# Evaluation of Paste Containing Gentamicin, Amoxicillin and Metronidazole in Endodontic Treatment of Primary Molars in Vivo

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**Objective:** *To evaluate and compare the efficacy of gentamicin, amoxicillin and metronidazole (GAM) antibiotic paste in noninstrumentation and instrumentation techniques in infected primary molars.*

**Methods:** *Sixty primary molars in children of 4 to 8 years were selected and divided into four groups: teeth without any periapical or furcation involvement undergoing pulpectomy by noninstrumentation (Group N1) and instrumentation (Group N2) technique using GAM antibiotic paste; teeth with periapical or furcation involvement undergoing pulpectomy by noninstrumentation (Group R1) and instrumentation (Group R2) technique using GAM antibiotic paste. Regular follow-up at 3, 6 and 12 months was carried out for each group and all the clinical and radiographic changes were evaluated statistically using SPSS software. The level of significance was set to $P < 0.05$.*

**Results:** *Overall, 73.3% of success was observed in Group N1, 71.4% in Group N2, 86.7% in both Group R1 and Group R2 ($P = 0.003$).*

**Conclusion:** *The GAM lesion sterilisation and tissue repair (GAM-LSTR) technique can be an alternative to conventional pulpectomy.*

**Key words:** *antibiotic paste, primary molars, pulpectomy, gentamicin, amoxicillin, metronidazole*

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The common problem in primary dentition is the premature loss of primary teeth. As this affects the development of the dentition, the retention of primary teeth as natural space maintainers is important[1]. However, limitations in young patients such as anxiety, fear and the lack of patience and cooperation makes procedures more difficult. Thus, there is a requirement for a simple and less time-consuming technique such as the concept of lesion sterilisation and tissue repair (LSTR) therapy[2]. The 3Mix paste, i.e. metronidazole, amoxicillin and minocycline that is used in the LSTR technique is an effective and long-lasting treatment option[3]. However, minocycline has been identified as causing tooth discolouration[4]. Therefore, to overcome this problem, a new combination of antibiotics is required. It is also noted that there is a paucity in the literature about the LSTR technique, especially regarding its use in primary teeth.

Gentamycin is an aminoglycoside with rapid bactericidal activity and comparatively low levels of resistance. Amoxicillin is a moderate spectrum, bacteriolytic, β-lactum used to treat susceptible gram-positive and gram-negative microorganisms. Metronidazole has a wide bactericidal spectrum. Hence, a new combination of antibiotics containing gentamycin, amoxicillin and metronidazole (GAM) was formulated in the department where this study was conducted.

The present study was designed to evaluate and compare the effect of GAM antibiotic paste in noninstrumentation and instrumentation techniques in infected primary molars.

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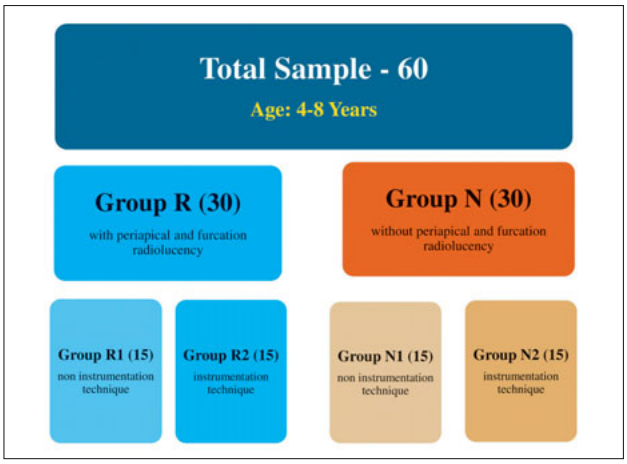


**Fig 1** Sample distribution.

## Material and methods

### *Preparation of GAM antibiotic paste*

The three antibiotic drugs gentamicin, amoxicillin and metronidazole (Teva Pharmaceutical Pvt Ltd, Gwalior, India) were used in pure powdered form and were stored separately in sealed, airtight porcelain containers to protect them from moisture and light. Fresh paste was prepared each time before use. The drugs were measured out with a ratio of 1:1:1 by weight and mixed with saline to form a homogenous paste. Unused GAM paste was discarded at the end of the clinical appointment.

