ORIGINAL ARTICLE

Comparative Evaluation of Calcium Hydroxide, Triple Antibiotic Paste, and Nanosilica-Enhanced Tri Antibiotic Paste for Root Canal Disinfection in Periapical Lesions

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Abstract

Background: Periapical lesions are typical pathologic processes occurring in periapical tissues of teeth and are commonly caused by bacterial infections as a result of pulpal necrosis. The appropriate diagnosis and treatment play an important role in maintaining the structure of the teeth and avoiding complications. **Aims:** The purpose of this study is to examine the effectiveness of Calcium hydroxide paste, Triple antibiotic paste (TAP), and nanosilica TAP (NTAP) as a root canal disinfectant in treating periapical lesions. **Materials and Methods:** A randomized controlled trial was carried out on 60 patients aged 15–45 years old with periapical lesions in maxillary anterior teeth, split into 3 groups: Calcium hydroxide paste, TAP, and NTAP. Both clinically and radiographically, the periapical index (PAI) was recorded at 3, 6, 12, and 18 months after endodontic evaluation. **Results:** PAI was discovered to exhibit no significant differences between scores 5 at baseline and at 3 months but significant differences at 6 months with 80% of the samples in the NTAP group achieving PAI score of 3 ($P = 0.029$) and 90% of the samples in the TAP group achieving a PAI score of 3 at 12 months. Calcium hydroxide (20%) and TAP (10%) showed failures but the NTAP group showed efficiency. **Conclusion:** NTAP has already been shown to be a successful root canal disinfectant in the treatment of periapical lesions without failures by lowering the PAI score. Periapical lesions can be treated successfully with early diagnosis and proper management. Although traditional root canal treatment is the norm, there are new regenerative methods that have the potential to save dentures.

Key words: Calcium hydroxide paste, innovation, nanosilica tri-antibiotic paste, periapical index, periapical lesion, product innovation, root canal disinfectant, tri-antibiotic paste

INTRODUCTION

The essence of endodontic therapy is aimed at removing microorganisms in the root canal system and preventing their reinfection, thus promoting healing of the periapical tissues. Periapical lesions are inflammatory diseases of microbial origin that develop when pulpal necrosis occurs and fail to be colonized by a complex polymicrobial biofilm. The virulence factors of these microorganisms include endotoxins, enzymes, and metabolic by-products that cause host immune responses resulting in periapical inflammation, bone resorption, and development of radiolucent lesions.[1,2]

Associated microbiota in infected root canals are arranged in a very organized biofilm structure that is much more resistant to antimicrobial agent usage than solitary bacteria. These biofilms are particularly difficult to eliminate in the

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complex root canal system with its lateral canals, isthmuses, apical deltas, and dentinal tubules and present a key obstacle to effective disinfection. Apical periodontitis and endodontic failure persist despite the development of improved instrumentation and irrigation techniques, with the difficulty remaining in achieving total elimination of microorganisms in these cases.[1,3]

The most important part of preparing the root canal is chemo-mechanical preparation, a technique that involves mechanical instrumentation as well as chemical irrigation. Research has indicated though that this method is incapable of fully destroying microorganisms, especially in the root canal system into which has inaccessible areas. Thus, it is necessary to use intracanal medicaments between appointments to decrease further microbial load, neutralize bacterial toxins, and establish an unfavorable environment in which bacterial survival is not possible.[4,5]

The gold standard intracanal medicament, long thought to be calcium hydroxide, has since been regarded as having a wide range of biological characteristics. Calcium hydroxide also releases hydroxyl ions, which cause antimicrobial effects by protein denaturation, breaking bacterial cytoplasmic membranes, and disrupting DNA, thereby facilitating the formation of hard tissue, inhibiting osteoclastic activity, and facilitating periapical healing. Its antimicrobial activity is, however, less effective against resistant microorganisms such as *Enterococcus faecalis* and *Candida albicans*.[6] Moreover, it can cause a diminished performance in the long run due to the low buffering capacity of dentin and low penetration into dentinal tubules.

