successor in the maintained space.⁹

In Pakistan the local research on efficacy of formocresol and calcium hydroxide pulpotomy is meager and requires increased emphasis in its execution, which may help in the determination of the best and cheapest material for pulpotomy in the preservation of the primary dentition. Even the methodology adopted by the west is not sufficient for recommending a particular technique for treatment of pulpally involved primary molars.¹⁰

This study was conducted to allow the dental professionals in poising their efforts in their selection of an efficient and cheaper material for pulpotomy in this part of the subcontinent that would help in the preservation of the primary teeth especially of the destitute population of this area.

METHODOLOGY

This study was carried out at 28 Military Dental Centre, Lahore. The duration of study was one year after the selection of the patients and execution of the pulpotomy procedure. The study was carried out on 60 children comprising of 30 males and 30 females divided into two groups of pulpotomy with age ranging from 04 to 06 years. The entire sample was selected from the outpatient department.

Non-probability, convenience sampling was adopted. The subjects were divided into two groups, the formocresol (Group F) and the calcium hydroxide (Group C). The samples were selected alternatively from the two genders to be included in the two groups of pulpotomy for equal representation of the two genders and the reliability of the results with equal implication on the two groups. It was a Quasi-experimental study.

The inclusion criteria for selection included cariously exposed vital primary teeth, mechanically or cariously exposed vital teeth, children falling within 04 years to 06 years age, children with good oral hygiene and physical status and children with intact mental status. The exclusion criteria selected was divided into clinical criteria for exclusion and radiological criteria for exclusion. The clinical criteria for exclusion comprised of cardiac conditions (congenital valvular malformations), spontaneous pain at night, extra oral/intra oral swelling, fistula, tenderness to percussion and pathological migration. The radiological criteria for exclusion included external resorption, internal resorption, periapical and inter radicular radiolucency, pulp calcifications and pathological root resorption.

The cases were selected according to inclusion/exclusion criteria. The treatment was initiated after the explanation of the procedure to be performed to the parents and their consent for the pulpotomy procedure.

The teeth of patients in Group F were treated by coronal pulp amputation followed by a five minute application of a 20% Buckley's formocresol solution while the teeth of patients in Group C were treated by coronal pulp amputation, hemostasis followed by placement of calcium hydroxide powder, containing 99% calcium hydroxide, (Sigma-Aldrich Chemical Company Ltd, Poole Dorset, UK) to the radicular pulp stumps.

The allocation to the F or C Group was achieved by convenience sampling, selecting alternate individuals from different genders and assigning them the 'F' and 'C' groups according to the procedures selected for their treatment. The antimeres if present and did not require vital pulp therapy, were recorded as negative control in order to rule out any assigned failure due to the different procedure to be a physiological resorption due to an early shedding of the antimere effecting the efficacy of the two procedures indirectly.

The radiographs were taken by specific holders available for the paralleling technique for achieving ideal interpretation of the radiographs. Review ra-

diographs were taken at the intervals of 03 months, 06 months and one year and the failures and success related to the radiographs were recorded in the Data Analysis Proforma.

Topical anesthesia was achieved with 20% benzocaine gel (Xylonor gel, Septodont Incorporate, Newcastle, Delaware, USA) before 2% lignocaine with 1:100,000 adrenaline local anesthetic solution (Septodont Incorporate, Newcastle, Delaware, USA) was administered.

Isolation was achieved with cotton wool rolls and saliva ejection. Cavity outline was established at high speed with a water-cooled air rotor with initial penetration by round diamond bur and later finishing by fissure diamond bur. Caries was removed with slow-speed air turbine and round steel burs. The pulp chamber was entered and the roof removed with a sterile, non-end cutting slow-speed bur (Batt cone bur ISO 016, Maillefer Instruments SA, 1338 Ballaigues, Switzerland). Sterile, physiological saline was delivered by syringe and needle to wash away dentine debris.

Coronal pulp amputation was achieved with small and medium slow-speed sterile round burs, taking care to avoid cutting the pulp chamber floor. The remaining pulp tissue was excavated with sterile excavators and the chamber irrigated with sterile, physiological saline. Hemorrhage was controlled using sterile pledget of dry cotton wool and pressure.

For Group F pledget of cotton wool was placed in 20% solution of Buckley's formocresol and immediately blotted dry on sterile gauze. The pledget was placed directly over the radicular pulp stumps and covered with dry cotton wool, to avoid seepage of the agent from the cavity. The cotton wool was removed after 5 minutes and tooth was restored. For Group C, Calcium hydroxide powder was delivered to the pulp chamber using a small, sterile endodontic amalgam carrier ('PD' Messing root canal gun, Produits Dentaires SA, Vevey, Switzerland) after haemostasis.

