ORIGINAL RESEARCH

Success of Lesion Sterilization and Tissue Repair Therapy and Pulpectomy in the Management of Infected Primary Molars with Poor Prognosis

Iram Sefa[1], Nishita Garg[2], Lumbini Pathivada[3], Ramakrishna Yeluri[4]

Abstract

Background and aim: To establish lesion sterilization and tissue repair (LSTR) therapy as an alternate treatment option in managing infected primary molars with poor prognosis that were indicated for extraction, thereby fulfilling the objective of retaining the primary tooth till its normal exfoliation in the dental arch.

Materials and methods: A total of 84 children who met the inclusion criteria requiring extraction in 142 teeth involving primary molars were included in the study. The selected patients were allocated to two groups, that is, group I—LSTR therapy with 3Mix-MP paste and group II—pulpectomy with metapex. All the treated teeth were then clinically and radiographically evaluated after 1, 3, 6, 9, and 12 months, respectively, to determine the success between groups I and II. Pearson's Chi-squared test along with the z-test was used to compare the clinical and radiographic success of the two groups ($p < 0.05$).

Results: Pain and tenderness were completely resolved within one month of follow-up in both groups. Abscesses were resolved completely at 1 month in the pulpectomy group and mobility was resolved at 6 months follow-up in both groups. Interradicular and periradicular radiolucency persisted even at 12 months of the follow-up period in both groups. The intergroup comparison revealed no statistical differences between LSTR and pulpectomy procedure and both were equally effective at all time intervals ($p > 0.05$).

Conclusion: Both LSTR therapy with 3Mix-MP and pulpectomy with metapex showed 100% clinical success rates. Radiographically no changes were observed even at the 12-month follow-up period in both groups. LSTR therapy can be an alternative treatment option for pulpally involved primary teeth with poor prognosis and in cases where mechanical instrumentation could not be achieved due to physiologic root resorption.

Keywords: 3Mix-MP, Lesion sterilization and tissue repair therapy, Noninstrumentation endodontic treatment, Primary teeth.

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Introduction

Early childhood caries is a distinct type of widespread decay of the deciduous teeth, defined as a lesion with a rapid onset destroying the coronal tissue of many or all of the erupted with many showing signs of early involvement of the pulp.[1] Atypical anatomy of the primary teeth, such as increased permeability, reduced hardness, and decreased enamel and dentin thickness, further promote quick spread of infectious processes in the pulpal tissue, thereby initiating root resorption and inflammatory process.[2] Enhanced destruction of the coronal structure leading to infection of the pulp tissue which progresses to chronic abscesses can progress toward complete destruction of the primary dentition.

Usually, infected teeth with extensive destruction of the tooth surface, limited bone support, extensive resorption of the root, increased internal or external resorption, and infection in the furcal or periapical area close to the succedaneous tooth crypt are considered for extraction.[3–5] However, premature loss of deciduous dentition may lead to various problems, such as drifting of erupted teeth, ectopic eruption, disturbed eruption sequence, loss of space for the succedaneous teeth, development of aberrant habits, speech alterations, and impaired function.[6] Hence, it becomes necessary to maintain primary dentition and make them disease-free and capable of normal functioning. Primary teeth with poor prognosis have been advocated for extraction followed by placement of space maintainers. However, there are some disadvantages of these appliances, like cost effectiveness, lack of oral hygiene care, and being nonfunctional in nature. Successful sterilization and restoration of an intact tooth clinically is definitely superior to any other space maintainer.[7]

In cases where the prognosis is poor and indicated for extraction, an optional therapy was developed in 2004, that is noninstrumentation endodontic treatment (NIET) "lesion

