Evaluation of Success Rate of Lesion Sterilization and Tissue Repair Compared to Vitapex in Pulpally Involved Primary Teeth: A Systematic Review

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Abstract

Background: Vitapex has been a popular obturating material for several decades. In recent times, lesion sterilization and tissue repair (LSTR) has shown promising results. This technique uses a mixture of 3 antibiotics for sterilization of the root canals and healing of periradicular tissues.

Objective: The objective of this systematic review was to compile all the literature comparing Vitapex and LSTR for pulpally involved primary teeth and evaluate the success rate in terms of clinical and radiographic outcomes.

Materials and Methods: This review is based on PRISMA guidelines. The electronic search on MEDLINE via PubMed database and Google scholar, cross‑referencing and hand search of journals was carried out for articles from January 1, 2000 to December 31, 2019. Articles only in the English language were selected. Out of the 17 articles, 3 unique articles were identified for the review, of which 2 were randomized controlled trials and 1 was a retrospective study.

Results: All the three articles were assessed for their quality and all had a low risk of bias. It was found that LSTR and Vitapex had a high clinical success after 12 months. The radiographic success after 6 months was high but decreased after 12 months in both the groups.

Conclusion: There is no difference in the success rate of LSTR as compared to Vitapex for the treatment of pulpally involved primary teeth.

Keywords: 3Mix paste; lesion sterilization and tissue repair; primary molars; pulpectomy; triple antibiotic paste; Vitapex

INTRODUCTION

One of the most valuable services a pediatric dentist can provide for the child patient is the treatment of pulpally involved primary teeth.[1] Pulp therapy is a method of eliminating the pulpal infection to maintain the tooth, which would otherwise be lost.[2] Early loss of primary teeth can affect the function, proper dental and skeletal form and psychological development of a child.[3] To avoid these problems, many treatment procedures have been proposed such as indirect pulp capping, direct pulp capping, pulpotomy, and pulpectomy.[2,4] In some clinical situations, pulpectomy results in compromised treatment. The reasons being anatomic complications liked curved roots, the closeness of permanent tooth buds, apparent connection between the coronal floor with the intraradicular area and difficulty in obtaining hermetic seal due to ongoing physiologic root resorption. Another challenge is behavior management of pediatric patients.[5-7] Inspite of these limitations, pulpectomy is still preferred over-extraction as a natural tooth acts as a superior space maintainer than an appliance.[8]
Obturation of primary teeth has been done using various materials. Iodoformized calcium hydroxide pastes like Metapex and Vitapex are preferred over zinc-oxide eugenol. Vitapex is a resorbable obturating material and has shown a high success rate.\cite{9,10} However, Vitapex needs complete removal of the pulp tissue, has a mild antibacterial action and faster rate of resorption leading to reinfection, which questions its long term success.\cite{11,12}

To overcome the shortcomings of Vitapex, an alternative concept developed by the Cariology Research Unit of Niigata University (School of Dentistry) known as lesion sterilization and tissue repair (LSTR) in which a mixture of three antibiotics (triple antibiotic paste/TAP/3Mix paste) is used to eliminate bacteria and sterilize the root canals and the periradicular region with the advantage of noninstrumentation endodontic treatment.\cite{13}

The earliest successful clinical study of LSTR was reported by Takushige et al.\cite{13} in 2004. Since then, several studies have been conducted using LSTR for pulpally involved primary teeth.\cite{14-18}

The objective of this systematic review was to compile all the literature comparing Vitapex and LSTR for pulpally involved primary teeth and evaluate the success rate in terms of clinical and radiographic outcomes.

**PICO**

- **P** - Participants: Children between the age group of 3–10 years having pulpally involved primary teeth
- **I** - Intervention: LSTR
- **C** - Comparison: Vitapex
- **O** - Outcomes: Clinical success: Reduction in pain, abnormal mobility, and swelling/abscess; Radiographic success: Decrease in interradicular radiolucency and absence of internal resorption.