To combat these restrictions, intracanal medicaments like triple antibiotic paste (TAP) which are based on antibiotics have been introduced. TAP is a combination of metronidazole, ciprofloxacin, and minocycline with a broad-spectrum antimicrobial effect against the various microflora that can be found in infected root canals. The antimicrobial efficacy of TAP has been shown to be superior to that of calcium hydroxide in various studies, and it has been commonly used in regenerative endodontic therapy and the treatment of large periapical lesions.[4,7]

Although TAP has some benefits, there are some disadvantages related to its use, such as tooth discoloration caused by minocycline, the possible cytotoxic effects of stem cells, and the fear of the emergence of antibiotic resistance. These restrictions are what will require seeking alternative options and recent drug delivery modalities to improve antimicrobial efficacy and reduce adverse effects. The latest developments in nanotechnology have brought new methods in disinfection of endodontics. The properties of nanoparticles that have garnered interest include high surface area/volume ratio, elevated reactivity, and enhanced penetration into dentinal tubules and biofilms.[9,10]

Nanosilica particles in particular have demonstrated great potential as drug delivery vehicles, allowing sustained release of antimicrobial agents and enhanced interaction with microbial cells. Nanosilica has been added to intracanal medicaments, e.g., to nanosilica-enhanced triple antibiotic paste (NTAP), which has been demonstrated to increase antimicrobial activity through better drug stability, penetration, and bioavailability. Further, nanoparticle-based systems have been shown to affect biofilm structure and enhance bactericidal efficacy against resistant microbes. These benefits make NTAP an attractive future in root canal disinfection protocols.[3,8,11]

Periapical healing needs to be accurately assessed to determine the outcome of the treatment. The periapical index (PAI), which is a standardized radiographic scoring tool, is a dependable and replicable way of evaluating periapical condition and tracking the healing process longitudinally. The PAI, an index that is a standardized radiographic scoring system, is a reliable and reproducible method of measuring periapical condition and long-term healing. Since there have always been problems with the full disinfection of the root canal system and the constraints of traditional intracanal medicaments, a greater desire to consider newer modalities of treatment is becoming more and more necessary. Thus, the current research will attempt to comparatively evaluate the clinical and radiographic effectiveness of calcium hydroxide, triple antibiotic paste, and nanosilica-enhanced triple antibiotic paste (NTAP) in the non-surgical treatment of periapical lesions. The null hypothesis exists that these intracanal medicaments significantly differ in their effect in promoting periapical healing.

MATERIALS AND METHODS

The study is underway as a prospective clinical trial to measure and determine clinical and radiographic outcomes following nonsurgical treatment of periapical lesions with Novel Nano Silica TAP, triple antibiotic paste, and calcium hydroxide as root canal disinfectants. Out of the outpatient section of the Department of Conservative Dentistry and Endodontics, Best Dental Science College, Madurai, 60 patients with periapical lesions in the maxillary anterior region were chosen between June 2019 and December 2019. The patients were assigned to intervention through a random allocation software that divided the patients into three groups of 20.

Study design and ethical protocol

The Institutional Ethical and Scientific Review Board of Saveetha Institute of Medical and Technical Sciences, India, approved this single-center, prospective, randomized, double-blinded clinical trial (IHEC No: SDC/PhD-01/19/13).

Inclusion criteria

Patients with periapical lesions of the maxillary anterior region aged between 15 and 45 years.

Exclusion criteria

- When patients have a positive allergy patch test (triple antibiotic paste) but are under medication
- Previously, endodontically treated teeth
- Patients who have had any form of systemic illness in the past
- Pregnant and lactating women
- Coronal perforation and vertical root fracture of the tooth
- The calcific degenerated tooth
- There is either external or internal root resorption
- Blunderbuss apex.

Clinical parameters

1. Sensitivity to pressure and percussion of the teeth
2. Tenderness to palpation of adjoining soft tissues
3. Existence of a contingent sinus tract or distention of the adjoining soft tissues
4. Periodontal probing profile around the tooth
5. Nature and existence of a satisfactory coronal restoration and seal.