### *Inclusion and exclusion criteria*

Included in the study were cases with deep carious lesions with pulp exposure, a failed pulpotomised tooth, gingival abscesses, sinus/fistula openings, clinical mobility and furcation involvement or periapical pathology on the radiograph.

Excluded from the study were cases with nonrestorable teeth, internal/external root resorption, canal obliteration, physiologic root resorption of more than half of the root length, pulpal floor perforations, excessive furcal bone loss involving underlying tooth germ, medically compromised children and children with a history of drug allergy to gentamicin, amoxicillin and/or metronidazole.

### *Selection and grouping of subjects*

The research protocol of the study was reviewed and approved by the ethical committee of the institution. After the initial screening, 82 healthy children between the ages of 4 and 8 years fulfilling the inclusion and exclusion criteria who needed endodontic treatment (pulpectomy) were identified. Based on the radiographic findings, 44 subjects had deep carious lesions involving pulp with periapical and furcation radiolucency, while 38 subjects had deep carious lesions involving pulp without periapical or furcation involvement. Among these, 30 subjects with periapical and furcation radiolucency (Group R) and 30 subjects with deep carious lesions involving pulp without periapical or furcation involvement were selected (Group N). Further, the subjects were randomly divided into subgroups depending on the treatment procedure, i.e. the noninstrumentation technique (Group N1 and Group R1) and the instrumentation technique (Group N2 and Group R2) (Fig 1).

### *Clinical procedure of LSTR therapy*

A thorough history was taken for each patient, followed by a clinical and radiographic examination. Anaesthesia was achieved using 2% lignocaine with 1:80,000 adrenaline. The tooth was isolated using rubber dam. Access was gained with a large round bur followed by coronal pulp amputation and saline irrigation. Haemorrhage, if present, was controlled by applying a moist cotton pellet against the pulp stumps for 1 min, and dried. GAM paste was placed at the root canal orifices, followed by zinc oxide eugenol and glass ionomer cement (Ketac Molar, 3M ESPE). The final restoration was done with preformed stainless steel crowns (3M ESPE) after 15 days when no signs and symptoms of infection were seen. This procedure was performed in Group N1 and Group R1. A similar procedure was then carried out in Group N2 and Group R2, with the exception that all the accessible radicular pulp was extirpated with the help of barbed broach.

After the treatment procedure, a regular follow-up at 3, 6 and 12 months was conducted for each group. The clinical and radiographic changes were recorded and evaluated statistically. The treated cases with evidence of bone regeneration without any clinical signs of pain and swelling were considered successful, whereas cases with pain, swelling, sinus/fistula, abnormal mobility, exfoliation and/or increase in radicular pathology at subsequent visits were considered as failures. All the procedures and follow-ups were carried out by the same researcher. However, the researcher was blinded during the follow-ups (did not know the groups to which the subjects belonged). Test-retest reliability was examined by re-administering the radiographs after 1 month on the initial examination radiographs. The intra-examiner reliability was found to be 0.94.

All the data were tabulated and processed by SPSS software (IBM SPSS Statistics Version 17.0, Chicago, IL, USA). The level of significance was set to $P < 0.05$.

## Results

Gender distribution (male: female) in the 4- to 6-year age group was 8:14 and in 6- to 8-year age group was 20:18 (Fig 2). This did not affect the outcome of the study as it was statistically insignificant ($P = 0.11$).

In Group N1, among 15 cases selected, 14 exhibited tenderness on percussion. One case showed grade II mobility at 3 months, at which time a conventional pulpectomy was performed and the case was excluded from the study. Radiographically internal resorption was seen in three (20%) cases, which were considered as failures (Table 1).

In Group N2, all the clinical signs and symptoms had decreased significantly at the 12-month follow-up (Table 2). One case exhibited grade I mobility and vertical fracture at 3 months. The tooth was therefore extracted and the case excluded from the study. Radiographically, furcation radiolucency was seen in two cases at the 12-month follow-up. Internal resorption was seen in three cases, which were considered as failures (Table 2).

