How to Cite:
Kharadly, D. Y. E., Tawil, S. B. E., Nasr, R. A., & Beshlawy, D. M. E. (2022). Triple antibiotic paste and simvastatin in the treatment of non-vital primary molars with inflammatory root resorption: A randomized control trial. *International Journal of Health Sciences*, *6*(S6), 3715–3728. https://doi.org/10.53730/ijhs.v6nS6.10439

Triple antibiotic paste and simvastatin in the treatment of non-vital primary molars with inflammatory root resorption: A randomized control trial

Dina Y. El Kharadly
Assistant Lecturer of Pediatric Dentistry, Faculty of Dentistry, October 6 University, Egypt
*Corresponding author email: dina.yousry.dent@o6u.edu.eg

Sherif B. El Tawil
Professor of Pediatric Dentistry, Faculty of Dentistry, Cairo University, Egypt
Email: drsherifbahgat@hotmail.com

Rania A. Nasr
Assistant Professor of Pediatric Dentistry, Faculty of Dentistry, Cairo University, Egypt
Email: rania.nasr@dentistry.cu.edu.eg

Dina M. El Beshlawy
Professor of Oral and Maxillofacial Radiology, Faculty of Dentistry, Cairo University, Egypt
Email: dinabeshlawy@yahoo.com

***Abstract*---**Aim: This study aimed to compare the success rate of pulp therapy of non-vital primary molars with inflammatory root resorption when treated using triple antibiotic mix or simvastatin as a component in the root filling material. Methodology: Lesion Sterilization and tissue repair was employed in the treatment of 30 non-vital primary molars exhibiting inflammatory root resorption and furcation radiolucency. The molars included in the study were randomly allocated into 2 equal groups. All root canals were instrumented 1mm from the radiographic apex, and an obturation mix was used to fill the canals to avoid the hollow tube effect. Triple antibiotic paste (TAP) was prepared by mixing ciprofloxacin, cefixime, and metronidazole in a 1:1:1 ratio. It was used as the active agent in group I and mixed with zinc oxide powder and polyethylene glycol + propylene glycol as a vehicle to prepare a filling material. For group II, simvastatin was used as the active agent alone. Following pulp

International Journal of Health Sciences ISSN 2550-6978 E-ISSN 2550-696X © 2022.
Manuscript submitted: 9 March 2022, Manuscript revised: 27 May 2022, Accepted for publication: 18 June 2022

therapy, all teeth were restored with stainless steel crowns, 1-week postoperative. Clinical evaluation was carried out at 1 week postoperative, then at 3, 6, and 12 months while radiographic evaluation was carried out at 6 and 12 months using predetermined criteria. Results: There was a non-significant difference in the clinical outcome between the triple antibiotic paste and simvastatin. For radiographic outcome, which corresponded to the overall outcome, there was also a non-significant difference between the 3 groups. However, for the secondary outcome, which was an increase of bone density in the furcation area, the was a significant difference, with simvastatin showing the greatest improvement. Conclusions: The use of both triple antibiotic paste, and simvastatin has shown an improved survival rate in primary molars presenting with inflammatory root resorption or pretreatment radiolucency. Simvastatin shows promise as a component in root filling materials of primary molars requiring non-vital pulp treatment since it is a biocompatible material with anti-inflammatory and osteogenic properties.

***Keywords*---**non vital, deciduous, simvastatin, triple antibiotic mix, 3 mix.

Introduction

Premature loss of primary teeth leads to changes in chronology and sequence of eruption of permanent teeth; thus, saving teeth in children is an important concept and frequently involves endodontic treatment. The main aim of pulp therapy in primary teeth is the preservation of the pulpally involved teeth until exfoliation to maintain arch integrity and length by acting as natural space maintainers. [1]. Primary molars often exhibit ovoid- or ribbon-shaped root canals in their coronal part and a more oval shape toward the apex. Such canals constitute a crucial challenge for adequate root canal cleaning, shaping, and disinfection, [2] Furthermore, the persistence of polymicrobial infection dispersed inside the root canal system and periradicular area of primary teeth is one of the significant variables associated with endodontic failure. After root canal preparation, viable microorganisms may linger in the dentinal tubules, un-instrumented regions of the canals, and other irregular spaces. These microorganisms can multiply and reinfect the root canal system in a supportive environment, resulting in root canal failure. Thus, for optimal success of endodontic treatment, substances with antimicrobial properties are advocated as obturating materials in deciduous teeth. [3]

In addition, teeth with clinical and radiographic signs of pulpal necrosis, e.g., fistula and abscesses, and teeth with furcal lesions and pathological root resorption before pulp therapy had lower survival rates than those found that did not present these conditions.[4]. The concept of “Lesion Sterilization and Tissue Repair” (LSTR) was developed at the Cariology Research Unit of Niigata University School of Dentistry, Japan. as a result of various studies conducted by Sato, Hoshino & Takushige which proved the efficacy of the mixture of antibacterial

drugs against endodontic micro-organisms. [5-10] A systematic review on the subject of non-vital primary tooth pulp treatments and, based on moderate levels of evidence, recommended that LSTR should be chosen over pulpectomy in teeth with root resorption or to retain teeth for up to 12 months that otherwise would be extracted. With its endorsement as a treatment modality suitable for primary teeth, which are not ideal for conventional pulpectomy treatment like teeth with periradicular involvement and extensive root resorption, the preservation of such teeth is now possible.[11]