Radiographic parameters

- Radiographs

Periapical radiographs were obtained using the long-cone paralleling technique.

- Radiographic examination.

The periapical state was determined using the PAI as described by Orstavik and Haapasalo by providing visual representations of the five categories in the scale, each tooth was attributed to one of the PAI scores [Table 1].[12]

PAI

- Favorable

Healed: 3, 4, 5 at initial pre-operative (IPO) --> 1–2 at follow-up or 1–2 at IPO -->1–2 at follow-up.
Healing: 3, 4, 5 at IPO improves but is not --> 1–2 at follow-up.

- Unfavorable not healed/healing

5–3 at IPO stays --> 5–3 at follow-up.
or
1–2 at IPO --> 3, 4, 5 at follow-up.

Table 1: Score criteria

S. No.	Periapical index
1	Normal periapical structures
2	Small changes in bone structure
3	Changes in bone structure with some mineral loss
4	Periodontitis with a well-defined radiolucent area
5	Severe periodontitis with exacerbating features

Determination of outcome treatment

Success was determined by two outcome indicators. There were no pain, no clinical evidence of inflammation or edema, and standard radiographic examination of complete healing/a normal periodontal ligament space. A successful therapy was determined by loose criteria (if the size of the lesion has shrunk but the periodontal ligament space width has not regained its normal size) and was determined without any discomfort, absence of clinical evidence of inflammation or edema, and conventional radiographic measures of complete healing/presence of a normal periodontal ligament space or partial healing. A tooth that had to be removed because of endodontic problems (persistent pain, swelling, sinus, or periapical radiolucent lesion) was considered a failure in the therapy.

General steps

The single operator who treated all the patients used a standardized procedure. The pulp chamber was opened and a rubber dam (GDC Rubber Dam Kit, India) was put. The depth of the apex was measured with the Root ZX electronic apex finder (Morita MFG. Radiograph data and Corporation, Kyoto, Japan). Draining was usually performed twice daily, for 2–4 days, until discharge through the canal was not possible. Once drained, the access cavities were waxed with zinc oxide eugenol cement, Dental Products of India, Mumbai, India. Intracanal medicines or photodynamic treatment was not applied to the canal until active draining had ceased. K-type files were then used to instrument the root canals with profuse irrigation of 1% sodium hypochlorite, 17% ethylenediaminetetraacetic acid, and 0.2% chlorhexidine all under rubber dam isolation.

- Group 1: It was calcium hydroxide paste (Multi-Cal, pulpdent, USA)
- Group 2: Tri-antibiotic paste (adapted by Hoshino *et al*., in quotes) included Ciprofloxacin (Cifran 500 mg, Ranbaxy Laboratories Ltd., India), Metronidazole (Metrogyl 400 mg, J.B. Chemicals and Pharmaceuticals Ltd., India), and Minocycline (Amoxil 500 mg, GlaxoSmithKline plc).
- Group 3 nanosilica TAP: The root canals were obturated with AH plus sealer (Dentsply, DeTrey, Konstanz, Germany) and gutta-percha (DentsplyMaillefer,

Switzerland) by a cold lateral condensation technique. After obturation of the root canals, permanent restoration with composite resin (Voco) was done in all the groups.

Postoperative maintenance

There was the prescription of antibiotics and analgesics. Clinical and radiographic post-endodontic evaluation was performed at 3, 6, 12, and 18 months.

Statistical analysis

Analysis of variance (ANOVA) was used to compare the differences between 3, 6, 12, and 18 months across the 3 groups; $P < 0.05$ was considered statistically significant.

RESULTS

Sixty patients were included in the study on both criteria. Those patients with a pre-operative score of 4 or 5 were selected. No significant differences in PAI scores existed between the three groups at the time when the trial began. The change in PAI score was not significant at the 3-month follow-up. The $P = 0.029$ changed significantly at 6 months, and 80% of the Nanosilica TAP group had a PAI score of 3. Nevertheless, the calcium hydroxide and triple antibiotic groups were only 30% and 45% moved on to a PAI 3 score, respectively. Nanosilica TAP group had two patients who dropped out of the study at the 12-month mark, and $Ca(OH_2)$ group had two. Based on the first PAI scores of 4 and 5, the other 18 patients decreased their PAI score to 3. The PAI score with triple antibiotic paste shifted to 3 in 90% of patients after 12 months.