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sterilization and tissue repair (LSTR)," by Niigata University School of Dentistry's Cariology Research Unit located in Japan.[8] This novel therapy is simple and less time-consuming, and has no use of mechanical instruments; therefore, the periapical tissues are not harmed due to over-instrumentation. This technique utilizes a mixture of three antibiotics (3Mix-MP) as a potion to get rid of the persisting microorganisms in endodontic lesions. The constituents of this paste are ciprofloxacin, minocycline, and metronidazole (3Mix)—mixed with propylene glycol (P) as a carrier and macrogol (M) as the medicament base. It is expected that if lesions are disinfected it can lead to repair of the damaged tissues.[8] It is evident from the existing literature that LSTR therapy can be used efficiently for the disinfection of the canal and successfully treat the periapical lesion. To the best of our knowledge there are only a few studies[6,9–11] available in the literature; comparing the success rate of LSTR therapy and pulpectomy in deciduous molars. There is no consensus regarding the use of LSTR treatment in place of pulpectomy in infected primary molars with poor prognosis. The aim of this experiment was to investigate the outcomes of LSTR therapy and pulpectomy in the management of infected primary molars both clinically as well as radiographically.

Materials and Methods

The present experiment proposal was submitted to the Institutional Ethics Committee for review and approval before the start of the experiment and was performed keeping in mind the declaration of Helsinki. Guardians/parents of the selected patients were given detailed information about the experiment including details about the materials being used along with their advantages, limitations, and drawbacks. They were then asked to sign a free informed consent form, allowing their children to participate in the study. A total of 168 children who reported to the pediatric and preventive dentistry department were screened. A total of 84 children in the age-group of 4–10 years meeting the chosen criteria; needing extraction in 142 teeth involving infected primary molars with poor prognosis were included in the study. For sample size calculation the power analysis was kept at >95%. The inclusion and exclusion criteria followed in this study were in accordance with Trairatvorakul and Detsomboonrat.[12] All the selected teeth were randomly[13] assigned to one of the two groups; group I (LSTR therapy) and group II (conventional pulpectomy procedure). The randomization process for this study was performed by the parent selecting one of the two colored stickouts from an opaque bag containing the name of the procedure (either LSTR therapy or conventional pulpectomy procedure) on the day of appointment with an allocation ratio of 1:1.

Preparation of 3Mix-MP Paste

Commercially available antibiotic drugs of metronidazole (Metrogyl, Ankleshwar, India), ciprofloxacin (Ciplox, Sikkim, India), and minocycline (Minolox, Hosur, India) were obtained and weighed using an electronic balance. The tablets' enteric coating was scraped off with the help of a Bard–Parker blade and weighed again. All three drugs were ground using a clean and disinfected mortar and pestle. The prepared powder was then sealed and stored in separate airtight containers till their use. Antibiotics were dispensed in the ratio of 1:1:1 as 3Mix and mixed with propylene glycol and macrogol (MP) to form a paste. The remaining 3Mix-MP paste was disposed of after the procedure.[14]

Lesion Sterilization and Tissue Repair Therapy Procedure

Local anesthesia (Lignox, 2% Adrenaline, Indoco Remedies Ltd., Mumbai, India) was administered and the tooth was isolated with the help of a rubber dam. A conventional method was used for access cavity preparation followed by the removal of necrotic coronal pulp. Sodium hypochlorite (NaOCl) with 2.5% concentration was used for irrigation of the pulp chamber. Hemostasis was achieved by placing little cotton balls soaked with 10% NaOCl above the pulp stumps if necessary. After drying the access cavity, 3Mix-MP paste was deposited on the pulpal floor and covered with restorative glass ionomer cement.[14]

Clinical Procedure of Pulpectomy

After the administration of local anesthesia and rubber dam isolation, the pulp chamber was opened with a no. 557 round bur and flat end tapered bur followed by removal of necrotic coronal pulp tissue and radicular pulp tissue. A diagnostic radiograph was taken to determine the working length using 15 no. K-file with a rubber stop. Chemomechanical preparation was done almost 2–3 mm from the apex. The canals were enlarged to 2 or 3 instrument sizes more than the first file. Irrigation for all the canals was done with 2.5% NaOCl between different instruments in order to remove debris. The canals were then dried with paper points. The prepared canals were filled with metapex (Meta Biomed Co. Ltd., Korea) followed by the placement of a restorative glass-ionomer cement. If, the presence of excessive bleeding or pus exudates was evident, on subsequent appointment obturation was done after proper irrigation with 2.5% hypochlorite.