Common post application restorative procedure for both Groups C and Group F included a 3-4 mm thick lining of zinc oxide-eugenol cement (Kalzinol DeTrey, Konstanz, Germany), which was placed to seal the coronal pulp chamber, and allowed to set. The tooth was restored with amalgam (Dispersalloy Dentsply International Incorporate, Milford, D.E. USA), glass-ionomer cement (Fuji II, Japan) or compomer (Dyract DeTrey, Konstanz, Germany). Occlusal contacts were checked and adjusted where necessary.

The Patients were reviewed at three months, six months and one-year intervals. At one-year post pulpotomy the patients were assessed for designating success or failure to the executed procedures. Review radiographs were obtained for the teeth after 03 months, 06 months and 01 year.

When the treatment failed, clinical and radiographic reasons were documented on the Data Analysis Proforma. Treatment failure occurred when the test tooth showed either clinical signs or symptoms of infection with or without radiographic signs which were tenderness to percussion, pus discharge, mobility, extra radicular resorption, intra radicular resorption, peri-apical radiolucency, pulp calcification. In case of confusion or artifacts of the radiographs the procedure were repeated to deduct the actual changes related to the tooth in question.

The database of all the measurements was developed in SPSS version 17 software statistical packages. The Chi square test was applied to the data recorded at the end of the study to evaluate the p-value for significance (Table 1) and pie charts were plotted depicting the review at 03 months and 06 months (Fig 1, Fig 2).

RESULTS

Sixty patients were involved in the investigation (30 females and 30 males). 30 teeth were treated with formocresol and 30 with calcium hydroxide. In both Group F and Group C, 30 teeth in each group had untreated (negative) controls.

At 03 months, in Group F displayed 28 cases (93.3%) were successful and 02 cases (6.7%) reported with failure due to intra radicular resorption while Group C presented with a success of 29 cases (96.7%) and a failure of only 01 case (3.3%) due to internal resorption as shown in Fig 1.

At 06 months review, Group F displayed success of 27 cases (90%) and further failure of 01 case due to chronic inflammation, making the sum of failures to 03 (10%) and Group C presented with success of 18 cases (60%) and further failure of 11 cases in which 03 cases failed due to intra radicular resorption, 07 cases with chronic inflammatory changes (peri-apical radiolucency) and 01 case with pulpal calcification making the sum of failures to 12 (40%) as shown in Fig 2.

At the end of the study in Group F, 27 cases (90%) exhibited success and 03 cases (10%) with failure and Group C presented with a success of 17 cases (56.7%) and failure of 13 cases (43.3%) as shown in Table 1.

TABLE. 1: COMPARISON OF TWO VITAL PULP THERAPY TECHNIQUES (01 YEAR)

Sr. No.	Pulpotomy Group	Success n	Failure n	Success %	Failure %	p-value
1.	Group F (n=30)	27	3	90%	10%	0.004
2.	Group C (n=30)	17	13	56.7%	43.3%	0.004

TABLE. 2: FAILURE STATISTICS OF TWO VITAL PULP THERAPY TECHNIQUES (01 YEAR)

Sr. No.	Pulpotomy Group	Intra- radicular resorption n (%)	Pulp calcifications n (%)	Peri-apical radiolucency n (%)
1.	Group F (n=3)	2(67%)	0	1(33%)
2.	Group C (n=13)	4(31%)	2(15%)	7(54%)

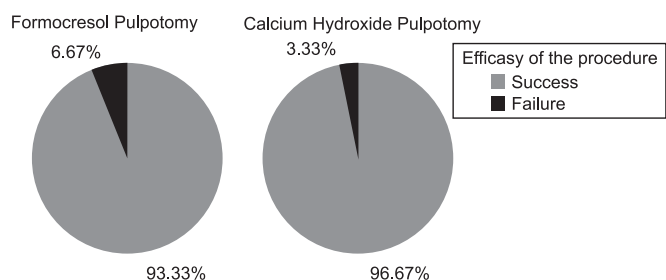


Fig 1: Distribution of efficacy of two vital pulp therapy techniques (03 months)

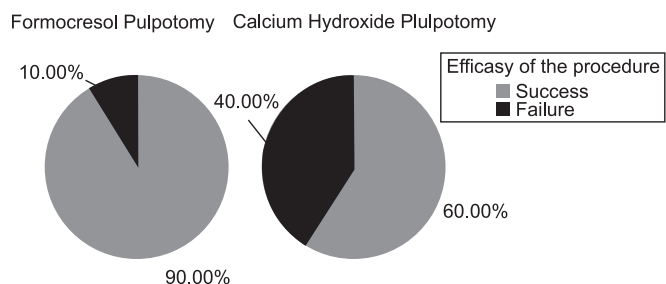


Fig 2: Distribution of efficacy of two vital pulp therapy techniques (06 months)