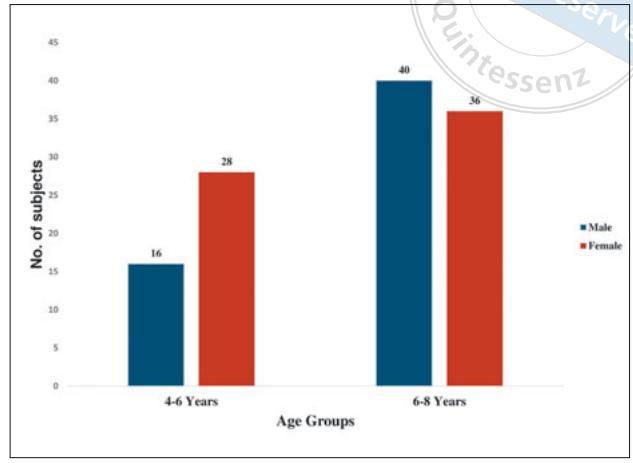


**Fig 2** Distribution of subjects according to age and gender.

**Table 1** Clinical and radiographic signs and symptoms of subjects in Group N1.

| Clinical signs and symptoms | | | | | |
|---|---|---|---|---|---|
| | | Baseline | 3 months | 6 months | 12 months |
| TOP | Present | 14 (93.33%) | 2 (13.33%) | 0 | 0 |
| | Absent | 1 (6.67%) | 13 (86.67%) | 14 (93.33%)[#] | 14 (93.33%) |
| Spontaneous pain | Present | 9 (60%) | 0 | 0 | 0 |
| | Absent | 6 (40%) | 15 (100%) | 14 (93.33%)[#] | 14 (93.33%)[#] |
| Intraoral swelling | Present | 1 (6.67%) | 2 (13.33%) | 0 (0%) | 0 (0%) |
| | Absent | 14 (93.33%) | 13 (86.67%) | 14 (93.33%)[#] | 14 (93.33%)[#] |
| Sinus/fistula | Present | 1 (6.67%) | 0 | 0 | 0 |
| | Absent | 14 (93.33%) | 15 (100%) | 14 (93.33%)[#] | 14 (93.33%)[#] |
| **Radiographic signs and symptoms** | | | | | |
| | | **Baseline** | **3 months** | **6 months** | **12 months** |
| Lamina dura | Continuous | 7 (46.67%) | 7 (46.67%) | 7 (46.67%) | 10 (66.67%) |
| | Discontinuous | 8 (53.33%) | 8 (53.33%) | 7 (46.67%) | 4 (26.67%) |
| Internal resorption | Present | 1 (6.67%) | 2 (13.33%) | 2 (13.33%) | 3 (20%) |
| | Absent | 14 (93.33%) | 13 (86.67%) | 12 (80%) | 11 (73.33%) |

[#] Pulpectomy was performed in one case at the 3-month follow-up and the patient was excluded from the study due to pain and mobility; TOP: tenderness on percussion.

**Table 2** Clinical and radiographic signs and symptoms of subjects in Group N2.

| Clinical signs and symptoms | | | | | |
|---|---|---|---|---|---|
| | | Baseline | 3 months | 6 months | 12 months |
| TOP | Present | 14 (93.33%) | 2 (13.33%) | 0 | 0 |
| | Absent | 1 (6.67%) | 13 (86.67%) | 14 (100%)[#] | 14 (100%)[#] |
| Spontaneous pain | Present | 7 (46.67%) | 2 (13.33%) | 0 | 0 |
| | Absent | 8 (53.33%) | 13 (86.67%) | 14 (100%)[#] | 14 (100%)[#] |
| Intraoral swelling | Present | 1 (6.67%) | 0 | 0 | 0 |
| | Absent | 14 (93.33%) | 15 (100%) | 14 (100%)[#] | 14 (100%)[#] |
| Sinus/fistula | Present | 0 | 0 | 0 | 0 |
| | Absent | 15 (100%) | 15 (100%) | 14 (100%)[#] | 14 (100%)[#] |
| **Radiographic signs and symptoms** | | | | | |
| | | Baseline | 3 months | 6 months | 12 months |
| Lamina dura | Continuous | 9 (60%) | 8 (57.14%) | 10 (71.43%) | 11 (78.57%) |
| | Discontinuous | 6 (40%) | 6 (42.86%) | 4 (28.57%) | 3 (21.43%) |
| Internal resorption | Present | 0 | 0 | 0 | 3 (20%) |
| | Absent | 15 (100%) | 14 (93.33%) | 14 (93.33%) | 11 (73.33%) |

[#] One case was excluded from the study due to vertical fracture; TOP: tenderness on percussion.