Permanent restoration was done with the help of stainless-steel crowns for all the teeth. A postoperative intraoral periapical radiograph was indicated and served as a reference for comparison in future follow-up. All the teeth in both groups were followed up clinically and radiographically at 1, 3, 6, 9, and 12 months to evaluate the success of both treatment procedures based on predetermined criteria.[15]

Statistical Analysis

Statistical analysis of the collected tabulated information was done using the Statistical Packages for the Social Sciences (SPSS) (SPSS Inc., Chicago, Illinois) version 17 for Windows. Pearson's Chi-squared test was done for intergroup comparison and intragroup comparison was done using z-test for proportion. The significance level was kept at $p < 0.05$ for all the statistical analyses performed in this study.

Results

The average age of the study objects was recorded as 6.68 ± 1.55 years. The distribution of teeth assessed at various follow-up intervals; 1, 3, 6, 9, and 12 months is illustrated in Figure 1. The clinical and radiographic outcomes of primary molars treated by LSTR and pulpectomy at various time intervals can be observed in Tables 1 to 5. Pain and tenderness were completely resolved within 1 month of follow-up in both groups. Abscesses were resolved completely at 1 month in the pulpectomy group and mobility was resolved at 6 months follow-up in both groups. Regarding radiographic evaluation, it is evident from these tables that inter/periradicular radiolucency persisted even after 12 months in both groups (Figs 2 and 3). The intergroup comparison revealed no statistical differences between LSTR and pulpectomy procedure and both were equally effective at all time intervals ($p > 0.05$).

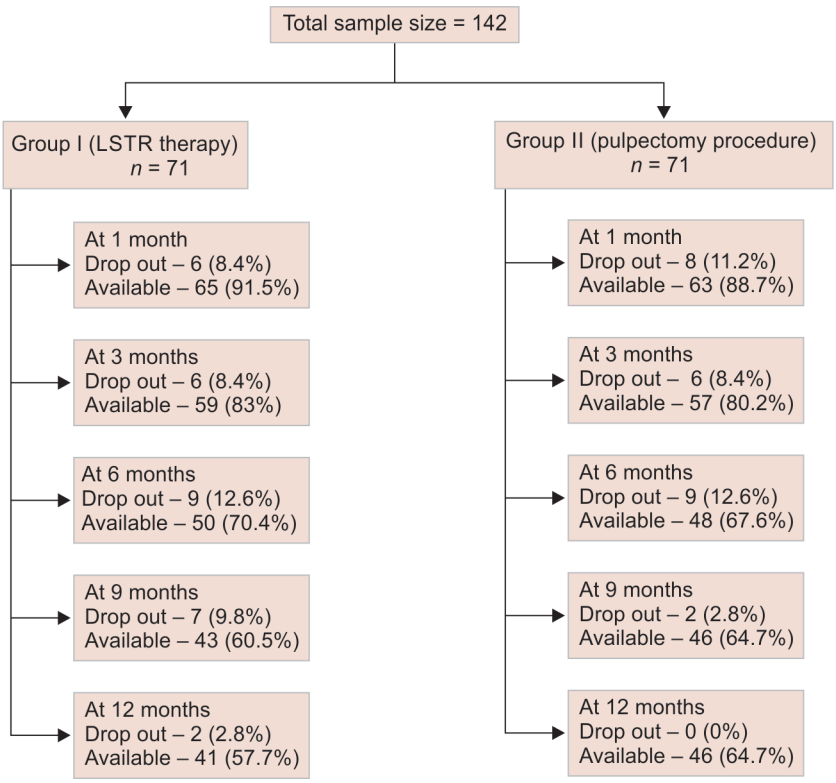


Fig. 1: Distribution of teeth available at various follow-up intervals (1, 3, 6, 9, and 12 months)

Table 1: Clinical and radiographic assessment of primary molars treated by LSTR therapy and pulpectomy at 1 month follow-up period