In Group F, 02 cases (67%) out of 03 cases reported with intra radicular resorption and 01(33%) case with peri-apical radiolucency (sign of chronic inflammation) at the end of the study (Table 2). While in Group C, 07(54%) cases out of 13 cases reported with peri-apical radiolucency, 02(15%) cases with pulp calcifications and 04(31%) cases with intra radicular resorption at the end of the study (Table 2). The presenting signs of failure of the two procedures at the end of 01 year are shown in Table 2. The statistical analysis revealed a significant difference in the proportion of successful outcomes of teeth from Group F or Group C (p-value=0.004) at the end of one year.

DISCUSSION

Pulpotomy is the treatment option constituting the conservative attempt to preserve the primary teeth

which saves time and money and allows treating the child with minimum discomfort as compared to the pulpectomy procedure which is more time consuming and may affect the cooperativeness of the child due to the long appointments required for completion.¹⁰

The proportion of the number of teeth treated with Buckley's formocresol (n= 30) was equal to that of teeth treated with calcium hydroxide powder (n = 30) and the selection of patients on alternate basis from population of both the gender was to have a study that extrapolated the effect on both the sexes on equal grounds.

In this study, there appeared a considerable difference between the clinical outcomes for both medications. When the number of successful outcomes in Group F is compared with Group C, 27 of 30 teeth from Group F (90%) and 17 of 30 teeth from Group C (56.7%) were classed as both clinically and radio graphically successful. This decision was taken at the last review each tooth received that was at the end of one year.

The success rate of 90% for Group F in the current study compares favorably with previous studies performed by different researchers. Water house PJ, Nunn JH, Whitworth JM presented a success rate of 95% and 61% for formocresol and calcium hydroxide respectively at the end of 1 year which is in concordance to the present study depicting a greater efficacy for formocresol as compared to calcium hydroxide.⁴

Wyne AH, Al Shalan TA studied the effects of formocresol individually and found formocresol to be less effective having a success rate of 61%, which is not in equivalence to this study.⁷ The cause of failure in their study was mobility clinically which also contradicts the present study where the prevalent cause of failure was internal resorption 02 cases (67%) (Table 2).

Recent study by Alacam A, Odabas ME, Tuzuner T, Sillelioglu H, Baygin O compared the clinical and

radiographic success rates of 3 pulpotomy techniques: formocresol, calcium hydroxide, and calcium hydroxide/iodoform.⁸ The follow-up evaluations revealed that the clinical success rates were 89.7% for formocresol, 33.3% for calcium hydroxide, and 17.2% for calcium hydroxide/iodoform. The radiographic success rates were 89.7% for formocresol, 33.3% for calcium hydroxide, and 13.8% for calcium hydroxide/iodoform. This study revealed similar results as compared to our study that Formocresol was superior to calcium hydroxide in primary molar pulpotomies.

Sasaki H, Ogawa T, Koreeda M, Ozaki T, Sobue S, Ooshima T in their 02 years study with calcium hydroxide used as a dressing material for the pulp found the efficacy of calcium hydroxide low as success rate of his study was 57%, which is congruent to this study.¹¹

The current study clearly implies the use of formocresol to be more successful than calcium hydroxide, concluding a significant difference in the success of the two materials ($p=0.004$). Rubber Dam should had been utilized for isolation in order to eliminate any discrepancy related to isolation in this study but due to increased time consumption and greater requirement of cooperation for its utilization lead to foregoing the plan of application of rubber dam and consolidating to isolation by cotton rolls. Although the crowns of the deciduous molars were restored by Amalgam and Glass ionomer but the factor of micro leakage was not considered in the study. All the teeth at the end of the study had the restoration till the end. Stainless steel crowns should have been the final restoration, provided to eliminate the chances for prevention of micro leakage and strengthening the tooth during the study.

Research related to formocresol and calcium hydroxide vital pulp therapy in this part of the subcontinent is lacking in extent and needs further exploration especially related to the comparison of these two financially acceptable vital pulp therapy procedures.

CONCLUSION

Formocresol was found more efficacious as compared to calcium hydroxide, as an agent in pulp treatment of cariously exposed, vital primary molar teeth.

CONFLICT OF INTEREST

All the authors declare that there was no conflict of interest in conducting the current study.

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