Comparative Evaluation of LSTR Using Minimum versus No-instrumentation Techniques with Augmentin–Metronidazole Mixture in Primary Molars

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ABSTRACT

Introduction: Deep carious lesions on primary teeth usually cause rapid infectious changes in pulp. Bacteria and their byproducts play a key role in the initiation of pulpal and periapical pathosis. Lesion Sterilization and Tissue Repair (LSTR) therapy is done in pulpally involved carious teeth with poor prognosis. Traditional LSTR therapy advocates for no-instrumentation, whereas minimum instrumentation technique have shown better outcomes.

Objective: The aim of the present study was to compare the efficacy of LSTR therapy with minimum and no-instrumentation techniques using mixture of amoxicillin with clavulanic acid (augmentin) and metronidazole as antibiotic paste.

Methodology: Sixty-eight primary molars (34 in each technique) from 44 children of age group five to twelve years were included in the study. The primary molars were treated with mixture of augmentin and metronidazole with propylene glycol as vehicle using two different techniques of LSTR; no-instrumentation and minimum instrumentation in a single visit. Postoperative clinical evaluation was done in one week, one month, three months and six months and radiographic evaluation was done in one month, three months and six months.

Result: Clinical and radiographic success rate was found to be 79.4% in no-instrumentation and 97% in minimum instrumentation technique. Chi square-test was done to assess the statistically significant difference where confidence interval was set at 95%. The minimum instrumentation technique was highly significantly than the no-instrumentation technique, based on clinical and radiographic findings ($p<0.05$).

Conclusions: Lesion Sterilization and Tissue Repair with minimum instrumentation technique has shown better clinical and radiographic success rate as compared to no-instrumentation technique. Augmentin and metronidazole can be used, as the mixture has shown good clinical and radiographic outcome, and minimal side effects.

Keywords: Augmentin; lesion sterilization and tissue repair; metronidazole; minimum instrumentation; no-instrumentation.

INTRODUCTION

Deep carious lesions on primary teeth usually cause rapid infectious dental pulp changes. Bacteria and their products play a key role in the initiation and perpetuation of pulpal and periapical pathosis.[1]

Citation

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Pulpectomy has been proposed to treat infectious primary teeth. Pulpectomy in primary teeth is aimed primarily to remove all bacterial infection by endodontic instrumentation and proper irrigation, and to obturate the root canals with a filling material.[2] However, pulpectomy is compromised by factors like extensive root resorption, inadequate bone, and periodontal support.[3]

Since primary teeth are considered natural space maintainers, a ray of hope for the clinician as well as the patient arose after the development of lesion sterilization and tissue repair therapy (LSTR). Clinicians claim the significance of LSTR in cases that have a poor prognosis with conventional pulpectomy. The principle behind LSTR is that it repairs by the natural defense mechanisms of the host.[4] It medicates and treats pulpitis and root canal infection.

In LSTR, triple antibiotic pastes, which are a mixture of three antibiotics (ciprofloxacin, minocycline and metronidazole), are used.[5] Minocycline is a broad-spectrum antibiotic but its major disadvantage is discoloration of teeth.[6] Therefore, different antibiotics were used as alternatives, like Amoxicillin, Augmentin, Cefaclor, Cefroxadine, Fosfomycin or Rokitamycin.[4] Augmentin is a broad-spectrum antibiotic,[7] found to be 100% effective against common endodontic pathogens and has more potent antibacterial properties.[8]

However, numerous studies have been conducted using several combinations of antibiotics.[4,9,10] Conventional LSTR follows the 'no instrumentation' technique, but various studies using the 'minimum instrumentation' technique have also been done, which have shown superior outcomes.[11,12] Thus, the present study aimed to compare the efficacy of LSTR therapy between two different techniques: no-instrumentation and minimum instrumentation using an antibiotic mixture of amoxicillin with clavulanic acid (Augmentin) and metronidazole.