In Group R1, all the clinical signs and symptoms diminished significantly by the end of study. Radiographically, bone regeneration was observed in 13 (86.67%) cases, with a significant difference in the furcation radiolucency from the baseline data to the 12-month follow-up (Table 3).

In Group R2, there was a significant difference in relation to intraoral swelling ($P < 0.0001$, standard deviation [SD] = 61.21). Four cases showed the presence of sinus tract at the start, but this significantly resolved during the course of the study. Radiographically, bone regeneration was observed in 11 (73.33%) cases (Table 4).

### *Treatment success*

Cases with complete resolution of all the clinical findings were considered as clinical successes. Cases with bone regeneration or no change in bone architecture were considered as radiographic successes. Cases with either clinical or radiographic failure were considered as failures in the overall success criteria (Table 5). An intergroup comparison was carried out with descriptive and inferential statistics using the chi-square test. No significant difference was seen between Group N1 and Group N2 ($P = 0.75$) and between Group R1 and Group R2 ($P = 1.00$), indicating that, irrespective of the procedure used, GAM paste itself helped for the bacterial decontamination and healing of the pulpally involved primary molars.

A difference was found between Group N1 and Group R1 ($P = 0.013$) and between Group N2 and Group R2 ($P = 0.005$) with respect to the overall success of the treatment (Table 5). This shows a co-relation between the success rate of the GAM-LSTR technique and the severity of the radicular pathology. The more severe cases showed rapid healing compared with the cases with initial radicular pathology.

## Discussion

Endodontic treatment in primary teeth presents a challenge to clinicians due to the typical primary tooth mor-

**Table 3** Clinical and radiographic signs and symptoms of subjects in Group R1.

| Clinical signs and symptoms | | | | | |
|---|---|---|---|---|---|
| | | Baseline | 3 months | 6 months | 12 months |
| TOP | Present | 15 (100%) | 1 (6.67%) | 0 | 0 |
| | Absent | 0 | 14 (93.33%) | 15 (100%) | 15 (100%) |
| Spontaneous pain | Present | 10 (66.67%) | 0 | 0 | 0 |
| | Absent | 5 (33.33%) | 15 (100%) | 15 (100%) | 15 (100%) |
| Intraoral swelling | Present | 7 (46.67%) | 2 (13.33%) | 1 (6.67%) | 0 |
| | Absent | 8 (53.33%) | 13 (86.67%) | 14 (93.33%) | 15 (100%) |
| Sinus/fistula | Present | 3 (20%) | 0 | 0 | 0 |
| | Absent | 12 (80%) | 15 (100%) | 15 (100%) | 15 (100%) |
| **Radiographic signs and symptoms** | | | | | |
| | | Baseline | 3 months | 6 months | 12 months |
| Lamina dura | Continuous | 0 | 1 (6.67%) | 3 (20%) | 7 (46.67%) |
| | Discontinuous | 15 (100%) | 14 (93.33%) | 12 (80%) | 8 (53.33%) |
| Furcation radiolucency | Present | 15 (100%) | 15 (100%) | 15 (100%) | 15 (100%) |
| | Decreased | - | 9 (60%) | 12 (80%) | 13 (86.67%) |
| | Static | - | 5 (33.33%) | 2 (13.33%) | 1 (6.67%) |
| | Increased | - | 1 (6.67%) | 1 (6.67%) | 1 (6.67%) |
| Internal resorption | Present | 0 | 0 | 0 | 1 (6.67%) |
| | Absent | 15 (100%) | 15 (100%) | 15 (100%) | 14 (93.33%) |

TOP: tenderness on percussion.

phology such as tortuous root canals, ramifications, the presence of multiple accessory canals and ample medullary bone spaces that favour the dissemination of infection. Hence, the use of an antibacterial drug capable of penetrating the tissues and controlling infection in cases of nonvital infected primary teeth is desirable[5]. The placement of topical antibiotics can sterilise the necrotic pulps of primary teeth where the lack of blood supply hampers the use of systemic antibiotics[6].

