ORIGINAL RESEARCH

Evaluation of Chitosan and Ferric Sulphate as Pulpotomy Agents in Primary Teeth: A Randomized Controlled Trial

Shirisha Guguloth¹, Sharada Reddy Jampanapalli², Tarasingh Patloth³, Konda Suhasini⁴, Hema Chandrika Ingua⁵, Hasanuddin Shaik⁶

ABSTRACT

Introduction: Preservation of healthy pulp tissue is detrimental for the function and vitality of carious primary teeth. Several hemostatic agents used for pulpotomy in primary teeth showed adverse effects on viable surrounding structures.

Aims: To assess the clinical and radiographic success of chitosan (CH) pulpotomy in primary molars and to compare it with ferric sulphate (FS). Materials and methods: A total of 40 carious lower primary second molars in 5–9 years children are selected for conventional pulpotomy technique. Over radicular stumps, FS is placed for 15 seconds in the control group, and CH for 4–5 minutes in the study group, followed by intermediate restoration (IRM). Intraoral periapical radiographs were taken immediately after 1 week and after 3rd and 6th months. The clinical

Results: Chitosan (CH) showed a 65% radiographical and 100% clinical success rate, and FS showed 55 and 95%, respectively.

Conclusion: Chitosan (CH) showed better results than FS as a pulpotomy agent in primary teeth.

Keywords: Chitosan, Ferric sulphate, Primary teeth, Pulpotomy.

and radiographic success rate is assessed and statistically analyzed.

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Introduction

The pulpotomy technique is the predominant pulp therapy for deciduous teeth due to their complicated anatomy of the root canals, the proximity of the successor tooth germ, and difficulty in finding an obturating material compatible with physiological root resorption.

Formocresol is one of the widely used pulpotomy agent chosen for many years, but certain disadvantages of it are inducing inflammation of the pulp, being distributed systemically, having carcinogenic potential, and also cytotoxic.^{1–3} Since then, there is a search for a better substitute. One such material is CH, a natural polysaccharide extracted from the exoskeleton of crustaceans. It is nontoxic, biocompatible, biodegradable, antibacterial, mucoadhesive, has a wound healing capacity, and hemostatic property.^{4,5}

Chitosan (CH) is the most promising pulp dressing material due to its direct hemostatic properties attributed to the sorption of plasma, erythrocytes coagulation, platelets adhesion, aggregation, and activiation. $^{6-8}$

Depending on these properties of CH, it is selected as a pulpotomy agent in the present study; as most of the properties of CH are correlating with FS, it is decided to compare CH with FS. The ferric and sulphate ions of FS will react with blood causing agglutination of blood proteins. It has antimicrobial activity on various microorganisms due to its acidic pH and cytotoxicity. Until now, not many studies are published comparing CH and FS as pulpotomy medicaments in deciduous teeth. Therefore, a study is designed to evaluate the clinical and radiographical success rate of these two materials as pulp dressing agents in deciduous molars.

MATERIALS AND METHODS

The children who attended the pedodontia department at Government Dental College and Hospital, Hyderabad, Telangana, India, were screened for the study, of which 78 children met the inclusion criteria. Only 46 parents out of 78 gave their consent for

¹⁻⁶Department of Pedodontics, Government Dental College and Hospital, Hyderabad, Telangana, India

Corresponding Author: Sharada Reddy Jampanapalli, Department of Pedodontics, Government Dental College and Hospital, Hyderabad, Telangana, India, Phone: +91 9290970400, e-mail: sharadagdchyd@gmail.com

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the study. About six of the patients dropped out due to personal reasons. Finally, 40 patients of age in between 5 and 9 years were selected and grouped as follows:

- Group I: Chitosan (CH) capsules (INLIFE Healthcare, GR Health Care Laboratories, Hyderabad, India).
- Group II: Ferric sulphate (FS) (15.5%) (Astringedent, Ultradent products Inc., United States of America).

The Inclusion Criteria for Teeth Selection

The teeth with the deep carious lesions; without spontaneous pain, swelling, or alveolar abscess; absence of tooth mobility; and teeth with not more than one-third physiologic root resorption were included in the study.

Exclusion Criteria

The teeth with spontaneous pain, swelling or fistula, periapical or bifurcation radiolucency, internal resorption of the tooth, and teeth with more than one-third root resorption were excluded.