METHODOLOGY

An interventional comparative clinical study was conducted among children in the age group five to twelve years visiting the outpatient department of the Department of Pediatric and Preventive Dentistry, People's Dental College and Hospital, Kathmandu, Nepal (PDCH). The study period was one year ('October 1, 2021 – September 30, 2022'). Ethical clearance was obtained from the Institutional Review Committee, PDCH (Reference number: 1 CH No. 17, 2078/2079 IRC PDCH 2021 24) before commencement of the study. The sampling technique was non-probability convenience sampling. Sample size was calculated in reference to the study done by Nakornchai S[13] using the following formula:

$$\text{Sample size (n)} = \frac{\{2\,(Z\alpha + Z\beta)^2\,pq\}}{d^2}$$

Where $Z\alpha = 1.96$ (at 95% confidence interval), $Z\beta = 0.84$ (at 80% power), p (average prevalence) = 18, $q = 100\text{-}p$, $d = 28$ and $n = 34$. Thus, the sample was calculated to be 34 for each technique. For all participants, informed written consent from parents and assent from children above seven years were taken.

The inclusion criteria clinically were teeth with dental caries involving pulp with/without pain and/or tender on percussion and/or gingival swelling and/or gingival sinus and/or pathological mobility apart from exfoliative, and radiographically teeth with more than 50% of root resorption with/without peri-radicular radiolucency and/or external root resorption and/or internal root resorption and/or calcific metamorphosis. The exclusion criteria were patients with a known history of allergy to penicillin and nitroimidazole group of drugs, children with special healthcare needs, clinically unrestorable tooth, and radiographically tooth showing complete root resorption, excessive internal root resorption and/or excessive bone loss in the furcation area.

Freshly prepared mixture of antibiotic paste (Augmentin and Metronidazole) was used in both techniques. The chemotherapeutic agents used were amoxycillin with clavulanic acid 625 mg tablet and metronidazole 400 mg tablet in the ratio of 1:1. After the removal of the enteric coating of tablets with the help of a number 15 Bard Parker blade, the

drugs were pulverized one by one into fine powder using a sterilized mortar pestle. The powder was mixed with propylene glycol solvent on a mixing pad to make a fresh antibiotic paste of soft ball like 1-2 mm diameter during treatment. If the mix was soft, more antibiotic mix powder was added. If the preparation becomes flaky, dry and too hard, then more solvent was added.

In both techniques, adequate anesthesia (2% lignocaine hydrochloride with adrenaline 1:80,000) was achieved using local infiltration or nerve block, and the selected primary molar was isolated with a rubber dam. Access into the pulp chamber was obtained with a round bur number 2 (Mani Inc, Japan) and a straight fissure bur number 556 (Mani Inc, Japan). Necrotic pulp was removed with a sharp spoon excavator and the pulp chamber was thoroughly irrigated with normal saline solution. In the no-instrumentation technique (NIT), instrumentation was not done, and in the minimum instrumentation technique (MIT), instrumentation was done with 10 Kerr (K), 15 Hedstrom (H) and 20 H file (Mani Inc, Japan). In both techniques, canals were irrigated using normal saline followed by 2% chlorhexidine. The orifices of the canals were enlarged with a round bur number 2 to receive the medicament, which was termed as 'medication cavity'. The cavity was dried with cotton pellets. The medication cavity was half-filled with a freshly prepared antibiotic mixture. The teeth were restored with glass ionomer cement as the base and composite resin as the final restoration.

The whole procedure was completed in a single visit by a single operator. Resolution of clinical signs and symptoms was evaluated in 1 week, 1 month, 3 months and 6 months, and radiographic changes were evaluated in 1 month, 3 months and 6 months.

The treated teeth were considered clinically successful if there was an absence and/or resolution of preoperative clinical signs and symptoms and also exfoliation of teeth during the research period. The treated teeth were considered radiographically successful when postoperative peri-radicular radiolucency decreased or remained the same as compared to preoperative radiolucency. Persistent clinical signs and symptoms and an increase in size of postoperative peri-radicular radiolucency were considered as treatment failure. The failure cases were reintervened, and excluded from the study.

The data were entered in Microsoft Excel and analyzed using Statistical Package of Social Sciences (SPSS) version 22. Descriptive statistics were presented in the form of frequency and percentages and continuous variables as mean and standard deviation. The comparison of categorized data was done using the chi-square test. The probability of significance was set at a 95% confidence interval where $p \leq 0.05$.