		Clinical criteria				*Radiographic criteria*
		Pain	*Tenderness*	*Abscess*	*Mobility*	*Inter/periradicular radiolucency*
Group I (LSTR) (*n* = 65)	Preoperative	60 (84.2%)	43 (60.5%)	39 (54.9%)	44 (61.9%)	71 (100%)
	1 month	0	0	3 (4.6%)	19 (29.2%)	65 (100%)
	p-value	NA	NA	<0.001*	0.002*	1.000
Group II (pulpectomy) (*n* = 63)	Preoperative	68 (95.7%)	56 (78.8%)	39 (54.9%)	46 (64.7%)	71 (100%)
	1 month	0	0	0	25 (39.6%)	63 (100%)
	p-value	NA	NA	NA	0.003*	1.000
Total (*n* = 128)	Preoperative	128 (90.1%)	99 (69.7%)	78 (54.9%)	90 (63.3%)	142 (100%)
	1 month	0	0	3 (2.3%)	44 (34.3%)	128 (100%)
Intergroup comparison	*p*-value	NA	NA	NA	0.635	1.000

*, significant; NA, not applicable

Discussion

Endodontic treatment in primary teeth remained controversial for several reasons. The perceived difficulty of behavior management in the pediatric population, appropriate timing of resorption of primary teeth, differences in form and function of primary and permanent teeth, and difficulties with obturation materials have added to the reluctance among clinicians to carry out the procedure.[7] Few cases do not show a favorable response to the established endodontic treatment protocol. This may be due to the variable anatomical features of the root canal system, antimicrobial resistance, and the presence of biofilm in the apical region.[16] Effective healing of the periradicular region can be achieved by proper sterilization[17,18] with the help of different antimicrobial mediums like intracanal drugs, irrigants, and comprehensive antibiotic concoctions. Using antibiotics locally, systemically, or as prophylaxis along with endodontic treatment can enhance the treatment results.[19] The oral intake of antibiotics is dependent on patient cooperation in maintaining a dosing schedule, its absorption through the digestive system, and dissemination through the blood to the infected site. So, it can be said that the infected area needs regular blood circulation for the antibiotics to act. This is not possible for cases with necrotic pulpal tissue and pulpless teeth. Hence, local administration of antimicrobial agents within the root canal of teeth may be a better technique for delivering the medicament.[11]

The NIET procedure is applied to the use of LSTR. This procedure uses antibacterial agents in combination with macrogol and propylene glycol as vehicles to introduce the antibacterials within the tooth.[8] Various studies[20,21] have shown that the dentinal matrix contains reservoirs of bioactive molecules and odontoblasts

Table 2: Clinical and radiographic assessment of primary molars treated by LSTR therapy and pulpectomy at 3 months follow-up period

		Clinical criteria				*Radiographic criteria*
		Pain	*Tenderness*	*Abscess*	*Mobility*	*Inter/periradicular radiolucency*
Group I (LSTR) (*n* = 59)	1 month	0	0	3 (4.6%)	19 (29.2%)	65 (100%)
	3 months	0	0	0	8 (13.5%)	59 (100%)
	p-value	NA	NA	NA	0.109	1.000
Group II (pulpectomy) (*n* = 57)	1 month	0	0	0	25 (39.6%)	63 (100%)
	3 months	0	0	0	11 (19.2%)	57 (100%)
	p-value	NA	NA	NA	0.039*	1.000
Total (*n* = 116)	1 month	0	0	3 (2.3%)	65 (50.7%)	128 (100%)
	3 months	0	0	0	19 (16.3%)	116 (100%)
Intergroup comparison	*p*-value	NA	NA	NA	1.000	1.000

NA, not applicable, *, significant

Table 3: Clinical and radiographic assessment of primary molars treated by LSTR therapy and pulpectomy at 6 months follow-up period

