Comparative Evaluation of Clinical and Radiographical Outcomes of Propolis as a Pulpotomy Agent for Primary Teeth

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Abstract

Objectives: The systemic and local toxic effects of formocresol have led to research in the area of alternative medicaments for pulpotomising primary teeth. Propolis is a natural, biocompatible material with therapeutic advantages. The aim of the present study was to evaluate and compare clinical and radiographic success of formocresol and 15% propolis tincture in pulpotomy of primary molars at 3, 6, and 12 month intervals.

Study design: 40 primary molar teeth from 33 children aged between 4-7 years were selected and randomly divided into two groups of twenty teeth each. Group 1 was pulpotomised with formocresol and Group 2 with propolis. The pulpotomised teeth were evaluated clinically and radiographically at 3, 6 and 12 months. The obtained data was subjected to Chi squared test.

Results: The results showed no statistically significant difference in the overall success between the two groups at 3, 6 and 12 months. There was a 100% clinical success in both the groups and radiographically no significant difference was found between the groups except in relation to periapical/furcal radiolucency.

Conclusion: Propolis can be a promising medicament in pulpotomy of primary teeth. However, further studies have to be carried out to determine its concentration and mode of use

with a larger sample size and longer follow up periods.

Key words: Formocresol, Propolis, Pulpotomy

Introduction: The importance of maintaining primary teeth in the arch until normal exfoliation is unequivocal. Primary tooth offers the best space maintenance and acts as a template for the eruption of permanent teeth, aids in mastication, helps in developing proper speech and also contributes to aesthetics in a child [1]

The treatment of cariously involved vital primary teeth has always been a very controversial and debatable topic [2] Carious primary teeth with sound pulp which needs pulp therapy or teeth diagnosed with reversible pulpitis are best treated with vital pulp therapy. Three vital pulp therapy procedures currently exist for treatment of deep dentin carious lesions which closely approximate the pulp in vital primary teeth viz indirect pulp treatment, direct pulp capping and pulpotomy. [3]

Formocresol has for a long time remained the 'gold standard' medicament in pulpotomy of primary teeth because of its bacteriostatic and fixative properties making its comparison with newer pulpotomy agents a commonality.[4] Although formocresol offers incredible clinical and radiographic success rates, the fact that it remains a potential mutagenic, carcinogenic and also causes immune sensitization has led to research in newer pulpotomy medicaments.[5]

In recent times, MTA and Biodentine have shown outstanding success rates in pulpotomy of primary teeth and have come close to replacing formocresol. However, MTA and Biodentine both have disadvantages of not being cost effective and need a high setting time.[6] [7] Therefore, the search for an ideal pulpotomy material goes on and as a part of a growing trend to use naturally occurring medicines, Propolis has been one of the most recently used pulpotomy agents. Propolis is a natural bee product with therapeutic properties like antioxidant, antibacterial, antifungal, antiviral, anti-inflammatory, antitumor and immunomodulating properties. [8] [9]

Hence, the present study aimed to evaluate and compare clinical and radiographic signs after pulpotomy with formocresol and 15% propolis tincture in primary molars at 3, 6, and 12 months.

Materials and Methods:

Study Design: A double blind clinical trial was conducted to evaluate and compare the clinical and radiographic success of pulpotomy of primary molars with formocresol and propolis. The participating children and their parents were informed about the protocol of the study and prior parental consent was obtained regarding the potential benefits and possible

risks involved with the study. Ethical clearance to conduct the study was obtained from the institutional review board.

Subjects: 40 carious teeth from 33 children (18 girls, 15 boys) aged between 4-7 years were included in the study.

Criteria for tooth selection: Primary molars selected in this study were based on clinical & radiographic screening.

Table 1: Inclusion and Exclusion criteria

Inclusion criteria:	Exclusion criteria:
1. Healthy Co-operative patient.	1. Continuous pain.
2. Carious exposure of vital pulp.	2. Existence of abscess or fistula in relation to teeth.
3. No clinical and radiographic evidence of pulpal degeneration.	3. Tooth close to natural exfoliation.
4. Radiographic evidence of presence of 2/3rd of the root.	4. Presence of inter radicular bone loss.
5. Possibility of proper restoration of primary molars.	5. Evidence of internal resorption.
6. Children with prior parental consent.	