Hoshino et al. (1990) used combinations of antibiotics like metronidazole 500mg, ciprofloxacin 200 mg, minocycline 100 mg in a 1:1:1 ratio.[8] Takushige et al.,1998 used the above antibiotics in the ratio 1:3:3.3.[9] Metronidazole belonging to the nitroimidazole group bind to DNA and acts against gram-positive and gram-negative anaerobes. Ciprofloxacin is categorized under fluoroquinolone group acts by inhibiting DNA Gyrase and facilitating the destruction of gram-negative organisms. Minocycline is a broad-spectrum antibiotic that inhibits protein synthesis, collagenases, and matrix metalloproteinase. It destroys gram-positive as well as gram-negative microorganisms and spirochetes. Propylene glycol and macrogol were mixed in a 1:1 ratio by volume. A ratio of 7:1 by volume was used for mixing the powder and vehicle to create the wildly used paste. This paste is usually referred to as triple antibiotic paste, TAP, 3mix, or 3mix MP in reference to the vehicle used to deliver it into the canal. [5-10]

Discoloration, which occurs due to the photo-induced reaction, being a disadvantage of minocycline, antibiotics like amoxicillin, cefaclor, cefroxadine, fosfomycin or rokitamycin can be used as alternatives. Similar success rates have been reported with other replacements.[12] Therefore, the American Academy of Pediatric Dentistry AAPD Guidelines on Use of Non-Vital Pulp Therapies in Primary Teeth recommends antibiotic mixtures used in LSTR should not include tetracycline. [11]. Statins are structural analogs of HMG-CoA- (3-hydroxyl-3-methylglutaryl-CoenzymeA). These drugs are the first line for hyperlipidemia and have been recognized as a safe and low-priced drug due to their long-time worldwide usage.[13]

Statins exert various beneficial effects on different aspects of oral health including their positive effects on bone metabolism, their anti-inflammatory and antioxidant properties, and their potential effects on epithelization and wound healing. Additionally, they possess antimicrobial, antiviral, and fungicidal properties. Results of an extensive review by Tahamtan et al., 2020 have indicated that statins possess a promising effect on several aspects of dental and oral health, including chronic periodontitis, alveolar bone loss due to either extraction or chronic periodontitis, osseointegration of implants, dental pulp cells, orthodontic tooth movement, and orthodontic relapse, tissue healing (wound/bone healing), salivary gland function, and finally, anti-cancer effects. [14]. Within the present study, the use of TAP and simvastatin as components of root canal filling material was examined.

Materials and Methods

30 children with a total number of 30 primary second molars showing signs and symptoms of odontogenic infection and inflammatory root resorption were enrolled in this study from the Outpatient's Clinic of Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University, according to the following eligibility criteria:

Inclusion criteria

Young cooperative patients with no history of systemic disease that may contraindicate pulp therapy with an age range of 5-7 years. Patient has to have at least one restorable second primary molar that exhibits signs and symptoms of odontogenic infection with inflammatory root resorption and requires pulpectomy and the patient's parents are willing to participate in this study and will be able to follow up.

Clinical Criteria include

- Spontaneous pain
- Intraoral Abscess
- Extraoral Abscess
- Tender to percussion
- Presence of abnormal mobility other than that associated with exfoliation

Radiographic Criteria include

- Radiolucency in furcation area
- Periapical root resorption or excessive bone destruction and/or perforation in the coronal third of roots due to infective or inflammatory conditions.

Exclusion criteria

Patients with systemic disease or those who cannot attend follow up were excluded. Primary molars that are unrestorable or exhibited pathology of permanent tooth follicle were also excluded. Selection bias was avoided by randomization and allocation concealment. Performance bias was reduced by following a standardized treatment protocol for both study groups performed by the same operator (principal researcher). Ascertainment bias was avoided by blinding the radiographic outcomes' assessor and one of the clinical outcomes' assessors. Selective reporting bias was avoided by reporting all the collected data to the blinded statistician.

Construction of the Radiographic Stents

An individualized radiographic stent was fabricated for each patient and combined with an Extension Cone Paralleling (XCP) dental x-ray film positioning devices for a standardized digital radiographic recording of the eligible molars.