**METHODS**

**Eligibility criteria**

Inclusion criteria: All the studies reporting comparative evaluation of LSTR and Vitapex using randomized controlled trials or retrospective study designs in children having pulpally involved primary teeth between the age group of 3–10 years and reporting at least a 6 months follow-up period; articles published in English language only and where there is a possibility to translate the foreign language to English; articles published from January 1, 2000 to December 31, 2019.

Exclusion criteria: Reviews, case reports and series, abstracts, letters to editors, editorials and in-vitro studies; articles reporting only about LSTR or Vitapex individually; articles reporting LSTR as an intracanal medicament.

**Information sources and search strategy**

The electronic search was initially conducted on MEDLINE through PubMed database with a search strategy [Table 1]. In addition, Google Scholar was also searched. Manual hand search for the reference list of eligible studies to ensure the identification of relevant published and unpublished studies was undertaken. The study authors were also contacted to provide full-text article.

**Study selection and data collection process**

Two reviewers (SA, VB) independently performed the first stage of screening by titles of all the identified studies. Round two included screening by the abstracts, and round three was full-text assessment. The duplicates were removed, and finally, eligible articles were selected for the review.

A standardized pre-piloted form was used to extract data from the included studies for evidence synthesis. One review author (SA) extracted data independently, and the second author (VB) cross-checked the data. Discrepancy, if any, were identified and resolved through discussion with the third author (PK) where necessary. The data items included were: Author Name, Year of publication, Age of participants, Intervention, Comparison, Outcomes: Clinical success: Reduction in pain, abnormal mobility, and swelling/abscess; Radiographic success: Decrease in interradicular radiolucency and absence of internal resorption follow up.

**Risk of bias assessment in individual studies**

Three authors (SA, VB, PK) assessed the quality of the included studies. The risk of bias assessment tool provided by the Dutch Cochrane Centre\cite{19} was used to assess the Randomized controlled trials and MINOR’s Checklist\cite{20} for non-randomized studies.

**RESULTS**

**Study selection**

Figure 1 shows the PRISMA flowchart of the search result and study selection.

The PubMed database search provided with a total of 14 articles and Google scholar search provided 3 articles. A total of 17 articles were screened for their title. Six articles were excluded of which, in 4 of these articles, LSTR was used as an intracanal medicament; 1 was not related to LSTR and 1 did not compare LSTR with Vitapex. From the remaining 11 studies, 7 were excluded as these were duplicates. From the 4 studies which were finally screened for full texts, 1 was excluded as it did not mention clear objective parameters for radiographic assessment. Hence, a total of 3 unique articles were included in this review which met all the inclusion criteria.
Characteristics of each study

Tables 2a and b summarizes the characteristics of individual studies.

Of the 3 potentially reviewed studies comparing LSTR with Vitapex, the study by Doneria et al.\(^{21}\) and Nakornchai et al.\(^{22}\) were randomized controlled trials while a study by Duanduan et al.\(^{23}\) was a retrospective study. The duration of the intervention was 18 months for study by Doneria et al.,\(^{21}\) 12 months for Nakornchai et al.\(^{22}\) and 72 months for Duanduan et al.\(^{23}\) A follow-up of 12 months was considered for the results to be comparable. Clinical and radiographic evaluation was made on common criteria included in each study to make the results comparable.

Doneria et al.\(^{21}\) conducted a study on 24 participants in the age group of 4–8 years using TAP for LSTR containing Ornidazole + Ciprofloxacin + Cefaclor. The control group had 20 participants and were given vitapex obturation. Clinically, at the end of 6 months, LSTR group reported 100% success with no pain, no gingival swelling/abscess and no abnormal mobility while at 12 months, 100% success with no pain but 96% with no gingival swelling/abscess and no abnormal mobility, respectively. At 6 months, vitapex group reported 96% no pain, no gingival swelling/abscess, and no abnormal mobility and 100% at 12 months for all the clinical success parameters. No statistically significant difference was present. Radiographically, LSTR group reported 88% decrease in interradicular radiolucency and no internal resorption while vitapex group reported 85% and 100% success for radiological parameters, respectively. At 12 months, LSTR group showed 75% decrease in interradicular radiolucency and 87.5% with no internal resorption and vitapex group showed 85% and 100% success, respectively. There was a statistical significance observed between the individual radiographic criteria, but there was nonsignificant difference in the overall success.

