

Clinical and Radiographic Evaluation of the Efficacy of Formocresol, *Allium sativum* Oil, and *Aloe barbadensis* Gel as Pulpotomy Medicaments in Primary Molars: A Randomized Controlled Trial

Kumar Abirami¹, Hemalatha Ramkumar², Dakshinamurthy Senthil³

ABSTRACT

Aim: The aim of the study was to clinically and radiographically evaluate the efficacy of formocresol, *Allium sativum* oil, and *Aloe barbadensis* gel as pulpotomy medicaments in primary molars.

Materials and methods: Eighty-two primary molars indicated for pulpotomy were included in the study. The molars included were divided into three groups by simple random sampling, and treatment was done with formocresol as control, comparing it with *Aloe barbadensis* gel and *Allium sativum* oil.

Results: The teeth were then followed up for 6 and 12 months clinically and radiographically. Chi-square test was used to compare the clinical and radiographic results between the groups. McNemar test was used to compare the clinical and radiographic results at 6 and 12 months. The results revealed that there was no significant difference between the groups when comparing the experimental groups to the control.

Conclusion: The study shows that *Aloe barbadensis* gel and *Allium sativum* oil may be used as an alternative to formocresol as pulpotomy medicaments.

Keywords: Herbal extracts, Pediatric endodontics, Pulpotomy.

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INTRODUCTION

Dental pulp is greatly liable to abuse from the oral microflora when exposed.¹ Since the primary dental pulp is blessed with rich vascular supply, it inherently has the capacity to combat any injurious stimuli.² Safeguarding primary teeth until the permanent teeth erupts is important because deciduous teeth help in determining the form of alveolar process, maintaining normal dental spacing, prevent unfavourable speech and habits, and preserve esthetics and chewing function.^{3,4}

The choices for managing deciduous teeth where caries or mechanical procedures results in exposure of the pulp are numerous. Such options include direct pulp capping, pulpotomy, and pulpectomy.³ If infection remains contained in the coronal pulp and the radicular pulp is healthy, pulpotomy procedure is then recommended. The pulp from the coronal chamber is excavated, and the healthy radicular pulp tissues are retained.⁵

Buckley introduced formocresol in 1904, which is the most commonly used medicament for pulpotomy. The success rate of formocresol pulpotomy ranged from 70 to 98%.⁶ Histological findings observed with the use of formocresol ranged from slight inflammation to total degeneration and necrotic changes. The International Agency for Cancer Research has concluded in 2004 that the fumes released from formaldehyde have the potential to cause nasopharyngeal cancers in humans and has termed it as a carcinogen. This move has made formocresol become obsolete in dentistry irrespective of its unproven toxic effects from previous studies, and an active search for a new material to replace formocresol is being made.⁷ Modern trends in dentistry are searching for more biocompatible substances to substitute

¹Department of Pedodontics, SRM Dental College, Chennai, Tamil Nadu, India

²Department of Pedodontics and Preventive Dentistry, SRM Dental College, Chennai, Tamil Nadu, India

³Department of Pedodontics and Preventive Dentistry, Chettinad Dental College and Research Institute, Kanchipuram, Tamil Nadu, India

Corresponding Author: Kumar Abirami, Department of Pedodontics, SRM Dental College, Chennai, Tamil Nadu, India, Phone: +91 9840870550, e-mail: abiramik1092@gmail.com

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formocresol as the choice of medicament for primary teeth pulpotomies.⁸

Aloe vera, known by the scientific name *Aloe barbadensis* miller, has been employed as a herbal medicine for burn injuries and wounds.⁹ Acemannan, a major polysaccharide obtained from *Aloe barbadensis* gel, has been acknowledged for its cytocompatibility and wound-healing properties.¹⁰ *Allium sativum* (common garlic) has been gifted with therapeutic effects that are seen in folklore and in the scientific literature.¹¹ Several clinicians have found that garlic extract exhibits antibacterial activity.¹²

The aim of the study was to evaluate the efficacy of formocresol, *Allium sativum* oil, and *Aloe barbadensis* gel as pulpotomy medicaments in primary molars both clinically and radiographically.