Groups: The selected teeth were randomly divided into two groups of twenty teeth each. Group 1 was pulpotomised with Formocresol IP (Pharma dent Dental products) and Group 2 with 15% Propolis tincture (Nature's Goodness Australia Pty Ltd).

Procedure: All the selected teeth were anesthetized and isolated with rubber dam. After the removal of infected dentine with a large slow-speed round bur, access cavity preparation was done using a No.330 carbide bur mounted in a water-cooled high speed turbine, pulp chamber was de-roofed followed by irrigation with saline. Coronal pulp amputation was achieved with a round bur or spoon excavators and the pulp chamber was irrigated with copious amounts of saline. Haemorrhage was controlled by applying gentle pressure with moist sterile cotton pledgets for two to three minutes.

In the formocresol group, a cotton pledget was saturated with 20% solution of Buckley's

Formocresol and after removing the excess formocresol, the pledget was placed directly over the radicular pulp stumps and covered with dry cotton wool. The cotton pledget was removed after 1 minute. After a minute, the pulp chamber was observed for brownish to black discoloration of fixed radicular pulpal tissue on the root canal orifices. A 3-4 mm thick lining of zinc oxide eugenol cement was placed to seal the coronal pulp chamber, followed by restoration with miracle mix.

Whereas, in the propolis group, a cotton pledget dampened with 15% propolis tincture was placed over the pulp stumps for about 5 minutes till a brownish to black discoloration of the radicular pulp stumps could be seen. A 3-4 mm thick lining of zinc oxide eugenol cement was placed to seal the coronal pulp chamber, followed by restoration with miracle mix.

The teeth were restored with stainless steel crowns immediately after pulpotomy. The children were recalled at 3, 6 and 12 months interval for clinical and radiographic evaluation. Two examiners blinded to the treatment performed the evaluation.

The results were tabulated and subjected to statistical analysis using the Chi squared test.

Table 2: Criteria for postoperative evaluation

Clinical success:	**Radiographic success**
1. No pain	1. No radiolucency in periapical/furcationarea
2. No discolouration of tooth	2. No external or internal resorption
3. No swelling and/or fistula	3. No widening of periodontal space
4. No sensitivity to percussion	
5. No pathologic tooth mobility	

Results: 40 teeth from 33 children were randomly divided in to two groups and treated with formocresol and propolis. At 3 months, out of the 33 children, two children (one tooth each from the formocresol and propolis group) dropped out of the study after the pulpotomy was

performed as they left the city. 38 treated teeth were evaluated at 3 and 6 months. At the 12 month follow up 5 children (7 treated teeth) dropped out of the study as they moved to another locality and could not return for follow up visit and so, only 33 treated teeth were evaluated clinically and radiographically.

Both the groups showed a 100% clinical success at the end of twelve months. Radiographically, in the propolis group, at the end of twelve months, 5 (29%) teeth showed periapical and furcal radiolucency, 5 (29%) teeth showed internal resorption and 1 (6%) tooth showed widening of the periodontal ligament space. Whereas, in the formocresol group, there was no periapical and furcal radiolucency, 3 (19%) teeth showed internal resorption and widening of the periodontal ligament space was not seen in any teeth. However, at 12 months, a statistically significant association was seen with respect to periapical/furcal radiolucency (P=0.027). The overall success of formocresol and propolis groups was 84% and 68%respectively.