First Appointment: Pulp extirpation and instrumentation

Each tooth was anesthetized by applying topical anesthesia (20% benzocaine) at the site of needle insertion, followed using 4% articaine (Articaine (D.C.I) 40.00mg hydrochloride, Epinephrine (D.C.I) (tartrate) 0.01mg) using a disposable needle and metallic dental syringe. Involved teeth were isolated using a rubber dam, then access cavity and deroofing of the pulp chamber were performed using a water-cooled high-speed round carbide bur then flaring using an Endo Z bur for better visibility of the root canals. Sharp excavator was used to remove any remnants of necrotic tissue. Necrotic pulpal tissues were then removed, and careful instrumentation was performed using manual endodontic k-files sizes 15, 20, 25, 30, respectively. Root length was determined by the aid of the endodontic file positioned loosely in the canal and using conventional periapical radiographs. Instrumentation was carried out 1 mm short of the apex. (Using side vented needles (single vented), the root canals were passively irrigated first with 2% Chlorohexidine (20ml for 5 min), followed by sterile physiological saline (5ml). The root canals were dried with paper points to prepare the canals to receive the intracanal obturating mix. Placement of the intracanal obturating mix was done according to which group the tooth was allocated to either Tri-antibiotic mix (Group I) or Simvastatin (Group II).

Preparation of Intracanal obturation Mix

The measurements were done by an analytical balance with 0.1 mg accuracy. The preparation process was trained and supervised by a consultant pharmacist. The mixtures were stored in dark, tightly sealed containers.

Preparation of Triple Antibiotic Mix

Triple antibiotic Mix was prepared by mixing three commercially available antibiotics; ciprofloxacin (Memphis for pharmaceuticals and chemical industries co, Egypt), metronidazole (Sanofi co, Egypt) and cefixime (Hikma Pharm co, Egypt). Minocycline was replaced by cefixime because of its contraindication in children. After removal of the capsules or coating materials that enclosed the drug products, they were pulverized to fine powders using autoclavable mortars and pestles. In order to prepare the antibiotic mix for each patient. Two scoops of each antibiotic were dispensed onto a glass slab. This was determined by pre-measuring the capacity of the scoop on a scale with 0.1 mg accuracy. The capacity of each scoop of powder found to be about 0.15 mg.

Preparation of Simvastatin

Simvastatin pure powder (EGYPHAR, Egypt) is stored in a dark container. The optimal dose for Simvastatin is: 0.1μM Since the amount of simvastatin powder in a dose is difficult to measure (0.00042 g) accurately, a decision was made to prepare 10 ml of a stock solution by adding 0.418 g of simvastatin to 10 ml of physiologic saline. The stock solution is prepared weekly and kept in the refrigerator at 2-8 °C. To obtain the amount required in a single dose, a micropipette was used to draw 0.1 ml of solution (100μL setting). Zinc Oxide Powder and vehicles are added to obtain a workable mix. Zinc Oxide Powder: was

added to improve the radiopacity of the mix and allow it to be formed into a homogenous packable mass. Vehicle used was Propylene glycol and Polyethylene glycol. The Powder to vehicle ratio in the triple antibiotic mix in our study was 7:1. The components are placed on a clean, dry, polished glass slab or paper pad and mixed using a stainless-steel spatula to form a homogenous paste. The access cavity is then sealed with a thick Medicem Glass ionomer cement mix.

Second Appointment (1 week later)

A clinical evaluation was done. If there were signs and symptoms of persistent infection (in terms of persistence of pain, swelling, sinus, or fistula), the temporary restorative material was removed, and the intracanal dressing was refreshed for another 2 weeks. Otherwise, the tooth was prepared to receive a stainless-steel crown. Using wheel stone, needle stone, and tapered round stone size 11. The stainless steel was cemented using Medicem Glass ionomer cement. Full mouth treatment in addition to preventive measures was offered to all participants. Patients were instructed to follow up on the tooth one year after the end of the trial.

Follow-up Protocol

All patients were planned to be recalled for clinical follow-up after 3 months, 6 months, and 12 months. Radiographic follow-up was planned to be at 6 months and 12 months. The criteria of a failed pulp treatment have been defined as any case that required retreatment or extraction after completing the pulpectomy procedure. All treated teeth were evaluated for clinical success criteria such as absence of pain associated or tenderness to percussion , no abnormal mobility (Grade 1: Acceptable, Grade 2: Questionable; Grade 3 Failure), absence of swelling and fistula. To consider clinical success, all clinical criteria should be present. Otherwise, it will be considered a failure. Radiographic Success Criteria included absence or decrease of furcation radiolucency, absence or decrease of radicular radiolucency, absence of internal/external root resorption or other pathological changes.