		Clinical criteria				*Radiographic criteria*
		Pain	*Tenderness*	*Abscess*	*Mobility*	*Inter/periradicular radiolucency*
Group I (LSTR) (*n* = 50)	3 months	0	0	0	8 (13.5%)	59 (100%)
	6 months	0	0	0	0	50 (100%)
	p-value	NA	NA	NA	NA	1.000
Group II (pulpectomy) (*n* = 48)	3 months	0	0	0	11 (19.2%)	57 (100%)
	6 months	0	0	0	0	48 (100%)
	p-value	NA	NA	NA	NA	1.000
Total (*n* = 98)	3 months	0	0	0	19 (16.3%)	116 (100%)
	6 months	0	0	0	0	98 (100%)
Intergroup comparison	*p*-value	NA	NA	NA	NA	1.000

NA, not applicable

Table 4: Clinical and radiographic assessment of primary molars treated by LSTR therapy and pulpectomy at 9 months follow-up period

		Clinical criteria				*Radiographic criteria*
		Pain	*Tenderness*	*Abscess*	*Mobility*	*Inter/periradicular radiolucency*
Group I (LSTR) (*n* = 43)	6 months	0	0	0	0	50 (100%)
	9 months	0	0	0	0	43 (100%)
	p-value	NA	NA	NA	NA	1.000
Group II (pulpectomy) (*n* = 46)	6 months	0	0	0	0	48 (100%)
	9 months	0	0	0	0	46 (100%)
	p-value	NA	NA	NA	NA	1.000
Total (*n* = 89)	6 months	0	0	0	0	98 (100%)
	9 months	0	0	0	0	89 (100%)
Intergroup comparison	*p*-value	NA	NA	NA	NA	1.000

NA, not applicable

which have the capability of directly repairing tissues. Therefore, sterilization of infected pulp tissue can help to maintain and preserve a reservoir source of growth factors secreted by functional odontoblast and pulp fibroblast in the dentin matrix.

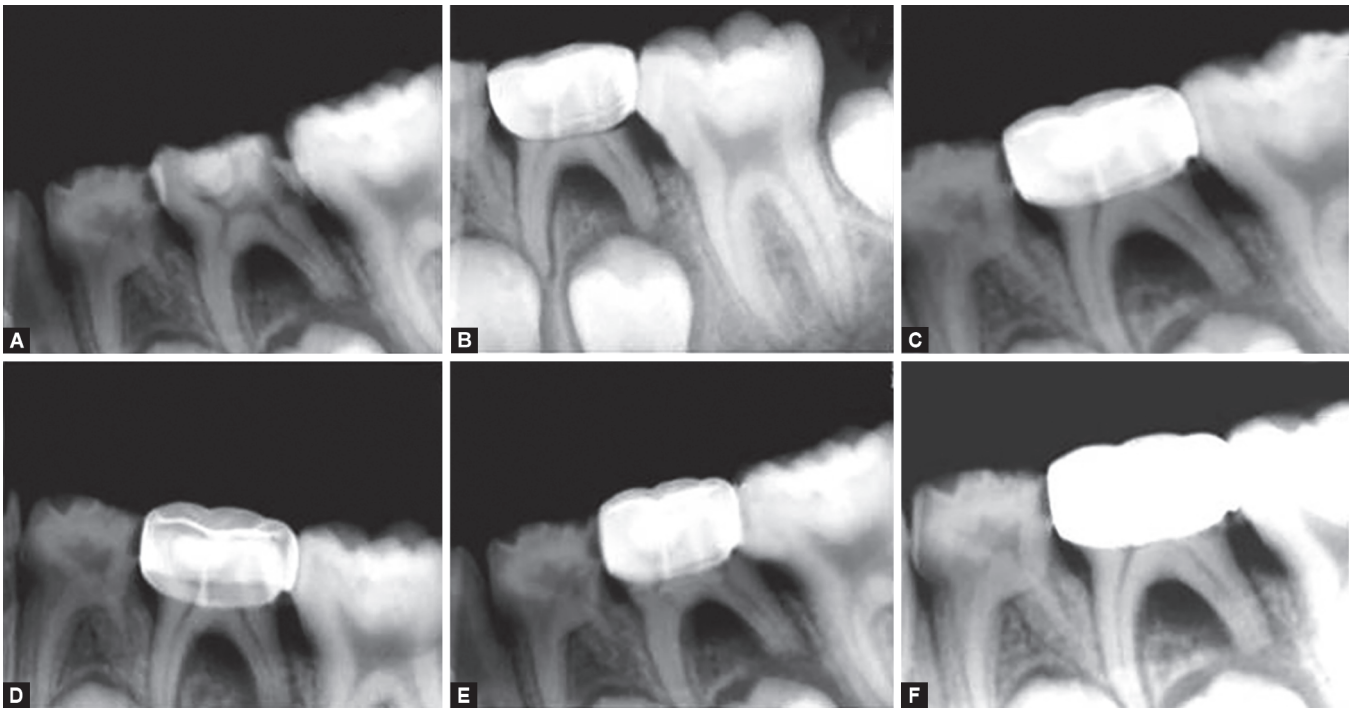
Outstanding results with LSTR therapy in the management of infected deciduous teeth may be attributed to the bactericidal action of the combination of drugs (3Mix). Prior studies[6–8,10–12,15,19,20,22–24] have manifested that 3Mix has the ability to eliminate bacteria from infected dental tissues in both primary and permanent teeth. It has also been seen that, *in situ*, the drug combination could be easily and efficiently carried by propylene glycol[25] and within 1 day could penetrate the endodontic lesions of deciduous teeth and kill all the cultivable microorganisms. This indicates that lesions can be disinfected, by local application of the 3Mix paste[26] in primary as well as in permanent teeth.[27] Gomes-Filho et al.[28] also concluded in their study that the triantibiotic paste is biocompatible in nature.