MATERIALS AND METHODS

The current study was designed as a double-blinded, randomized controlled trial with three parallel arms to compare the clinical and radiographic success of pulpotomy performed using aloe vera, *Allium sativum*, or formocresol. Ethical clearance and approval for the study was obtained from the Institutional review board of SRM Dental College, Ramapuram. (IRB NO: SRMDC/IRB/2016/MDS/No.801). This research was done in the Department of Pedodontics and Preventive Dentistry, SRM Dental College, Ramapuram, from January 2017 to June 2018. After examining 100 children, 50 children with 82 primary molars indicated for pulpotomy were included in the study with parental consent.

Inclusion Criteria

- Patients aged 5 to 9 years.
- Patients with no systemic diseases.
- Primary molars indicated for pulpotomy.
- Primary molars having deep carious lesions.
- Sufficient tooth structure for restoration with a stainless steel crown (SSC).
- Primary molars with at least two-thirds of the root length.

Exclusion Criteria

- Presence of spontaneous pain, tenderness to percussion, abscess, sinus opening, or abnormal tooth mobility.
- Presence of radiolucency at the furcation and periapical region, obliteration of the pulp and root canal, or internal/external root resorption.
- When hemorrhage from the site of amputation is not controllable even after 5 minutes.^{13,14}

A total of 82 primary molars enrolled in the study were divided into three groups (I, II, and III) by simple random sampling. A single operator performed the treatment for all the groups. The allocation of the medicaments for each group was determined by lottery method. For group I-Formocresol, group II-*Allium sativum* oil, and group III-*Aloe barbadensis* gel was used. Allocation concealment of the operator was done using the closed envelope method prior to treating each tooth. The operator could not be blinded, as the mode of delivery for each material differed. Blinding was done for the patient, and the postoperative evaluator. The procedure and the possible risks vs success of the treatment were described to the informer, and consent was procured before starting the investigation.

Procedure

The pulpotomy procedure done here was similar to the one advocated by Yildirim et al.¹⁵

- A topical anesthetic gel was applied to the mucosal surface for 2 minutes with a cotton swab prior to induction of 2% lignocaine.
- Then rubber dam was placed. All pulpotomy procedures were performed by a single dentist. All carious tissues were removed using a round bur with high speed handpiece.
- After obtaining access, the roof was removed using a non end-cutting bur. Amputation of the coronal pulp tissue was with a

sharp spoon excavator. The entire coronal chamber was checked for residual pulpal tissue which is then removed followed by debridement with saline.

- A sterile moist cotton pellet soaked in saline was then placed in the pulp canal; hemorrhage control was obtained with mild pressure for 3–5 minutes.

Group I (Formocresol)

This is the control group. After bleeding was arrested, formocresol (Deor RC Cresol) was placed into the canal by being impregnated in a cotton pellet and the excess squeezed using a piece of gauze. The formocresol pellet remained over the root stumps for 5 minutes. The pellet was removed and checked for bleeding and whether the pulp tissue had turned brown. Zinc oxide eugenol was then kept on the pulpal floor, and the cavity was sealed by using glass ionomer cement, and postendodontic restoration was done with stainless steel crown.

Group II (Garlic Oil)

In this group, the procedure was similar to formocresol pulpotomy as given by Mohammad et al.¹⁶ After hemorrhage control, a cotton pellet dipped in garlic oil and left in contact with pulp stumps and allowed to remain for 5 minutes. The radicular tissue turns to brown, similar to that of formocresol. Then, zinc oxide is mixed with garlic oil and packed into the pulp chamber and sealing was achieved with glass ionomer cement followed by semi-permanent restoration.

Group III (Aloe barbadensis Gel)

The procedure was done similar to the one by Gupta et al.¹⁷ Aloe-Vera gel loaded in syringe was placed over each root stump following hemostasis. The gel was placed only on the pulp stumps and the excess removed using a dry cotton pellet. This was followed by placement of zinc oxide eugenol on the pulpal floor, followed by glass ionomer closure of the cavity, and stainless steel crown restoration.

The teeth were evaluated clinically and radiographically at 6 and 12 months with the criteria adopted from Farsi et al.¹⁸ All the findings were recorded by a trained evaluator who evaluated the teeth both clinically and radiographically for the presence or absence of pathology.