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Methodology

After anesthetizing the tooth and isolation with a rubber dam, access cavity preparation was done using a high-speed airotor handpiece (NSK, Panamax, Japan) with a number 6 round bur. The pulp chamber was exposed and then the coronal pulp was removed with a spoon excavator. After amputation of the coronal pulp, bleeding was controlled by a moist cotton pellet.

- Group I: Chitosan (CH) (3%) was used as a pulpotomy agent.
 About 3 mg of CH powder was weighed and dissolved in
 100 mL of 3% glacial acetic acid (3 mL of glacial acetic acid is
 dissolved in 97 mL of distilled water). A cotton pellet moistened
 with CH solution is placed in the pulp chamber for 5 minutes
 (Figs 1 and 2).
- Group II: Nearly 15.5% FS was applied in the pulp chamber for 15 seconds with a brush applicator provided by the manufacturer (Fig. 3).

Following pulpotomy, the teeth were restored with intermediate restorative material (IRM, Dentsply Sirona, Germany) over which glass ionomer cement (GC corporation, Tokyo, Japan) was placed. After 1 day, tooth preparation was done and the stainless steel crown (Unitek 3M ESPE, Seefeld, Germany) was fixed. These children were evaluated clinically and radiographically immediately after

the procedure, 1st week, 3rd, and 6th months and recorded using the following evaluation criteria (Fig. 4):

Clinical Criteria

- · Pain.
- Swelling.
- · Draining sinus opening.
- · Pain on percussion.
- · Pathological mobility.

Radiographic Criteria

- · Periodontal ligament widening.
- · External or internal resorption.
- Furcational radiolucency.
- · Periapical abscess.

All the clinical and radiographical findings were recorded, and results were subjected to Chi-squared test.

RESULTS

Clinical assessment of CH and FS pulpotomy group after 1 week, 3, and 6 months did not present with a history of pain, draining sinus, pain on percussion, and pathological mobility except swelling in



Fig. 1: Application of CH for 5 minutes



Fig. 3: Application of FS for 15 seconds



Fig. 2: After the application of CH



Fig. 4: After the application of FS



one tooth in the FS group after 6 months, but it is not statistically significant (Table 1).

Radiographic assessment of both the groups revealed all the signs and symptoms under inclusion criteria after 6 months, among which the CH group showed less number of teeth with pathological resorption (15%), radiolucency in bifurcation (5%), and periapical abscess (20%) when compared to FS group, which is not significant (Table 2).

Discussion

In the present study, the clinical and radiographic success rates of CH were 100 and 65%, respectively, and FS showed 95% clinical and 55% radiographic success rates but this difference was not significant statistically (p > 0.05) (Table 3).

Clinical parameters are checked in both the groups for a period of 6 months follow-up. There was no history of pain, draining sinus, pain on percussion, or pathological mobility in any of the teeth after 1 week, 3, and 6 months in both CH and FS pulpotomy groups. The swelling was not seen till 3 months in both groups, but the FS group presented with one case of swelling in the 6th month, whereas no swelling was seen in the CH pulpotomy group.

Radiographical parameters in both the groups for a period of 6 months follow-up showed pathological resorption in three teeth of CH and five teeth of the FS group with no statistically significant difference. Widening of the periodontal ligament was seen in two teeth of the CH pulpotomy group and five teeth in the FS group after

6 months with no statistically significant difference. Radiolucency in bifurcation was presented only in one tooth in each of the groups. Formation of the periapical abscess was seen in four teeth of CH pulpotomy group and six teeth in the FS group after 6 months with no significant difference statistically.

Considering the results of the present study, CH has shown good results as a pulpotomy agent. This can be because of its good hemostatic and wound healing enhancing properties, along with antibacterial action and biocompatibility.¹⁰ These results were coinciding with a study conducted by Jian Jian et al.¹¹

Though the clinical success rate in this study was similar to other studies, radiographic success was not similar to other studies. There were failures after 6 months in the FS group when compared to the CH group. Clinically postoperative swelling was seen after 6 months in one case in the FS pulpotomy group, which might be due to chronic inflammation of the pulp and periradicular tissue leading to edema, which progresses into pathologic mobility as explained by Havale et al.¹² The FS group showed 95% success rate clinically which was similar to study done by Giosure¹³ who suggested that the clinical success of FS is dependent on pulp status, as it is not an antimicrobial agent and could not heal pulp or stimulate pulp regeneration. Hence, out of 21 teeth, five teeth treated with FS showed pathological resorption, five teeth showed widening in periodontal ligament, one tooth showed radiolucency in bifurcation, and six teeth showed formation of periapical abscess. Periapical radiolucency could be attributed to the release of toxins by the bacteria via the periapical foramina (Goyal et al.). 14 The