In the present study, the LSTR technique involved the use of three broad-spectrum antibiotics – gentamycin, amoxicillin and metronidazole. This mixture was termed GAM antibiotic paste. GAM has a good antimicrobial effect against E. faecalis compared with other intracanal medicaments like povidone iodine, chlorhexidine, *Curcumin longa* and *Syzygium cumini*[7]. The synergism of metronidazole and amoxicillin has been proven in a variety of mixed bacterial infections in humans[8]. Gentamycin has a rapid bactericidal activity and is therefore recommended therapy for infections caused by gram-negative pathogens. It also has comparatively low levels of resistance[9].

A further challenge clinicians face in rendering effective endodontic treatment is the behavior management of uncooperative children. LSTR has proved very effective in counteracting this major issue when treating paediatric patients as it is a simple and less time-consuming procedure and reduces the need for multiple visits[10]. Mechanical instrumentation causing too much enlargement of root canals and unnecessary

**Table 4** Clinical and radiographic signs and symptoms of subjects in Group R2.

| Clinical signs and symptoms | | | | | |
|---|---|---|---|---|---|
| | | Baseline | 3 months | 6 months | 12 months |
| TOP | Present | 15 (100%) | 0 | 0 | 0 |
| | Absent | 0 | 15 (100%) | 15 (100%) | 15 (100%) |
| Spontaneous pain | Present | 6 (40%) | 0 | 0 | 0 |
| | Absent | 9 (60%) | 15 (100%) | 15 (100%) | 15 (100%) |
| Intraoral swelling | Present | 5 (33.33%) | 0 | 1 (6.67%) | 1 (6.67%) |
| | Absent | 10 (66.67%) | 15 (100%) | 14 (93.33%) | 14 (93.33%) |
| Sinus/fistula | Present | 4 (26.67%) | 1 (6.67%) | 0 (0%) | 0 (0%) |
| | Absent | 11 (73.33%) | 14 (93.33%) | 15 (100%) | 15 (100%) |
| **Radiographic signs and symptoms** | | | | | |
| | | Baseline | 3 months | 6 months | 12 months |
| Lamina dura | Continuous | 0 | 6 (40%) | 7 (46.67%) | 7 (46.67%) |
| | Discontinuous | 15 (100%) | 9 (60%) | 8 (53.33%) | 8 (53.33%) |
| Furcation radiolucency | Present | 15 (100%) | 15 (100%) | 15 (100%) | 15 (100%) |
| | Decreased | - | 9 (60%) | 12 (80%) | 11 (73.33%) |
| | Static | - | 5 (33.33%) | 3 (20%) | 3 (20%) |
| | Increased | - | 1 (6.67%) | - | 1 (6.67%) |
| Internal resorption | Present | 0 | 0 | 0 | 0 |
| | Absent | 15 (100%) | 15 (100%) | 15 (100%) | 15 (100%) |

TOP: tenderness on percussion.

irritation to periapical tissues is not required, especially in teeth with root resorption. GAM paste becomes easily distributed through these regions and induces a sterile zone, which is expected to promote tissue repair. Furthermore, the LSTR technique reduces the need for unnecessary extraction and the placement of a space maintainer by maintaining the primary tooth until its exfoliation is chronologically appropriate[11].

The groups in the present study were divided into instrumentation and noninstrumentation categories in order to evaluate whether the necrotic tissue in the canal acted as a matrix (or not) to regain the vitality or whether it hindered the healing process. This categorisation was also undertaken in an attempt to discern the technique with the minimum amount of pain for the patient. The two groups were compared to ascertain their clinical and radiographic success.