RESULTS

The samples were selected according to the inclusion criteria for a period of 1 year, and pulpotomy was done after obtaining parental consent. The teeth were separated into three groups, and pulpotomy was done using one of the study materials. The teeth were then followed up for 6 and 12 months clinically and radiographically. The data obtained was analyzed with IBM. SPSS statistics software 23.0 Version. Chi-square test was used to compare two independent categorical variables (Clinical and radiographic result vs groups) for association. McNemar test was used to compare two dependent categorical variables (6 months vs. 12 months) for association.

Table 1 and Figure 1 reveal the intergroup comparison of clinical and radiographic findings at 6 and 12 months. The values reveal that there was no statistical significance in the success or failure between the groups at the end of 12 months.

Table 2 shows the clinical success or failure between the three groups. The values reveal that there were no clinical failures

Table 1: Radiographic success and failure at 6 and 12 months

		Group			Total
		Group I	Group II	Group III	
6 months	Failure	2	2	3	7
	Success	24	24	24	72
	Total	26	26	27	79
12 months	Failure	3	4	4	11
	Success	22	22	22	66
	Total	26	26	26	78

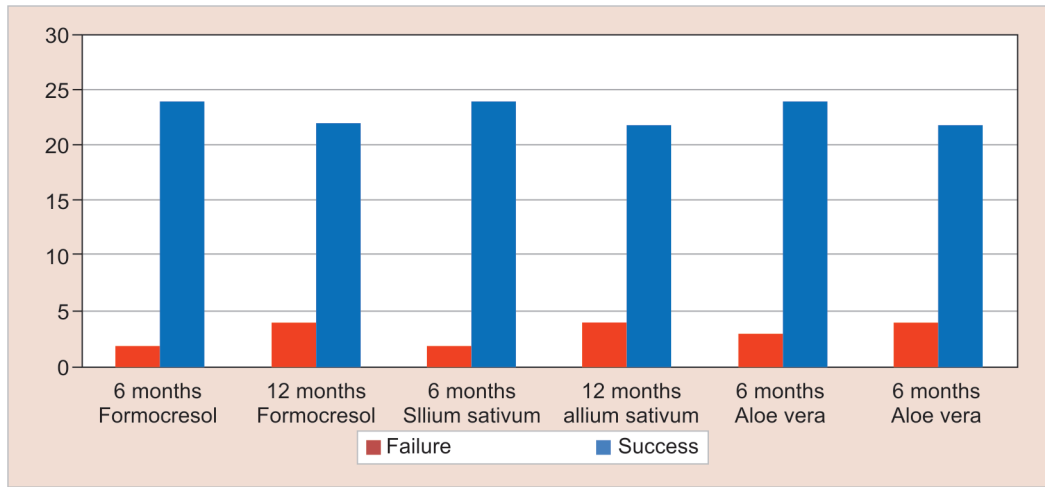


Fig. 1: Intergroup comparison of clinical and radiographic findings

Table 2: Clinical success and failure at 6 and 12 months

Group			
Group I	Group II	Group III	Total
26	26	27	79
26	26	27	79
26	26	26	78
26	26	26	78

observed. Hence, a statistical test could not be performed for these findings.

DISCUSSION

The vitality of pulp has always influenced the treatment plan for the tooth, especially a primary tooth that has a short life in the human body. Proper pulpal diagnosis leads to the correct use of material and treatment modality in the primary dentition.¹⁹ Vital pulp therapy has always been the treatment of choice when dental caries has advanced close to or into the coronal pulp chamber.²⁰

Formocresol has been used in pulpotomy for a long time. The first incidence of formocresol pulpotomy has been given by Sweet in 1930.^{21,22} Ever since numerous studies have researched the effects of each component of formocresol such as formaldehyde and tricresol. These studies have examined the effect of formocresol as a whole or separate for their toxicity on the skin, oral mucosa, pulp tissue on the permanent tooth bud and systemic effects.²³⁻²⁵ Grundy et al., in 1984 in his case series, have discussed the prevalence of cysts in patients who were treated endodontically with formocresol.^{26,27} Ranly et al. in 1976 found that cresol

hindered the pulp healing in rat pulp tissue.²⁸ Jeng et al., in 1987 examined, the cytotoxicity of formocresol, formaldehyde cresol, and glutaraldehyde using cultures of pulp fibroblast. On comparing with formocresol or 19% formaldehyde, 2.5% glutaraldehyde was 15–20 times less cytotoxic and cresol measured 40 times less toxic.²⁹