RESULTS

In the present study, 68 primary molars from 44 children were categorized into two techniques: no-instrumentation (NIT) and minimum instrumentation (MIT). Each technique consisted of 34 primary molars. Among 44 children 23(52%) were male and 21(48%) were female. The mean age was 8.5 ±1.41 years.

Clinically, preoperative findings predominantly included spontaneous pain and tenderness to percussion, followed by gingival swelling, pathological mobility, and a sinus tract. Radiographically, most teeth had peri-radicular radiolucency and internal resorption (Table 1).

Resolution of clinical signs and symptoms was higher in the minimum instrumentation (MIT) group as compared to the no-instrumentation (NIT) group (Table 2).

At 6-month follow-up, the minimum instrumentation (MIT) group showed less periradicular radiolucency compared to the no-instrumentation (NIT) group. Both techniques showed no change in external resorption or calcific metamorphosis (Table 3).

Both the clinical and radiographic successes were significantly higher in the minimum instrumentation technique as compared to no-instrumentation ($p<0.05$) (Table 4).

Table 1: Distribution of pre-operative clinical and radiographic findings in NIT and MIT.

Groups	NIT n (%)	MIT n (%)
Clinical Signs and Symptoms		
Spontaneous pain	33 (97)	29 (85.3)
Tender to percussion	22 (64.7)	18 (52.9)
Gingival swelling	7 (20.6)	12 (35.3)
Pathological mobility	7 (20.6)	12 (35.3)
Sinus tract	2 (5.9)	3 (8.8)
Radiographic Findings		
Periradicular radiolucency	32 (94.1)	31 (91.2)
Internal resorption	2 (5.9)	3 (8.8)
External resorption	0 (0)	0 (0)
Calcific metamorphosis	0 (0)	0 (0)

Table 2: Distribution of post-operative clinical signs and symptoms.

Follow up period	1 week		1 month		3 months		6 months	
Techniques	NIT	MIT	NIT	MIT	NIT	MIT	NIT	MIT
Spontaneous pain n (%)	1(2.9)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Tender to percussion n (%)	1 (2.9)	0 (0)	1 (2.9)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Gingival swelling n (%)	3 (8.8)	1 (2.9)	3 (8.8)	1 (2.9)	6 (17.6)	1 (2.9)	6 (17.6)	1(2.9)
Pathological mobility n (%)	0 (0)	0 (0)	1 (2.9)	0 (0)	1 (2.9)	0 (0)	1 (2.9)	0 (0)
Sinus tract n (%)	1(2.9)	0 (0)	1 (2.9)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 3: Distribution of post-operative radiographic findings.

Follow up period	1 month		3 months		6 months	
Techniques	NIT	MIT	NIT	MIT	NIT	MIT
No change n (%)	27 (79.4)	33 (97.0)	27 (79.4)	33 (97.0)	27 (79.4)	33 (97.0)
Peri-radicular radiolucency n (%)	7 (20.6)	1 (3)	7 (20.6)	1 (3)	7 (20.6)	1 (3)
Internal resorption n (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (17.6)	0 (0)
External resorption n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Calcific metamorphosis n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 4: Distribution of clinical and radiographic success.

Follow up period	NIT n (%)	MIT n (%)	p-value
Clinical Success			
1 week	28 (82.3)	33 (97)	0.046
1 month	28 (82.3)	33 (97)	0.046
3 months	27 (79.4)	33 (97)	0.024
6 months	27 (79.4)	33 (97)	0.024
Radiographic Success			
1 month	27 (79.4)	33 (97)	0.024
3 months	27 (79.4)	33 (97)	0.024
6 months	27 (79.4)	33 (97)	0.024

*Statistically significant at p-value <0.05.