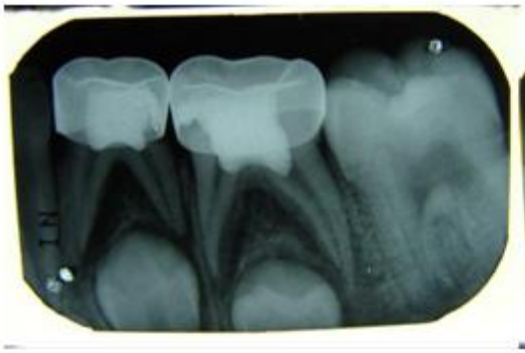


Figure 1: Furcal Radiolucency

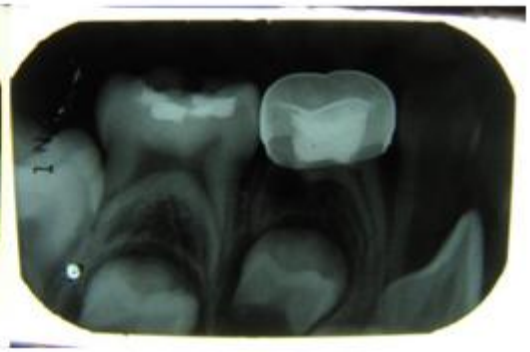


Figure 2: Internal Resorption

Table 3: Post-operative clinical evaluation

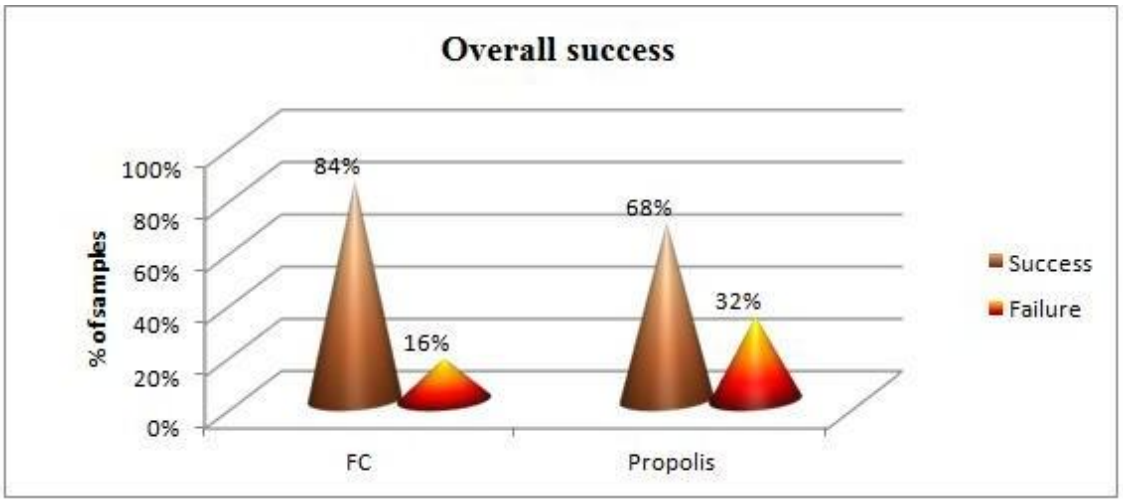
Group	Total no. of treated teeth	3rd month				6th month				12th month				1 to 12 months follow up			
		S	%	F	%	S	%	F	%	S	%	F	%	S	%	F	%
FC	16	16	100	0	0	16	100	0	0	16	100	0	0	16	100	0	0
P	17	17	100	0	0	17	100	0	0	17	100	0	0	17	100	0	0
Total	33	33	100	0	0	33	100	0	0	33	100	0	0	33	100	0	0