In the present study, the need to find an alternative to the gold standard formocresol has been addressed. The use of herbal products for treating ailments has been on the rise recently, and the effect of various plant based products has been evaluated in pediatric endodontics. *Aloe barbadensis* miller, commonly known as aloe vera, is an established naturally available medicament for the management of soft tissue injuries like burns and wounds for ages. Acemannan, a polysaccharide obtained from *Aloe barbadensis* gel, has been acknowledged for its cytocompatibility and its wound-healing properties.¹⁰ Jittapiromsak et al. found that acemannan when exposed to pulp tissue caused deposition of dentin which occurs by pulp cell proliferation, and differentiation into odontoblast-like cells, and mineral deposition, thus creating a dentin barrier on the exposed pulp tissue.¹⁰ Khairwa et al. have used *Aloe barbadensis* gel along with zinc oxide powder as a pulpectomy medicament with success.³⁰ Songsiripradubboon et al. used aloe vera extract, Acemannan, in direct pulp capping and found that there was clinical and radiographic success after 6 months.³¹

Allium sativum, the common garlic, has shown therapeutic properties recorded in folk medicine and scientific literature. Many studies have evaluated the antibacterial activity of garlic extracts.¹¹ Allicin and other thiosulfinates are believed to be responsible for the therapeutic effects of garlic. It is efficacious against both gram-positive and gram-negative organisms.¹² Mohammad et al. discovered that *Allium sativum* oil has found to have antibacterial

properties that enable it to fight intracanal microbes in primary molars having deep dentinal caries.³² Baroudi et al., in 2015, examined the efficacy of *Allium sativum* oil as a pulpotomy medicament in deciduous teeth with infected pulp and came to the conclusion that garlic oil showed promising results as a pulpotomy medicament.¹⁶ Thus, in our study, the effectiveness of *Aloe barbadensis* gel and garlic oil has been evaluated as pulpotomy medicament against the gold standard formocresol.

The clinical and radiographic success for each group was determined by scoring for the presence or absence of pathoses. This criteria was adopted from Farsi et al.¹⁸ In the presence of a pathological finding, the tooth was recorded as a failure and on absence considered a success. A blinded examiner who was not aware of the material being used for each group evaluated the clinical and radiographic findings at 6 and 12 months, respectively.

In the control group, after 6 and 12, months all the teeth accessible for review were considered as clinically successful, about two teeth at 6 months and three at 12 months were recorded as radiographic failures. In the study groups both *Allium sativum* oil and *Aloe barbadensis* gel showed 100% clinical success rate after 6 and 12 months and four teeth in each group was considered a failure after 12 months. There was no statistically significant difference found on intergroup comparison. Khan et al. and Durmus et al. compared ferric sulfate as a pulpotomy agent with formocresol as the control and found that both materials did not have a significant difference in success rate.^{33,34} Hugar et al. found similar results while comparing mineral trioxide aggregate (MTA) with formocresol as pulpotomy medicament.³⁵ After the 1-year mark, two more teeth in the aloe vera group presented as radiographic failures and one in *Allium sativum* group, these findings reveal that a longer follow-up is required to assess the efficacy of these material.

Aloe barbadensis gel and *Allium sativum* oil have shown similar efficacy to that of formocresol and may be an effective alternative. But a longer period of follow-up is required to know their long-term effects. Postoperative evaluation was done by a single evaluator which could have caused a bias. Future studies with a longer follow-up period is required to assess the effectiveness of these materials in pulpotomy.

CONCLUSION

Both *Aloe barbadensis* gel and *Allium sativum* oil performed similar to formocresol in the clinical and radiographic aspect. Although aloe vera group had more failures when compared to the other groups, the difference was not statistically significant. Thus, these new medicaments can be considered as an alternative to the gold standard formocresol.

CLINICAL SIGNIFICANCE

- Buckley's formocresol is no longer recommended as the gold standard for pulpotomy due to its cytotoxic and carcinogenic potential and hence, there has been a search for newer materials
- *Allium sativum* oil and *Aloe barbadensis* gel have been used in the present study as they are naturally occurring products and have been proven to be biocompatible.

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