Takushige et al.[8] observed the effectiveness of LSTR therapy using antibiotic paste comprising metronidazole, ciprofloxacin, and minocycline, in deciduous teeth with periradicular lesions. The authors deduced that LSTR therapy was successful in treating deciduous teeth with periapical pathology having or no physiologic root resorption. This endodontic treatment without mechanical

Table 5: Clinical and radiographic assessment of primary molars treated by LSTR therapy and pulpectomy at 12 months follow-up period

		Clinical criteria				*Radiographic criteria*
		Pain	*Tenderness*	*Abscess*	*Mobility*	*Inter/periradicular radiolucency*
Group I (LSTR) (*n* = 41)	9 months	0	0	0	0	43 (100%)
	12 months	0	0	0	0	41 (100%)
	p-value	NA	NA	NA	NA	1.000
Group II (pulpectomy) (*n* = 46)	9 months	0	0	0	0	46 (100%)
	12 months	0	0	0	0	46 (100%)
	p-value	NA	NA	NA	NA	1.000
Total (*n* = 87)	9 months	0	0	0	0	89 (100%)
	12 months	0	0	0	0	87 (100%)
Intergroup comparison	*p*-value	NA	NA	NA	NA	1.000

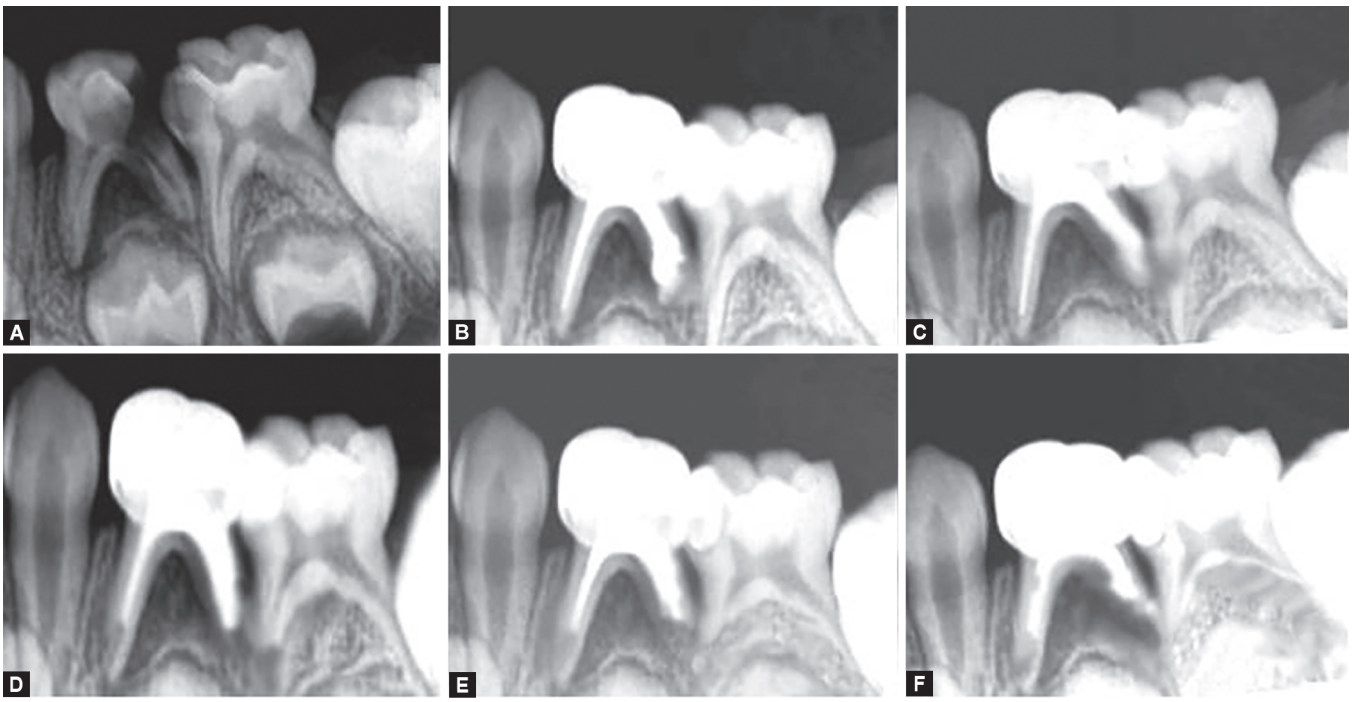
NA, not applicable



Figs 2A to F: Composite digital radiographic images of primary molar treated with LSTR therapy at various follow-up periods. (A) Preoperative; (B) 1 month; (C) 3 months; (D) 6 months; (E) 9 months; (F) 12 months. Inter/periradicular radiolucency persisted even at 12 months

instrumentation, particularly in cases with preoperative resorption of the root may show more favorable results. In deciduous teeth, the porosity of the pulpal floor due to accessory canals suggests a most expected path between pulpal and periapical tissues. Multiantibiotic paste spreads comfortably through these areas to create a zone of sterility, leading to the repair of the tissues.[15]