FC=Formocresol, P=Propolis, S=Success and F=Failure

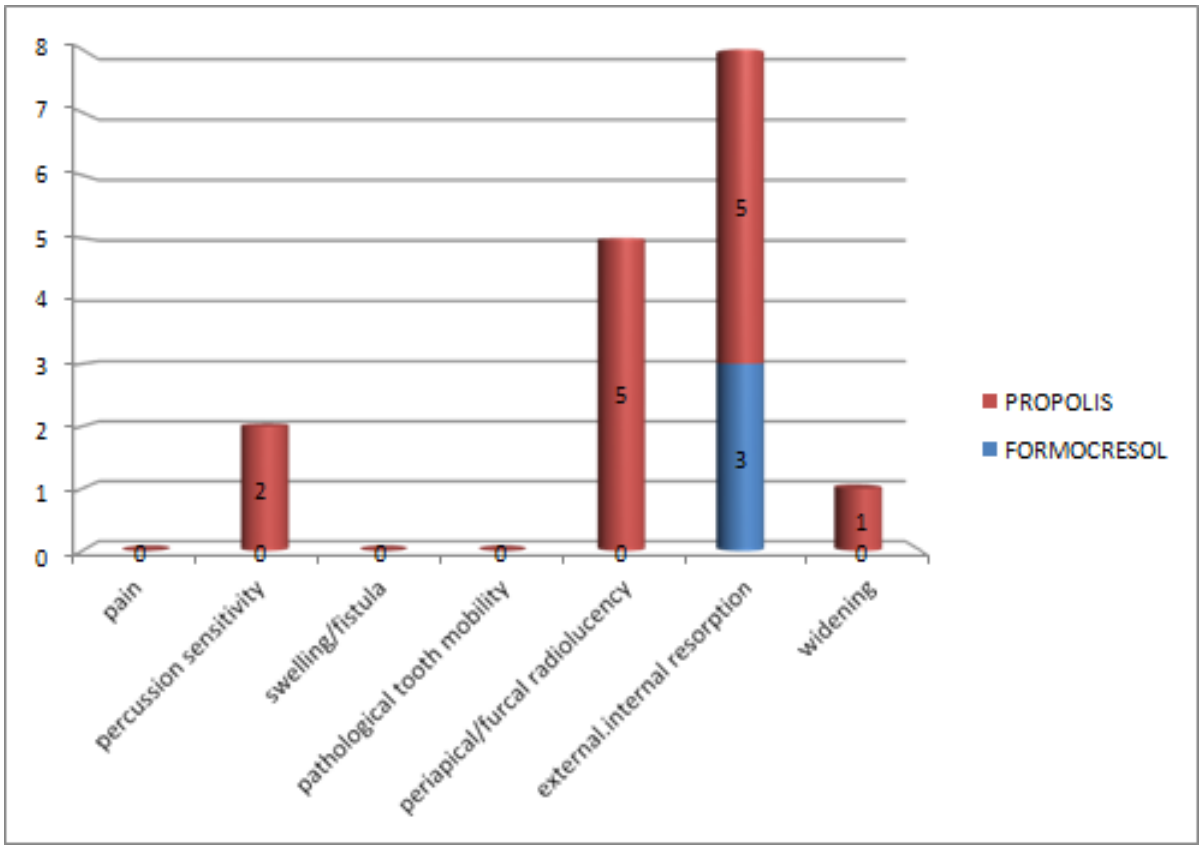
Table 4: Post-operative radiographic evaluation

Group	Total no. of treated teeth	3rd month				6th month				12th month				1 to 12 months follow up			
		S	%	F	%	S	%	F	%	S	%	F	%	S	%	F	%
FC	16	15	93.75	1	6.25	15	93.75	1	6.25	13	81.25	3	18.75	13	81.25	3	18.75
P	17	13	76.47	4	23.53	12	70.58	5	29.42	11	64.7	6	35.3	11	64.7	6	35.3
Total	33	28	84.85	5	15.15	27	81.81	6	18.19	24	72.3	9	27.7	24	72.3	9	27.7

Graph 1: Overall success



Graph 2: Incidence of clinical and radiographic findings



Discussion: Pulpotomy is one of the most frequently used treatments for retaining cariously involved primary molars. The successful outcome of treatment of primary teeth depends not only upon the treatment choice but also on the medicaments used in pulpotomy. Various materials have been tried till date, but formocresol remains to be the gold standard and has been used extensively worldwide for the past 80 years in pulpotomy of primary teeth since its introduction by Sweet in 1932.[10] It is available as Buckley's formocresol (19% formaldehyde, 35% cresol, 17.5% glycerin), which is a potent bacteriostatic and fixative agent and is routinely used in a 1:5 dilution.[11]