The present study showed a difference between the success rates and radicular pathology severity in the noninstrumentation and the instrumentation groups (Group N1 vs Group R1 and Group N2 vs Group R2). This may be due to the early appreciation of bone generation compared with the continuity of the lamina dura. No statistically significant difference was found between the noninstrumentation and instrumentation procedures (Group N1 vs Group N2 and Group R1 vs Group R2), which indicated the success of GAM paste in LSTR therapy, irrespective of the technique used.

In the present study, cases showing no change at the 6-month follow-up were categorised into a "further

**Table 5** Clinical, radiographic and overall success rates of GAM-LSTR technique.

| Intragroup comparison | Clinical success | Radiographic success | Overall success |
|---|---|---|---|
| Group N1 | 93.33% | 73.33% | 73.33% |
| Group N2 | 100% | 71.43% | 71.43% |
| Group R1 | 100% | 86.67% | 86.67% |
| Group R2 | 93.33% | 93.33% | 86.67% |
| $x^2$ value | 14.51 | 22.35 | 13.93 |
| *P* value | 0.002* | < 0.0001* | 0.003* |
| **Intergroup comparison** | **Clinical success *P* value** | **Radiographic success *P* value** | **Overall success *P* value** |
| Group N1 vs N2 | 0.007* | 0.75 | 0.75 |
| Group R1 vs R2 | 0.007* | 0.15 | 1.00 |
| Group N1 vs R1 | 0.007* | 0.013* | 0.013* |
| Group N2 vs R2 | 0.007* | 0.0001* | 0.005* |

* Significant.

observation group" and were considered as failures if no change in the pathological status was found at the 12-month follow-up. This is in accordance with the American Academy of Pediatric Dentistry's guideline on pulp therapy, which states that the radiographically evident pathology of pulpectomised teeth should resolve in 6 months[12]. The present study is noteworthy in that both clinical and radiographic criteria were taken into consideration for the sample selection as well as for the evaluation, using specifically defined recall periods.

Reduced radiographic success in the present study included cases of internal root resorption similar to those found in previous studies of pulpotomy treatment[13,14]. The failed cases with internal resorption could have been due to the inflammatory response of the residual pulpal tissue. The GAM medicament could produce an inflammatory reaction that may have been due to the vascular changes in the pulp along with the formation of granulation tissue, with an accompanying metaplasia of connective tissue and macrophages to form osteoclast-like multinucleated giant odontoclasts[15]. Internal resorption seen in the present study may have resulted from heat generation at the bur tip, vigorous coronal pulp amputation, the placement of medicament with strong manual pressure, incomplete pulp amputation or residual inflamed pulp tissue. When internal resorption was found in a tooth at the initial evaluation, the tooth was categorised as a failure, similar to Smith et al[13].

Treatment of abscessed primary molars using the LSTR technique is reported in which minocycline was replaced by clindamycin, and iodoform was added to make it radiopaque[16]. Clinical success in primary teeth using the LSTR technique has been reported[16-18]. However, there are few long-term follow-up studies of LSTR in primary teeth.

The high antibacterial effect of GAM paste and the noninstrumentation technique makes GAM-LSTR therapy more suitable in cases of poor prognosis. Another clinical advantage of the therapy is less chair time. Nonetheless, the authors would not advocate this therapy in a child with a risk of infective endocarditis. Also, the potential consequence of this treatment should be considered such as the risk of damage to the successor tooth or cyst formation if a nidus of chronic infection is left untreated.

Further clinical and histological studies with larger samples and a longer follow-up period (until the time of tooth exfoliation) are advocated to ascertain the efficacy of this novel treatment modality.

## Conclusion

No significant difference was found between instrumentation and noninstrumentation procedures using GAM

paste, making it an alternative intracanal medicament. Hence, the GAM-LSTR technique can be an alternative to conventional pulpectomy.

## Conflicts of interest

The authors reported no conflicts of interest related to this study.

## Author contribution

Dr Keyura PARAK performed the procedures and the follow-up, collected the data, analysed the data and prepared the manuscript; Dr Raghavendra M. SHETTY designed and finalised the study, critically reviewed the cases, analysed the data and finalised the manuscript.

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