In the present study, in the LSTR group, a 10% NaOCl-saturated cotton pellet was used as a hemostatic agent to control pulpal bleeding. NaOCl is nontoxic to pulp, has no effect on pulp recovery, aids in clot removal, and controls bleeding that may compromise the healing of the pulp tissue.[29,30] Prabhakar et al.[15] compared two techniques of LSTR; in one group the necrosed coronal pulp was eliminated, and in the other both the necrosed coronal and left-over radicular pulp tissue were extirpated. The results showed no statistically significant difference. According to Saskianti et al.,[23] Burrus et al.,[31] and Anila et al.,[32] 3Mix-MP treatment can be used as an alternative option for traditional pulpectomy treatment in deciduous molars with pulpal necrosis. Contrarily, Trairatvorakul and Detsomboonrat[12] suggested that 3Mix–MP LSTR cannot replace traditional obturating material used in pulpectomy as a long-term treatment modality in primary teeth. Though the treatment showed good clinical success it had a low radiographic success rate at a 2-year follow-up. Only a few studies[6,9–11] have been conducted to compare the success of LSTR therapy, clinically and radiographically with conventional pulpectomy procedures. Hence, this study was undertaken to evaluate and compare the success rate of LSTR therapy and conventional pulpectomy procedures in the management of infected primary molars with poor prognoses that were indicated for extraction. For our research, metapex was used for the obturation of pulpectomized teeth. Metapex is a calcium hydroxide and iodoform resorbable paste that is easily diffused or resorbed by macrophages if extruded into periapical or furcation