Two-thirds of the calcium hydroxide cases failed at 18-month follow-up, 10% of the triple antibiotic paste cases failed, and none of the nanosilica cases failed. The *P*-value was statistically significant. A PAI score of 3 was seen in 80% of the NTAP group [Table 2]. ANOVA revealed that there is no significant difference between groups 1 and 2, but group 3 which is Nano Silica TAP group had a significance value of <0.029 at 6 months. A marked difference was also noted in 18 months in Nano Silica TAP, establishing its efficacy in comparison to the other two groups [Table 3].

DISCUSSION

Effective control of the intracanal microbial load before obturation of the root canal is a critical factor that enhances the success rate of endodontic treatment and prevention and management of pulpal and periradicular infections.[13] The root canal system must be removed of bacteria and irritants, as much as possible, to have a better prognosis.[14] Inter-appointment dressing has been advocated in the past as a measure to fully disinfect the root canal system. Calcium hydroxide ($Ca(OH)_2$) is an example of a substance commonly used in endodontics, since it was introduced by Hermann in 1920 as a pulp-capping agent.[15] The pH of $Ca(OH)_2$ is about 12.5 and it exhibits a range of biological effects such as antibacterial effects, tissue dissolving effects, resorption of teeth, hard tissue formation, and periradicular healing when used in root canal treatment. Stuart KG E *et al*., state that, in addition to the apex, the effects of calcium hydroxide may be 4 times: (a) Anti-inflammatory effect, (b) acid products neutralization, (c) alkaline phosphatase activity, and (d) antibacterial effect.[16] Calcium hydroxide in an aqueous solution because of the diffusion of its hydroxyl (OH-) ions caused by ionization[17] creates a highly alkaline environment not conducive to the survival of microorganisms within the root canals[18] which ultimately destroys the bacteria in the inaccessible regions of the root canal system to facilitate healing and lessen post-operative pain.

It has been demonstrated by many studies that the use of calcium hydroxide in endodontic treatment of teeth

Table 2: PAI score in every 3-month review

Group	Pre-operative	3 months	6 months (%)	12 months (%)	18 months (%)
Calcium hydroxide	4 or 5	4 or 5	3 (30)	3 (90)	20 failure
Triple antibiotic paste	4 or 5	4 or 5	3 (45)	3 (45)	10 failure
Nano silica TAP	4 or 5	4 or 5	3 (80)	3 (80)	0 failure

PAI: Periapical index

Table 3: ANOVA showing the significance at various intervals

Groups	3 months		6 months		12 months		18 months	
	F	*P*-value	F	*P*-value	F	*P*-value	F	*P*-value
Calcium hydroxide paste	0.860	0.45	0.131	0.88	1.364	0.29	2.210	0.15
Tri-antibiotic paste	0.131	0.89	0.860	0.45	0.131	0.89	0.481	0.65
Nano silica TAP	1.345	0.28	0.606	0.029*	0.664	0.38	0.692	0.044*

ANOVA: Analysis of variance. * Significant at the level <0.05

with periapical lesions produced a success rate of 75[19]–80%.[20] Since the hydroxyl ions fail to bypass patent dentinal tubules to alkalize the media around the teeth, the extended periods of time that calcium hydroxide remained in the root canal did not elevate the antibacterial effect of calcium hydroxide.[21] However, maintaining a consistently high pH while administering the medicament remains a challenge. Due to these and other reasons, some species of microbes within a limited group of cases do survive to cause persistent infections. This quest for a superior alternative has therefore resulted in newer antimicrobial agents being discovered. A combination of metronidazole, ciprofloxacin, and minocycline (triple antibiotic paste, TAP) has been reported as an effective regimen in managing the root canal pathogen and in the management of non-vital young permanent teeth.

