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Treatment outcome with a revascularization protocol using double and triple antibiotic pastes in immature necrotic teeth – A double blinded randomized control clinical trial

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ABSTRACT

Aim: The aim of this clinical trial is to evaluate the regenerative potential of two antibiotic pastes in permanent teeth with necrotic pulp and open apex and compare it with a standard treatment using mineral trioxide aggregate.

Materials and methods: This interventional study was conducted to assess the revascularization potential. It was designed with two test arms and one control arm. LA was administered, access was established under rubber dam, irrigation was done, and each tooth received an antibiotic paste depending on the test arm to which it belonged. The control arm received a standard MTA apexification. Primary and secondary outcomes were assessed at baseline, 6 months and 12 months. Data were tabulated and analyzed.

Results: Though there was an increase in root length in the test arms, the difference was not statistically significant among the various groups at the different time intervals of assessment. Overall, the mean pain scores decreased over the study period in all the three groups. Though no root closure was found at baseline among the test groups, a statistically significant improvement in the root closure scores was observed in Group A, when compared to Group B, at the end of 6th and 12th month of intervention.

Conclusion: The results to this study show that the revascularization potential of triple antibiotic paste is superior to that of the double antibiotic group. The increase in the root length is statistically superior over the study period in the triple antibiotic arm when compared to that of the double antibiotic arm.

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1. Introduction

Pulpal necrosis of an immature tooth due to trauma poses many potential complications. It is difficult to insert an instrument into immature canal spaces using conventional endodontic techniques. The open apex is difficult or impossible to seal with conventional root filling methods because of the absence of an apical stop. Furthermore, the arrested development of the dentinal walls at the time of pulp necrosis leaves a weak tooth with thin dentinal walls that are susceptible to fracture.[1] For decades, such teeth have been treated by the apexification procedure, which involves placement of intracanal calcium hydroxide ($Ca(OH)_2$) to induce formation of a calcific barrier at the apex. The use of the $Ca(OH)_2$ based apexification technique has raised serious concern about the merit of this treatment approach due to the lengthy treatment period,[2,3] unpredictability of apical closure and susceptibility of cervical root fracture after prolonged exposure to $Ca(OH)_2$.[4]

More recently, the traditional apexification procedure has been modified by the introduction of artificial apical barrier methods with mineral trioxide aggregate (MTA). Although this approach might considerably shorten the treatment period, improve patient compliance, and result in favorable healing of the periapical tissues,[5,6] it still cannot stimulate the development of apical closure and thickening of radicular dentin.

Regenerative endodontic procedures can be defined as biologically based procedures designed to replace damaged structures, including dentin and root structures, as well as cells of the pulp-dentin complex.[7] One of the presently viable regenerative procedures is revascularization of the root canal. Revascularization depends mainly on disinfection of root canal, placement of matrix in canal for tissue growth, and impermeable seal of access opening. The primary parameter influencing success of this revascularization treatment is the disinfection of the root canal space.[8]

One combination that is effective against the bacteria commonly found in infected root canals is the use of Triple Antibiotic Paste (TAP), a combination of: (1) ciprofloxacin; (2) metronidazole; and (3) minocyclin. Hoshino et al.,[9] evaluated single and combined antibiotics against endodontic bacteria. They observed that the association of these three antibiotics eliminated bacterial colonization on the dentin surface.[10] Despite promising results, antibiotic paste may manifest some side effects such as crown discoloration due to the presence of minocycline.[11] In an attempt to minimize these undesirable effects, some authors have suggested decreasing the time of the antibacterial dressing to prevent discoloration.

Thus an attempt was made to eliminate the minocyline component, and a double antibiotic paste was formulated. The present randomized double blinded control trial was under taken to compare the clinical outcomes of Triple antibiotic paste versus a double antibiotic paste intracanal medicament with a standard treatment (immediate apexification with MTA) in single rooted maxillary permanent incisors with necrotic pulp and immature root development.

2. Aim

The aim of this clinical trial is to evaluate the regenerative potential of two antibiotic pastes in permanent teeth with necrotic pulp and open apex and compare it with a standard treatment using mineral trioxide aggregate.

3. Materials and methods

The present study was an interventional study conducted to assess the revascularization potential of a double anti-biotic paste when compared to that of a triple anti-biotic paste among a sampled population with necrotic immature pulp. Ethical clearance to conduct this study was obtained from the Institutions Review Board at Sri Venkeshwara Dental College and Hospitals. Individual informed consent was also obtained from the parents of the children who participated in this study, after explaining to them the treatment protocol. A total of 25 subjects who meet the inclusion and exclusion criteria were enrolled for the study.

3.1. *Inclusion criteria*

- Study subjects with a diagnosis of pulpal necrosis with apical periodontitis.
- Study subjects within the age group of 7–16 years.
- Study subjects having maxillary and mandibular restorable maxillary or mandibular anteriors, or lower premolar permanent tooth with open apices.
- Study subjects who gave consent to treatment plan with revascularization procedure.
- Study subjects belonging to ASA (American Society of Anesthetologists) Class I or II physical status and with no systemic health problems.

3.2. *Exclusion criteria*

- Study subjects with non-restorable teeth.
- Study subjects placed under ASA III and above physical status and having severe systemic disease that was considered constant threat to their life.
- Study subjects unable to give assent.

The study was designed with two test arms and one control arm.

- Test arm A consisted of study participants who received triple antibiotic paste as the intracanal medicament.
- Test arm B consisted of study participants who received double antibiotic paste as the intracanal medicament.
- Control arm consisted of study participants who received a standard treatment of mineral trioxide aggregate immediate apexification procedure.

Subjects were randomly divided into 2 test arms of 10 study participants each (Arm A and Arm B) and a control arm of 5 study participants. For allocation of the subjects, a

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