Nakornchai et al.\(^{22}\) conducted a study on 25 participants in the age group of 3–8 years using TAP for LSTR containing metronidazole + Ciprofloxacin + Minocycline. The control group had 25 participants and were given vitapex obturation. Clinically at 6 months, both the groups showed 100% no pain, no gingival swelling/abscess, and no abnormal mobility. At 12 months, the LSTR group showed 100% no pain and no abnormal mobility and 96% no gingival swelling/abscess. Vitapex group showed 96% no pain, no gingival swelling/abscess, and 100% no abnormal mobility. Radiographically, at 6 months, the LSTR group showed 85% decrease in interradicular radiolucency and 87.5% with no internal resorption and vitapex group showed 85% and 100% success, respectively. There was a statistical significance observed between the individual radiographic criteria, but there was nonsignificant difference in the overall success.

Duanduan et al.\(^{23}\) conducted a study on 23 participants in age group of 3–10 years using TAP for LSTR containing
LSTR is a simple and short procedure, may be superior to conventional pulpectomy in primary teeth.

Radiographic success of LSTR using modified 3Mix can be used as a substitute for conventional pulpectomy in primary teeth.

Both the studies used a proper randomization method but did not adequately conceal allocation. The operator and the outcome assessor were blinded. There was no missing outcome data and all the study protocols were available and prespecified outcomes of interest were reported. Hence, both studies can be considered to have low risk of bias.

MINORS checklist indicated that the nonrandomized study[23] had good methodological quality except there was the loss to follow-up of >5% and the baseline samples in both the groups were not equal as depicted in Figure 3. Hence, the study can be considered to have a low risk of bias.

**DISCUSSION**

LSTR Therapy or noninstrumental endodontic treatment, is a new biological approach for the treatment of pulply involved primary teeth which aims to place antibiotics locally into the rootcanals which offers an advantage over systemic administration as adverse effects are prevented.

**Risk of bias assessment**

Of the three studies included, 2 were randomized controlled trials (RCTs)[21,22] and the risk of bias is depicted in Figure 2.

**Table 2a: Study characteristics for clinical success**

| Author               | Intervention                        | Comparison                        | Clinical success | Clinical success |
|----------------------|-------------------------------------|-----------------------------------|------------------|------------------|
|                      |                                     |                                   | No pain | No gingival swelling/abscess | No abnormal mobility | Group I (%) | Group II (%) | Group I (%) | Group II (%) | Group I (%) | Group II (%) | Group I (%) | Group II (%) | Group I (%) | Group II (%) | Group I (%) | Group II (%) |
| Doneria D et al.     | n=24, ODZ + CIP + CEC + MP, medication cavity | n=25, MTZ + CIP + MIN + MP, no medication cavity | 96      | 100                          | 96                  | 100          | 96          | 100          | 96          | 100          | 96          | 100          |
| Nakornchai et al.   | n=25, vitapex obturation (pressure syringe method) | n=25, vitapex obturation (pressure syringe method) | 100     | 100                          | 100                 | 100          | 100         | 100          | 96          | 96           | 100         | 100          |
| Duanduan et al.     | n=50, vitapex obturation (pressure syringe method) | n=50, vitapex obturation (pressure syringe method) | 93      | 98                           | 100                 | 100          | 93          | 98           | 100         | 100          | 100         | 100          |

**Table 2b: Study characteristics for radiographic success**

| Author               | Radiographic success | Radiographic success | Inference |
|----------------------|----------------------|----------------------|-----------|
|                      | Decrease in interradicular radiolucency | No internal resorption |          |
|                      | 6 months | 12 months | 6 months | 12 months | 6 months | 12 months | 6 months | 12 months | 6 months | 12 months | 6 months | 12 months | 6 months | 12 months | 6 months | 12 months | 6 months | 12 months |
| Doneria D et al.     | 88      | 100     | 88      | 100     | 75      | 100     | 87.50    | 100     | LSTR using modified 3Mix can be used as a substitute for conventional pulpectomy in primary teeth |
| Nakornchai et al.   | 92      | 88      | 92      | 100     | 84      | 56      | 96       | 100     | LSTR is a simple and short procedure, may be superior to other materials used for root canal treatment in children |
| Duanduan et al.     | 93      | 83      | 100     | 100     | 72.73   | 90.90   | 100      | 91.30   | LSTR therapy may be appropriate for treatment of poor prognosis cases or cases for which mechanical instrumentation could not be achieved due to physiologic root resorption |