Table 1: Postoperative clinical assessment after 1st week, 3rd, and 6th month in both the groups

1st week		week	_	3rd i	nonth		6th m		
Clinical parameters	CH (n = 20)	FS (n = 20)	p-value	CH (n = 20)	FS (n = 20)	p-value	CH (n = 20)	FS (n = 20)	p-value
History of pain	00	00	-	00	00	-	00	00	-
Swelling	00	00	-	00	00	-	00	01 (5%)	0.374 ^{NS}
Draining sinus	00	00	-	00	00	-	00	00	-
Pain on percussion	00	00	-	00	00	-	00	00	-
Pathologic mobility	00	00	-	00	00	-	00	00	-

CH, chitosan; FS, ferric sulphate; n, number of teeth; NS, not significant

Table 2: Postoperative radiographical assessment after 1st week, 3rd, and 6th month in both the groups

	1st v	veek		3rd month			6th month		
Radiographical parameters	CH(n = 20)	FS (n = 20)	p-value	CH(n = 20)	FS (n = 20)	p-value	CH(n = 20)	FS (n = 20)	p-value
Pathological resorption	01 (5%)	02 (10%)	0.578 ^{NS}	02 (10%)	04 (20%)	0.413 ^{NS}	03 (15%)	05 (25%)	0.477 ^{NS}
Periodontal ligament widening	01 (5%)	03 (15%)	0.317 ^{NS}	01 (05%)	04 (20%)	0.169 ^{NS}	02 (10%)	05 (25%)	0.240 ^{NS}
Radiolucency in bifurcation	01 (5%)	00	0.300 ^{NS}	01 (05%)	01 (5%)	0.972 ^{NS}	01 (05%)	01 (5%)	0.972 ^{NS}
Periapical abscess	01 (5%)	00	0.300 ^{NS}	03 (15%)	02 (10%)	0.592 ^{NS}	04 (20%)	06 (30%)	0.523 ^{NS}

CH, chitosan; FS, ferric sulphate; n, number of teeth; NS, not significant

 Table 3:
 Intercomparison of the clinical and radiographical success rate of teeth in both the groups

	Success rate				
	СН		FS		
Groups	n	%	n	%	p-value
Clinical success	20	100%	19	95%	0.323
Radiographical success	13	65%	11	55%	0.412

n, number of teeth; p, probability

most common radiographic finding with the FS pulpotomy was internal resorption (Odabas et al.)¹⁵ could be due to the thinness of deciduous molar roots and also due to the reaction of eugenol in pulpotomies temporarily restored with zinc oxide eugenol cement. The eugenol will lead to the release of histamines in the pulpal blood flow, causing vasodilation, inflammatory response, and consequently progress to internal resorption.^{16,17}

Interradicular radiolucency might be attributed to the rapid spread of inflammation in primary teeth and also to the seepage of the medicament, bacteria, and their toxins into the apical region through the root canals from accessory canals or furcation area, which are usually thin, porous, and permeable in deciduous molars.¹⁸

The only advantage of FS over other pulpotomy medicament is the time required for homeostasis, that is, only 15 seconds is required for FS compared to 5 minutes for CH.

The clinical and radiographic success rates of the two agents in the present study were not statistically significant (p > 0.05). The probable reason for failures can be due to the infected radicular pulp, which is difficult to diagnose with current techniques. At present, methods are not available to assess the demarcation between inflammation of the coronal and radicular pulp, which is the main criterion for a successful pulpotomy. Clinical and radiographic diagnostic techniques which are currently used are not gold standard techniques. Hence, research is required to overcome this shortcoming in the diagnostic technique.

Limitations

Histological evaluation is the gold standard for the evaluation of any pulpotomy agent. But due to the shorter follow-up duration, smaller sample size, time constraints, and ethical considerations, it was not possible to perform the histological evaluation in this study.

Conclusion

After 6 months of follow-up, clinically, the success rates were 100% for CH and 95% for the FS group. A radiographic success rate was 65% with CH and 55% with FS. CH has shown superior results over the FS group both clinically and radiographically.

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