Measurement of Bone density

Images of the treated teeth were manipulated using specially designed software of the DIGORA system. Bone density changes in Region of Interest ROI measured using Digora image analysis software, i.e., Digora for windows. Relative pixel values using an 8-bit scale from full black (0) to full white (255). The first step was to calibrate the image by drawing a line that joins the boundaries of the image. Then, the software calculates the included number of pixels, and a value is entered corresponding to the width of the phosphor plate sensor used. In this case, it was a size 0 sensor whose width corresponds to 1.3758 inches. In the next step to measure bone density, a region of interest is drawn in the furcation area of the primary molar, and its coordinates are recorded to include the bone without including the roots or the supporting structures. It is worth noting that the coordinates of the ROI were customized for each case according to the amount of available bone. Finally, the average density of each digital image was recorded

to calculate the change in bone density in the given area between the preoperative and the follow-up images for each case individually

Criteria for Discontinuing or Modifying Intervention

In case of unsuccessful clinical outcomes, including any signs that the infection of the pulp extends beyond the apex, such as the presence of a soft tissue/dentoalveolar abscess and/or sinus, the tooth will be extracted and excluded from the study. Post-operative pain and flare-up will not be considered a clinical failure as it is within excepted squeale of pulp therapy in primary teeth.

Results

The results of the current study were interpreted using per-protocol analysis. All qualitative data were presented as frequency & percentages; all comparisons were performed by using the Chi-square test. All quantitative data were presented as mean & standard deviation and explored for normality by using Shapiro Wilk and Kolmogorov-Smirnov normality test, which revealed that all data is parametric data (P-value > 0.05). The P-value was considered statistically significant if less than or equal to 0.05, while not statistically significant if greater than 0.05. For both groups, there was a significant difference between success & failure regarding the clinical outcome as P < 0.05 (success was significantly higher than failure) while in radiographic & overall there was an insignificant difference between them as P > 0.05. Comparison between both groups regarding success and failure was performed and revealed an insignificant difference in the clinical, radiographic, and overall outcome, as presented in table (1).

Table 1
Comparison between both groups regarding success and failure of clinical, radiographic, and overall outcomes

		Group I		Group II		P-value
		N	%	N	%	
Clinical	Failure	2	18.2	1	7.7	0.41
	Success	9	81.8	12	92.3	0.38
Radiographic	Failure	4	36.4	3	23.1	0.44
	Success	7	63.6	10	76.9	0.43
Overall	Failure	4	36.4	3	23.1	0.44
	Success	7	63.6	10	76.9	0.43

N: count %: percentage P: probability level, which is significant at P ≤ 0.05

Comparison between both groups revealed an insignificant difference in different failure causes & in flare up, as presented in figure (1).

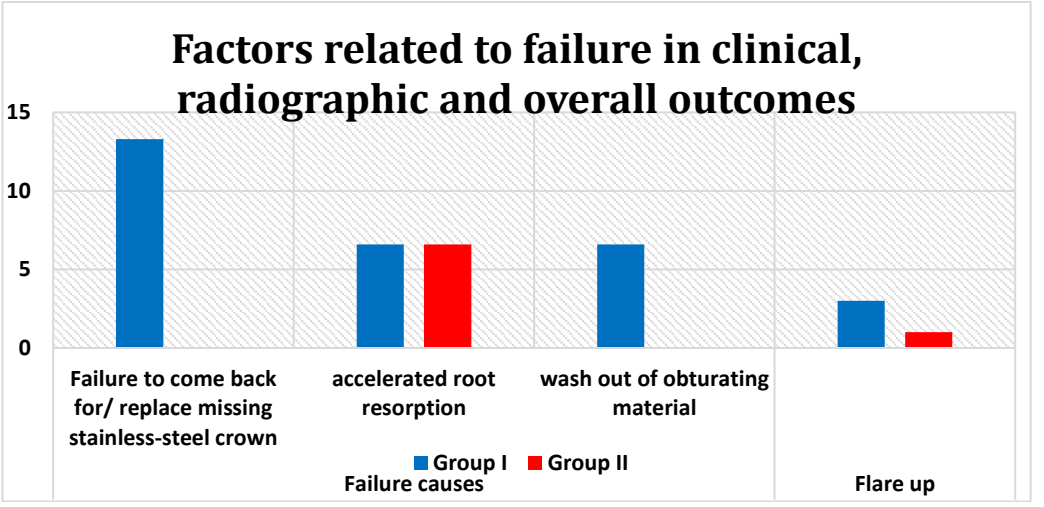

Figure 1. Comparison between two groups regarding factors related to failure in clinical, radiographic, and overall outcomes

Comparison between both groups regarding bone density at furcation area revealed that group I was significantly higher than group II as $P < 0.05$ preoperatively and after 6 months, while after 12 months there was insignificant difference between both groups as presented in figure (2)