Figs 3A to F: Composite digital radiographic images of primary molar treated with pulpectomy and root filling with metapex at various follow-up periods. (A) Preoperative; (B) 1 month; (C) 3 months; (D) 6 months; (e) 9 months; (F) 12 months. Inter/periradicular radiolucency persisted even at 12 months

region, within 1 or 2 weeks. It causes no adverse immune reaction and is therefore preferred as primary teeth obturating material.[33,34]

In this study, 100% clinical success was observed in the pulpectomy group at 12 months follow-up period, which was in accordance with the previous studies,[6,9–11,34–36] who reported clinical success rates of 96–100% at 12–22 months of follow-up. Regarding the radiographic success, the pulpectomy group showed no reduction in the size of radiolucency (furcation, periradicular and periapical) even at 12 months of follow-up. This was lower than that of Trairatvorakul and Detsomboonrat[12] who observed an 89% radiographic success rate. Research by Ozalp et al.,[37] Duanduan et al.,[10] and Nurko and Garcia-Godoy,[34] revealed a radiographical success rate of 77% at 12–24 months. However, the results of a study by Nakornchai et al.[9] were lower than that of other studies, which revealed a success rate of only 66% radiographically after a follow-up of 12–20 months which could be because of the method of sampling as only teeth with bad prognosis were taken. In the present study, it was concluded that the 12-month time period is reasonably low and not sufficient to observe any reduction in the radiolucency in the pulpectomy group.

The LSTR therapy also showed 100% clinical success at 12 month follow-up period, similar to the studies of Takushige et al.,[8] Nakornchai et al.,[9] and Prabhakar et al.[15] who reported 96–100% success clinically at follow-up periods of 12–20 months, but less in the studies by Trairatvorakul and Detsomboonrat[12] and Duanduan et al.[10] On evaluating radiographically, the LSTR therapy group also revealed no changes radiographically even at 12 months follow-up period. This was lower than that of Prabhakar et al.[15] (76.7%) and Nakornchai et al.[9] (76%). In the present study, teeth having poor prognoses were taken, as in the case of Nakornchai et al.[9] In the present study, the rate of radiographic success was lower than the study by Trairatvorakul and Detsomboonrat[12] who observed 36.7% success radiographically at 24–27 months follow-up. There were no statistical differences between the success rates of the LSTR and pulpectomy group at the end of the 12-month follow-up period, clinically or radiographically.

As per the observations of this study, traditional root canal treatment with Metapex® and LSTR treatment with 3Mix-MP paste revealed 100% clinical success. It can be stated that LSTR treatment with 3Mix-MP can be a good therapeutic option for teeth having a poor prognosis or in conditions where endodontic filing cannot be done because of natural root resorption.[8] Secondly, this treatment protocol requires less chairside time and is inexpensive. It can be recommended in case of uncooperative patients. But it has a disadvantage also, that is, cytotoxicity caused by antibiotics or vehicles. Chuensombat et al.[38] demonstrated the cytotoxicity of antibacterial drugs used in LSTR therapy. The cytotoxicity was time and concentration-dependent; 3Mix paste of 0.39 µg/mL concentration had less cytotoxicity and was successful in reducing bacteria isolated from necrotic teeth. LSTR therapy has some limitations also, like in the case of medically compromised patients and patients who are allergic to any antibiotics of 3Mix-MP paste, this technique cannot be performed.

Conclusion

The LSTR therapy and pulpectomy procedures were found to be equally effective in the management of infected primary molars with poor prognosis, where extraction and space maintenance are indicated. It is an ultraconservative procedure that can be completed in a single appointment in comparison with traditional pulpectomy procedures and is more economical. Patient compliance is predictable in LSTR therapy, which is of great concern in the management of pediatric patients, as it is an instrumentation-less technique. LSTR therapy can be considered a possible substitute for pulpectomy procedures.

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