In earlier *in vitro* experiments, TAP was found to last 30 days[22] and is more effective as an antibacterial agent than calcium hydroxide. In periapical lesions with large periapical lesions where the administration of calcium hydroxide is unable to overcome the symptoms, TAP has been applied clinically in case reports and series. Most of the bacteria found in the infected root canal dentin are obligate anaerobes. Metronidazole is very toxic to anaerobes and is viewed as an antimicrobial agent against protozoa and anaerobic bacteria.

At a high concentration, it is not able to kill all the bacteria, meaning that a combination of other drugs was needed. Minocycline is bacteriostatic and exhibits action against Gram-positive and Gram-negative bacteria. It also leads to an increase in interleukin-10, an inflammatory cytokine. In addition, the ciprofloxacin (the synthetic fluoroquinolone) has a rapid bactericidal effect and high antimicrobial effectiveness on Gram-negative bacteria, with low activity on Gram-positive bacteria. Ciprofloxacin is not effective against many anaerobic bacteria. Therefore, it is commonly combined with metronidazole to produce mixed infections to offset the narrow spectrum of metronidazole.[23,24] Hence, Gram-negative, Gram-positive, and anaerobic bacteria can be impacted by TAP, and such a combination may be useful against odontogenic microorganisms.[25]

In the presence of the TAP, ciprofloxacin, metronidazole, and minocycline are to be combined in equivalent proportions (1:1:1),[26,27] to a cumulative final concentration of 0.1–1.0 mg/mL. This paste may be delivered as a vehicle using propylene glycol.[28] With necrotic pulps, immature root formation, and apical periodontitis, the triple-antibiotic regimen is initially challenging to treat successfully. However, even though doses of medicines administered in this treatment were small and there were no reported side effects, persons who are allergic to chemicals or antibiotics must exercise caution.[29] This paste cannot be used on patients who test positive in a patch test of any of the ingredients. The combination of medications is ready as soon as it gets into place. It is effective against a broad spectrum of root canal flora with minimal risk of resistance.[30]

The study was performed to determine and compare the clinical and radiographic outcome of nonsurgical management of periapical lesions with Novel Nano Silica TAP, triple antibiotic paste, and calcium hydroxide as a root canal disinfectant.[31,32] When treated with calcium hydroxide, triple antibiotic paste, and Nanosilica TAP, a success rate of 80, 90, and 100 has been reported in an endodontic treatment of periapical lesion teeth. Our study found that 91% of the participants were successful after an 18-month follow-up. The clinical examination showed no difference between the three groups, but radiographically, there was a shift. No difference existed in the success of the groups when loose success criteria (which include partial and total accomplishment as a successful result) were applied.

Applying a rigid standard of success compared with other intracanal medicaments the calcium hydroxide group, the percentage of success is reduced to 35. It is, however, the most common, the cheapest, and most common intracanal drug. The PAI score reduced greatly between 3 months and 18 months, and 73% of patients had a PAI score of 2. Comparing triple antibiotic paste and NTAP, clinical parameters also present a similar success percentile. Using strict criteria, 13 out of 20 cases in this study were successful; this was far much higher than the calcium hydroxide group. On loose criteria and clinical assessment, we decided that we had a 100% success rate. Amazingly, there were no cases of failure. In 90% of cases, the NTAP group had a PAI score of 2 after 18 months. NTAP proved the most effective of the groups, irrespective of the means used to realize success (clinical and radiographic).

CONCLUSION

Nanosilica-enhanced triple antibiotic paste (NTAP) has emerged as a promising adjunctive root canal disinfectant, demonstrating significant reduction in PAI scores without reported failures. Its potent antimicrobial action enhances the elimination of resistant endodontic pathogens and improves disinfection within complex root canal anatomies. Early diagnosis and timely, appropriate management of periapical lesions are critical for achieving favorable treatment outcomes and preventing disease progression.

While conventional root canal therapy continues to be the gold standard for managing periapical pathology, advancements in regenerative endodontic procedures offer additional potential for biological healing, tissue regeneration, and preservation of tooth structure. These evolving approaches may further improve long-term prognosis and clinical success in endodontic therapy.

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