During recent times, there is a concern over formocresol as a pulpotomy medicament due to its systemic and local toxic effects. Casas et al state that the three areas of concern regarding formaldehyde are its mutagenicity, carcinogenicity and immune sensitization.[5] A press release in 2004 by the International Agency for Research on Cancer changed the status of formocresol from a “probable” to a “known” human carcinogen based on exposure levels to laboratory animals.[12]

However, contrary to Casas et al, Milnes had different views about the use of

formocresol. Milnes compared the amount of formocresol available for absorption to the dental pulp by soaking number 4 cotton pellets in full strength and 1:5 dilution formocresol and squeeze drying it and found that approximately 0.1 to 0.5 mg of full strength and 0.02 to 0.1 mg of 1:5 dilution of formocresol could be absorbed by the pulp tissue. It is also highly likely that the actual dose delivered to the pulp tissue is probably much smaller as majority of the formocresol will remain in the cotton pellet. He further stated that unless compelling evidence is found which validates the use of formocresol in pulpotomy to cancer or immune sensitization, there is absolutely no reason to discontinue its use in dentistry. [13]

The present study utilized a one-minute application of a 1:5 dilution of formocresol over the pulp stumps. Kurji in 2011 utilised a modified 1-minute application of full-strength Buckley's formocresol in human primary teeth which showed it to be an effective alternative to the conventional 5 minute formocresol technique achieving a 99.3% success rate. [14] [15]

In an effort to find a more biologically acceptable and effective alternative to formocresol, other agents and techniques have been examined. A variety of materials have been tried as a pulpotomy agent like gluteraldehyde, ferric sulfate, sodium hypochlorite, mineral trioxide aggregate, triple antibiotic paste, bone morphogenetic protein, enamel matrix derivatives, calcium enriched mixture cement, calcium phosphate cement, electrosurgery, laser, biodentine and propolis. Among these materials, propolis is a natural bee product which is biocompatible and therapeutic and therefore, could be considered as an alternative to formocresol in pulpotomy of primary teeth.

Propolis is a traditional medicine known for its claimed beneficial effects on human health. Propolis is a sticky, resinous substance collected by honey bees from the sap, leaves, and buds of plants, and then mixed with secreted beeswax. It is composed of resin and balsams (50-70%), essential oils and wax (30-50%), pollen (5-10%) and other constituents which are amino acids, minerals, vitamins A, B complex, E and bioflavonoids, phenols and aromatic compounds. The caffeic acid phenethyl ester (CAPE) present in propolis which is a biologically active compound and contributes to its anti-inflammatory and anti-oxidant properties.[8]

Propolis has a wide range of applications in pediatric dentistry due to its therapeutic effects. Propolis has been used as a mouth rinse, anti-cariogenic agent, direct pulp capping, pulpotomy, root canal irrigant, intracanal medicament, for wound healing, as an antiplaque agent, as a storage media avulsed tooth. [16] Despite the beneficial effects of Propolis, there are concerns regarding its safety. Propolis is generally safe for topical application on skin or

as a supplement. However, it may lead to allergies in people who are known to be allergic to other bee products and it could be ascribed to caffeic acid present in propolis. Allergy to propolis could manifest in an individual as rashes, itchiness, redness and swollen skin.[8] Taking a proper and detailed medical history of the patient, and using propolis judiciously could overcome this drawback. In the past decade, propolis has been used in various forms as a pulpotomy agent in primary teeth, achieving good clinical and radioghraphic success.