DISCUSSION

Primary teeth are considered natural space maintainers. Early loss of primary teeth may lead to space loss, disturbance in the eruption sequence and development of deleterious habits.[14] Therefore, primary teeth should be preserved within the dental arch in their functional state until exfoliation for proper dental and skeletal development of a child.[15] Conventional pulpectomy is not recommended in conditions where the tooth presents with resorbed roots or excessive bone loss extended to the succedaneous permanent tooth.[3]

The development of LSTR was a ray of hope for the preservation of primary teeth with a poor prognosis. The Cariology Research Unit of Niigata University, School of Dentistry in Japan has developed the concept of LSTR therapy given by Hoshino et al. in 1990 and was popularized by Takushige et al.[16] Medicament used was a mixture of metronidazole, ciprofloxacin, and minocycline along with solvent macrogol and propylene glycol and was called 3-mix MP pastes.[5]

Anaerobic bacteria have been isolated frequently from lesions of deciduous and permanent teeth.[17] Metronidazole was selected as the first choice among the antibacterial drugs as it has a wide spectrum of bactericidal action against oral obligate anaerobes. But metronidazole, even at a concentration of 100 µg/ml, could not kill all the bacteria.[18] Enterococcus faecalis has been shown to be the most common bacterium present in teeth after the failure of root canal therapy.[18] Therefore, there was a need for some additional drugs to sterilize the lesions.[19] Recently, newer combinations of drugs have been shown to improve the efficacy of LSTR therapy. Kaur et al. in vitro study observed the potential of combinations of amoxicillin and metronidazole, augmentin and metronidazole, amoxicillin and cloxacillin and metronidazole and triple antibiotic paste, where the most potent antibacterial effect and the most reliable result was appreciated with the augmentin and metronidazole group. Therefore, the present study used augmentin with metronidazole antibiotic paste and has shown the same effect as an in-vitro study done by Kaur et al.[9]

Previously, an antibiotic paste was placed in the pulp chamber without instrumentation. Recently, a study done by Prabhakar et al., where medicament was placed after removal of accessible radicular pulp, showed that minimum instrumentation would result in better prognosis. The clinical and radiographic success in teeth with instrumentation was 100% and 83.3% and without instrumentation was 93.3% and 36.7% respectively.[12] In the present study, the overall success rate was significantly higher in the minimum instrumentation when compared to the no-instrumentation technique. Both clinical

and radiographic success with minimum and no-instrumentation was 97% and 79.4% respectively, at six months follow-up.

The clinical success rate in the present study was higher compared to the results in the study by Patel et al.[10] (90%), Agarwal et al.[20] (38.8%) and Jaya et al.[21] (62%), both in minimum and no-instrumentation techniques, respectively. Similarly, the radiographic success rate was higher compared to the results obtained by Arangannal et al.[11] (91.2%), Lokade et al.[22] (95.2%), Patel et al.[10] (86.7%), Jaya et al.[21] (69%) and Trairatvorakul et al.[23] (54.4%), both in minimum and no-instrumentation techniques, respectively. Higher success rate in the present study may be because of use of more potent antibiotics, that is, augmentin and metronidazole. Augmentin is found to be most effective against common endodontic pathogens and has a more potent antibacterial effect when other antibiotics don't respond.[8]

The clinical success rate in the no-instrumentation technique in one week and one month was found to be 82.3% which reduced to 79.4% in three and six months. Whereas, in the minimum instrumentation technique, the clinical success rate was constant throughout the postoperative followup period, that is, 97%. The radiographic success rate of the present study in the no-instrumentation technique and minimum instrumentation technique was constant throughout the postoperative followup period, which was 79.4% and 97% respectively. The failure in the no-instrumentation technique could be attributed to the fact that, in the no-instrumentation technique, the infected radicular pulp tissue was not removed. Evidence is that the more the infected tissue is removed, the greater the chances of success.[24]

Limited sample size and short follow-up periods are the limitations of this study, constraint in time and resources being the reason. Further study among the larger sample with a longer follow-up period is recommended in the days to come.

CONCLUSION

Lesion Sterilization and Tissue Repair therapy is an effective technique for the conservation of the pulpally involved primary teeth with poor prognosis. LSTR with minimum instrumentation technique has a good clinical and radiographic success rate. Augmentin and metronidazole can be used as an antibiotic paste in LSTR, as the mixture has shown good clinical and radiographic outcomes.

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