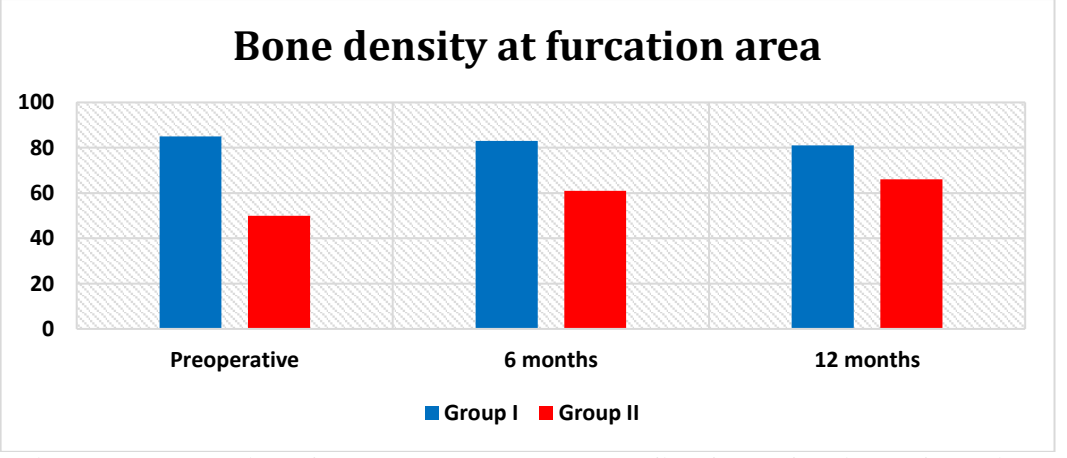

Figure 2. Comparison between two groups regarding bone density at furcation area during follow-up.

Comparison between both groups regarding percentage of changes in bone density at furcation area revealed significant difference between them in (preoperative- 6 months) and (preoperative- 12 months) only as $P < 0.05$. In all Group II was significantly higher than group I, as presented in table (2).

Table 2
Comparison between two groups regarding % of changes in bone density at furcation area during follow up

% of change	Group I	Group II	P value
Preoperative – 6 months	-2.30%	22%	0.04*
6 months – 12 months	-2.40%	8.10%	0.2
Preoperative – 12 months	-4.70%	32%	0.01*

There was a significant difference in the percentage of change in bone density in furcation area group III at 32%. In comparison, there was a non-significant difference between groups I and II at -.4.7% and 0.0%, respectfully.

Discussion

Modern pediatric dentistry's major goal is to retain the primary dentition's integrity until natural exfoliation in order to preserve function, aesthetics, and phonetics. A pulpectomy is the preferred treatment for radicular canals with partial or total irreversible pulpitis or necrotic pulp, provided the tooth is restorable. However, the existence of tortuous canals with numerous lateral and apical ramifications, as well as persistent polymicrobial infection, makes it challenging to treat in primary teeth. Both preoperative and post-operative factors can have an impact on the prognosis of pulpectomized teeth. Inflammatory root resorption and preoperative radiolucency were two factors that were found to have a significant effect on the survival rate of pulpectomized teeth. This study investigates the survival rate, as evidenced by both clinical and radiographic outcomes, of primary molars with inflammatory root resorption and furcal preoperative radiolucency treated with either a triple antibiotic mix or simvastatin.

The participants in this study ranged in age from 5-7 years old with the mean age for each Group as follows 5.93 ± 0.799 Group I, 5.67 ± 0.724 Group II, 5.87 ± 0.915 Group III. This selection was based on several factors, namely the age at which physiologic root resorption starts at about seven years old for primary molars, as well as the high prevalence of dental caries among this age group.[15] For Egyptian children, the prevalence of dental caries was reported between 60-70 %, with the highest percentage reported among 5-7-year-old children. [16] Age was also selected to ensure patient cooperation .The choice of second primary mandibular molars for this study was also based on several factors. It is easier to identify radiographic pathology as well as radiographic healing more precisely in mandibular rather than maxillary molars due to overlapping of the permanent tooth germ and the palatal root of the primary molar on the interradicular bone.[17] A wide range of morphologic variations and frequency of non-typical morphology has been reported increasingly in mandibular primary second molars dictating the use of disinfectant irrigants and root canal fillings with high antibacterial efficacies to decrease failures arising from these inaccessible areas. [18]

The degree of primary tooth root resorption was found to be the most critical preoperative predictor of pulpectomy success. Only 23.1 percent of those with

more than 1 mm of root resorption succeeded, which was significant (P = 0.001). Songvejkasem et al. found that teeth with a preoperative radiolucency were 3.9 times more likely than teeth with less severe or no pathology on preoperative radiography to be extracted or retreated.[19]. Radiographic examination was performed preoperatively, immediately postoperatively, and at 6- and 12-months follow-up intervals. Periapical radiographs were used since it is considered the practical detection method for root resorption, periapical tissue, periodontal status, osseous defects, and any changes in the surrounding structures. An extension cone paralleling (XCP) film holder for the posterior teeth was used, as well as a customized X-ray positioning stent to provide reliable linear measurements and reproducible, standardized images suitable for follow-up analysis.[20]

Lesion sterilization and tissue repair was the treatment of choice for primary teeth included in this study. Numerous studies reported that the superiority of one treatment over the other could not be determined. [21, 22] However, the systematic review and meta-analysis by Coll et al. 2020 reported a significant difference (P=0.001) for teeth with external or internal root resorption favoring LSTR. The LSTR success rate was 76 % compared to the pulpectomy success rate of 47%. This included teeth where the canals were filed or not before antibiotic placement for LSTR.[11]. Although LSTR is traditionally a non-instrumentation technique, several studies advocated that removal of non-vital pulp tissue from root canals might improve the outcome. Prabharkar et al. demonstrated a statistically significant difference when comparing the application of non-mechanical instrumentation and mixed antibiotic paste in primary teeth with and without root pulp extirpation favoring the group where radicular pulp tissue was extirpated. [23] As antibiotic resistance has become an emerging global problem these days, the development of multidrug-resistant strains may decrease the success of this treatment modality. Hence, the value of mechanical debridement in ultimate success is immense. Accordingly, the root canal was instrumented cautiously within 1 mm of the working length within this study.