LSTR: Lesion sterilization and tissue repair

metronidazole + Ciprofloxacin + Minocycline. The control group had 50 participants and were given vitapex obturation. Clinically, at 6 and 12 months, LSTR group showed 93% no pain, 100% no gingival swelling/abscess and no abnormal mobility and for Vitapex group, 98% no pain, 100% no gingival swelling/abscess and no abnormal mobility. Radiographically, at 6 months, there was 93% and 83% decrease in interradicular radiolucency in LSTR and Vitapex groups, respectively and 100% no internal resorption in both the groups. At 12 months, LSTR group showed 72.73% and 100% for decrease in interradicular radiolucency and no internal resorption, respectively and Vitapex group showed 90% and 91% for the decrease in interradicular radiolucency and no internal resorption respectively. No statistically significant difference was found in both the groups at 12 months follow-up, clinically and radiographically.
and presence of substantially higher concentrations in the root-canal system.3Mix can easily distribute through the ramifications of the tooth and induce a sterile zone, promoting tissue repair.11,12

The results of this review indicate that the clinical success was comparable in LSTR and vitapex groups while there were mild differences in the individual radiological parameter (intraradicular radiolucency and internal resorption) in studies by Doneria et al.21 and Nakornchai et al.22 Overall, the three studies are comparable but show some degree of heterogeneity. The study design differs as 2 studies are RCTs21,22 and 1 is a retrospective study.23 The composition of TAP differed in one of the study considered in the review while two studies have the same composition. Although there was a difference in the composition of TAP, the literature reveals that the overall success is not affected by this difference.15,18

Methodological techniques used for assessing pain, mobility, radiolucency, and internal resorption can influence the results. However, an assumption is made that the techniques may be similar, as none of the study has mentioned the assessment criteria in detail.

Overall, the three studies included in the review show a low risk of bias, and the results can be considered substantial.

All the three studies have shown similar clinical success in both the groups at 6 and 12 months.

At 6 months, in the radiological evaluation, all the studies have shown similar results. At 12 months, in the study by Nakornchai et al.,22 Vitapex group has shown a low radiographic success. The reason being, selection of poor prognosis cases before the start of the treatment. This review does not clearly substantiate any superior quality of LSTR over Vitapex at 12-month follow-up data.

In the study by Doneria et al.,21 18 months follow-up period showed comparable results for LSTR and vitapex and further in the study by Duanduan et al.,23 72 months of follow-up showed similar effectiveness between both the treatment options. In the latter study, it was observed that failures in the Vitapex and 3Mix groups were due to the leakage of temporary filling in two visits-nonvital pulp treated teeth and the deterioration and leakage of permanent restoration, such as composite resin or glass ionomer cement. These factors can lead to bacterial penetration. Thus, the influence of various permanent restorations and the time elapsed between the temporary and permanent restorations were found to be relevant to the success of nonvital pulp treatment in primary teeth.

In the study by Doneria et al.,21 it was observed that though the failures were considered due to internal resorption, it was confined to the tooth and did not show any clinical symptoms which showed no further increase in the resorption area at 12 months.

CONCLUSION

Hence, with the availability of this limited data, the review concludes that the success rates of LSTR and vitapex is comparable. LSTR can be considered as a treatment option for pulpally involved primary molars.

Limitations

LSTR has been used commonly for the treatment of pulpally involved primary teeth, but there is a paucity of literature, and it is recommended that future studies are needed with longer follow-up periods and standard criteria of assessment.

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Conflicts of interest

There are no conflicts of interest.
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