The obturation mix for each of the two groups consisted of an active component mixed with a vehicle and zinc oxide. The zinc oxide was incorporated in the mix to obtain a workable mix as well radiopacity for easier radiographic detection. [24] Propylene glycol and macrogol were used as a vehicle in 1:1 ratio by volume. This vehicle can act as a solvent, enhancing better diffusion of the drugs deep into the dentinal tubules, thus enhancing the antimicrobial action, which explains their use in the majority of studies.[25]. The active component in Group I was a triple antibiotic mix TAP. Its components were Metronidazole, ciprofloxacin and cefexime. The present mix contained cefixime replacing the traditionally used minocycline since it is an acceptable alternative. The three antibiotics were mixed in a 1:1:1 ratio. [26]

For the intervention group II, Simvastatin was selected for the numerous advantages of being anti-inflammatory, bioinductive by inhibiting bone resorption and osteocyte apoptosis and stimulating angiogenesis. Researchers found that simvastatin could accelerate bone regeneration and soft tissue healing by increasing osteoblastic differentiation and stimulating neovascularization via its influence on bone morphogenetic proteins and endothelial growth factors. Statins

may also show the anti-inflammatory effect by inhibiting the tissue degrading enzymes like matrix metalloproteinase (MMPs). Statins can stimulate bone formation by stimulating the production of bone morphogenetic protein-2 (BMP-2), which may be the reason for the radiographic improvement observed in this study in Group II. [27]. To the best of our knowledge, no studies were conducted where simvastatin was used to obturate root canals; hence drawing an exact cross-comparison is difficult. However, several studies showed that the root canals of non-vital teeth were instrumented, and triple antibiotic paste was used to obturate.

Clinical success rates were higher for Group II at 92.3%, while for Group I they were 81.8%. The radiographic success rate was also higher for Group II at 76.9% and 63.6% for Group I. The difference between them was considered to be insignificant. The variation between clinical and radiographic success rates for all groups is explained by the repair of damaged tissues which can be expected if lesions are disinfected. LSTR has shown a high clinical success rate in primary dentition as a substitute for pulpectomy. However, radiographic success is questionable in long-term follow-up.[23]

According to the AAPD, 2020 guidelines for pulp therapy, radiographic signs should resolve within 6 months, as evidenced by bone deposition in the radiolucent pretreatment areas. This was reflected within the present study with the decrease in furcation radiolucency with a significant difference between them in (preoperative- 6 months) and (preoperative- 12 months) only as $P < 0.05$. For Group, I 81% (N=9) of cases exhibited a decrease in radiolucency as compared to 66.7% (N=8) in Group II. For 12 Months, Group I dropped to 72.7% (N=8) while there was no change in Group III at 76.9% (N=10). The decrease in furcation radiolucency can be explained by the removal of infected pulp tissue from the root canals and the properties of each drug in the antibacterial combination. The drop exhibited in Group I was explained by Beniwal et al., 2019 as being due to an inflammatory response to the drugs being used, as it has been already documented that the medicament can produce vascular changes in the pulp leading to granulation tissue formation.[28] The number of cases that exhibited new furcation lesions was 44% compared to only 8.3% in the present study.

Although the success rates within this study are considered to be slightly lower than most studies, they were comparable to most studies whose exclusion criteria included teeth exhibiting root resorption like Doneria et al., 2017; Lokade et al., 2019. [29,30] Furthermore, the success rate within this study for the use of TAP in poor prognosis molars was higher than that reported by Beniwal et al., 2019, which was 76% clinically and 44%radiographically.[28] Therefore, it can be considered an improvement in the outcome of teeth exhibiting inflammatory root resorption and preoperative radiolucencies and necrotic teeth, which are considered to be of poor prognosis. Factors related to failure include failure to come back for a stainless steel crown (Group I N=2, 13%), (Group II, N=1 6.6%) accelerated root resorption (N=1, 6.6%) for both groups as evidenced by abnormal mobility, and wash out of obturating material (Group I, N=1 6.6%),(Group II = 3, 20 %). Failures related to failed or absent restoration were also reported by Daher et al., 2015 [31]. Washout of obturating material is also known as the hollow tube effect and is already a concern in LSTR where the canals were not filled. Empty

root canals may be infused with tissue fluids, becoming stagnant and eventually forming a nidus for infection.[32]. Most cases with washout of obturating material were reported in Group II, perhaps contributing to the lowest radiographic success rate among the two groups .

Conclusion

- The use of both triple antibiotic paste, and simvastatin have shown improved survival rate in primary molars presenting with inflammatory root resorption or pretreatment radiolucency
- Simvastatin shows promise as a component in root filling materials of primary molars requiring non-vital pulp treatment since it is a biocompatible material with anti-inflammatory and osteogenic properties. It may be considered as a suitable alternative to triple antibiotic paste in teeth undergoing lesion sterilization and tissue repair (LSTR)

References

1. Kher, M. S., Rao, A. (2020). “Pulp therapy in primary teeth.” Clinical Dentistry Reviewed, 4, 16.
2. Pawar, B., Pawar, A., Bhardwaj, A., Wahjuningrum, D., Rahardjo, A., & Luke, A. (2021). “Effect of adaptive, rotary, and manual root canal instrumentation in primary molars: A triple-armed, randomized controlled clinical trial”. Biology, 10(1), 42.
3. Navit, S., Jaiswal, N., Khan, S. A., Malhotra, S., Sharma, A., Mukesh, Jabeen, S., & Agarwal, G. (2016). “Antimicrobial efficacy of contemporary obturating materials used in primary teeth- An in-vitro study.” Journal of Clinical and Diagnostic Research, 10(9), ZC09–ZC12.
4. Lopes-Fatturi, A., de Souza, J. F., Menezes, J. V. N. B., Fraiz, F. C., & Assunção, L. R. S. (2020).” A survival analysis of different pulp therapies in decayed primary teeth”. Pesquisa Brasileira em Odontopediatria e Clínica Integrada, 20(4), e4822.
5. Hoshino, E., Kota, K., Sato, M., & Iwaku, M. (1988). Bactericidal efficacy of metronidazole against bacteria of human carious dentin in vitro. Caries Research, 22, 280–282.
6. Sato, T., Hoshino, E., Uematsu, H., & Noda, T. (1993). “In vitro antimicrobial susceptibility to combinations of drugs on bacteria from carious and endodontic lesions of human deciduous teeth”. Oral Microbiology and Immunology, 8, 172–176.
7. Sato, I., Ando-Kurihara, N., Kota, K., Iwaku, M., & Hoshino, E. (1996). “Sterilization of infected root-canal dentine by topical application of a mixture of ciprofloxacin, metronidazole and minocycline in situ”. International Endodontics Journal, 29(2):118–124.
8. Hoshino, E., Kurihara-Ando, N., Sato, I., Uematsu, H., Sato, M., Kota, K., Iwaku, M. (1996). “In-vitro antibacterial susceptibility of bacteria taken from infected root dentine to a mixture of Ciprofloxacin, Metronidazole and Minocycline”. International Endodontic Journal, 29(2), 125–130.
9. Takushige, T., Cruz, E. V., Asgor Moral, A., & Hoshino, E. (2004). “Endodontic treatment of primary teeth using a combination of antibacterial drugs.” International Endodontic Journal, 37, 132–138.

10. Takushige, T., Hataoka, H., Ando, M., & Hoshino, E. (2009). “Endodontic retreatment using 3 Mix-MP without removal of previous root canal obturation.” Journal of LSTR Therapy, 8, 3–7.
11. Coll, J. A., Dhar, V., Vargas, K., Chen, C. Y., Crystal, Y. O., AlShamli, S., & Marghalani, A. A. (2020). “Use of non-vital pulp therapies in primary teeth”. Pediatric Dentistry, 42(5), 337–349.
12. Kim J, Kim Y, Shin S, Park J, Jung I. (2010) “Tooth discoloration of immature permanent incisor associated with triple antibiotic therapy: a case report”. J Endod. 36:1086–1091
13. Murthy, P., Bhojraj, N., & Hegde, U. (2020). “Pattern of physiologic root resorption in deciduous teeth at different stages.” Journal of Clinical and Diagnostic Research.
14. Tahamtan, S., Shirban, F., Bagherniya, M., Johnston, T., & Sahebkar, A. (2020). “The effects of statins on dental and oral health: A review of preclinical and clinical studies.” Journal of Translational Medicine, 18(1).
15. Peretz, B., Nisan, S., Herteanu, L., & Blumer, S. (2013). “Root resorption patterns of primary mandibular molars and location of the premolar successors: A radiographic evaluation. Pediatric Dentistry”, 35(5), 426–429.
16. Abbass, M., Mahmoud, S. A., El Moshy, S., Rady, D., AbuBakr, N., Radwan, I. A., Ahmed, A., Abdou, A., & Al Jawaldeh, A. (2019) ”The prevalence of dental caries among Egyptian children and adolescences and its association with age, socioeconomic status, dietary habits and other risk factors. A cross-sectional study.” F1000 Research, 8, 8.
17. Yousry, Y., Abd Al Latif, A., Abd Al Gawad, R. (2021). “Clinical and radiographic evaluation of vital pulpotomy in primary molar using antioxidant mix as a novel pulpotomy medication versus formcresol: A randomized clinical trial.” Advanced Dental Journal, 3(1), 12–2
18. Ziya, M., Yüksel, B., & Sarı, Ş. (2019). “Root canal morphology of mandibular primary molars: A micro-CT study”. Cumhuriyet Dental Journal. DOI: 10.7126/cumudj.615843
19. Songvejkasem, M., Auychai, P., Chankanka, O., & Songsiripradubboon, S. (2021). “Survival rate and associated factors affecting pulpectomy treatment outcome in primary teeth. Clinical And Experimental Dental Research,” 7(6), 978-986.
20. Sadek, S., Abbas, H., Alfelali, M., & Almahdali, A. (2020). “Using acrylic customized X-ray positioning stents for long-term follow-up studies.” The Saudi Dental Journal, 32(3), 120–128.
21. Duarte, M., Pires, P., Ferreira, D., Pintor, A., de Almeida Neves, A., Maia, L., & Primo, L. (2020). “Is there evidence for the use of lesion sterilization and tissue repair therapy in the endodontic treatment of primary teeth? A systematic review and meta-analyses.” Clinical Oral Investigations, 24(9), 2959-2972.
22. Moura J, Lima M, Nogueira N, et al. “LSTR antibiotic paste versus zinc oxide and eugenol pulpectomy for the treatment of primary molars with pulp necrosis: A randomized controlled trial.” Pediatr Dent 2021; 43(6):435-42
23. Prabhakar, A. R., Sridevi, E., Raju, O. S., Satish, V. (2008). “Endodontic treatment of primary teeth using combination of antibacterial drugs: An in vivo study.” Journal of the Indian Society of Pedodontics and Preventive Dentistry, 26(Suppl. 1), S5–S10.

24. Abdel Gawad, F. K. (2014). “Comparative clinical and radiographic study on the efficacy of photo-activated oral disinfection and triple antibiotic mix in the management of primary molars” [Unpublished Doctoral dissertation]. Cairo University, Cairo, Egypt.
25. Jayam, C., Bandlapalli, A., Rao, H. M., & Kapil, S. (2014). “Lesion sterilization and tissue repair (LSTR): A review.” Journal of Scientific Dentistry, 4, 49–55.
26. Aminabadi, N., Huang, B., Samiei, M., Agheli, S., Jamali, Z., & Shirazi, S. (2016). “A randomized trial using 3Mixtatin compared to MTA in primary molars with inflammatory root resorption: A novel endodontic biomaterial”. Journal of Clinical Pediatric Dentistry, 40(2), 95–102.
27. Gupta, S., Del Fabbro, M., & Chang, J. (2019). “The impact of Simvastatin intervention on the healing of bone, soft tissue, and TMJ cartilage in dentistry: A systematic review and meta-analysis.” International Journal of Implant Dentistry, 5, 17.
28. Beniwal, P., Kalra, N., Tyagi, R., & Khatri, A. (2020). “Pulp therapy of primary molars using lesion sterilization tissue repair and traditional endodontic treatment.” Saudi Journal of Oral Sciences, 7, 181–188.
29. Doneria, D., Thakur, S., Singhal, P., & Chauhan, D. (2017). “Comparative evaluation of clinical and radiological success of zinc oxide-ozonated oil, modified 3mix-mp antibiotic paste, and Vitapex as treatment options in primary molars requiring pulpectomy: An in vivo study”. Journal of the Indian Society of Pedodontics and Preventive Dentistry, 35, 346–352.
30. Lokade, A., Thakur, S., Singhal, P., Chauhan, D., & Jayam, C (2019). “Comparative evaluation of clinical andradiographic success of three different lesion sterilization and tissue repair techniques as treatment options in primary molars requiring pulpectomy: An in vivo study”. Journal of Indian Society of Pedodontics and Preventive Dentistry, 37, 185–191.
31. Daher, A., Viana, K., Leles, C., & Costa, L. (2015). “Ineffectiveness of antibiotic-based pulpotomy for primary molars: A survival analysis”. Pesquisa Brasileira Em Odontopediatria E Clínica Integrada, 15(1), 205–215.
32. Suresh, S. (2021). “Lesion sterilization and tissue repair (LSTR) technique”. Academia Letters, 2.
33. Widana, I.K., Sumetri, N.W., Sutapa, I.K., Suryasa, W. (2021). Anthropometric measures for better cardiovascular and musculoskeletal health. *Computer Applications in Engineering Education*, *29*(3), 550–561. https://doi.org/10.1002/cae.22202
34. Yuriah, S., Kartini, F., & Isnaeni, Y. (2022). Experiences of women with preeclampsia. International Journal of Health & Medical Sciences, 5(3), 201-210. https://doi.org/10.21744/ijhms.v5n3.1901