Table 5: Studies using Propolis in various forms in pulpomy of primary teeth

Study	Sample size and Age	Inclusion criteria	Type of Propolis used	Compared with	Follow up	Evaluation criteria	Propolis Success Rate
Talat M Beltagy et al., 2013 [17]	40 teeth in 20 children, 4-8 years	Asymptomatic deep carious lesion	Propolis paste (mixing propolis extract powder with propylene glycol)	Formocresol	3, 6, 9 and 12 months	Clinical Radiographic	94.12% 94.12%
Bharti Kusum et al., 2015 [18]	75 teeth in 75 children, 3-10 years	Vital teeth with carious pulp exposure	1.5gm of standardized 100% propolis extract powder mixed with 1.75ml of polyethylene glycol	MTA Biodentine	9 months	Clinical Radiographic	84% 72%
H Alolofi et al., 2016 [19]	60 primary molars in 20 children, 4-6 years	Vital teeth with carious pulp exposure	Freshly prepared mix of zinc oxide powder and drops of propolis ethanolic extract (1:1 by volume)	Formocresol Thymus vulgaris	1, 6 and 12 months	Clinical Radiographic	88.2% 73.3%
Abd-El Moneim S et al., 2017 [20]	60 primary molars in 60 children, 4–9 years	Vital tooth with deep carious lesion	Propolis powder mixed with propylene glycol	Formocresol	3 months	Pain Swelling Sensitivity topercussion	90% 100% 100%
Shivayogi M Hugar et al., 2017 [21]	90 primary molars in 45 children, 4-9 years	Vital teeth with carious pulp exposure	33% green propolis extract for five minutes	Formocresol Turmeric gel Calcium hydroxide	1, 3 and 6 months	Clinical Radiographic	100% 93.3%

Aghazadeh et al., 2018 [22]	50 teeth in 25 children, 4-8 years	Vital teeth with carious pulp exposure	Standard propolis powder mixed with distilled water	MTA	3, 6 and 9 months	Clinical Radiographic	MTA is more suitable than Propolis
Venugopal Reddy et al., 2019 [23]	90 primary molars from 75 children, 5-10 years	Vital teeth with carious pulp exposure	Propolis powder (Ecuadian rain) with titanium dioxide powder (2:1) mixed with 70% ethyl alcohol	Formocresol Platelet Derived Growth Factor (PDGF)	3 and 6 months	Clinical Radiographic Histologic	96.3% 88.4%
Madan K et al., 2020 [24]	40 primary molars from 32 children, 4-9 years	Cariously exposed vital primary molars	15% Propolis tincture	MTA	3, 6 and 12 months	Clinical Radiographic	Higher success rate in MTA group

A readily available 15% propolis tincture was used in this study for its ease of application. Also, tinctures have been traditionally used since time immemorial. Tinctures are extracts of plant or animal materials dissolved in ethanol. Solvent concentrations of 25-60% are common, but may run as high as 90%. Chemically, tinctures are solutions which have ethanol as its solvent. The 15% propolis tincture used in the present study contained 150mg of propolis in 1ml of ethanol. The entire mechanism of action of 15% Propolis tincture is not fully established yet. However, the therapeutic properties of Propolis combined with the ethanol content of the tincture may contribute to its antiseptic and dehydrating effects on the oedematous tissue. Ethanolic extracts of propolis may also promote bone regeneration and induce hard tissue bridge formation in pulpotomies or pulp capping. [25] The 100% clinical success of pulpotomy with propolis in the present study is in accordance with the previous studies. [21] [26] In the present study the overall success of formocresol and propolis groups was 84% and 68% respectively and the association was not statistically significant. Though there was a 100% clinical success, radiographically, internal resorption and periapical/furcal radiolucency was seen in propolis group.

The increased periapical and furcal radiolucency in the propolis group could be attributed to the diluted form of propolis used. In a previous study, A Parolia used propolis as a pulp capping material, where, a 100% propolis powder was mixed with 70% ethyl alcohol

and was placed over the exposure site and the results showed that teeth capped with propolis exhibited lesser inflammation and more dentin bridge formation when compared to dycal which showed more inflammation and incomplete dentin bridge formation.[27] Over the last decade, propolis has been used in different concentrations and forms (powder, liquid) in various studies worldwide with favourable clinical and radiographic outcome. Therefore, it could be contemplated that the differences in the concentration, the form of the medicament, mode of use, the geographic area from which propolis is collected, could affect treatment outcome. Also, failure of pulpotomy could be accredited to undiagnosed inflammation in the residual pulp prior to treatment or pulpal contamination from microleakage. [28]

With the growing concerns of formocresol toxicity and its use in pediatric dentistry, alternative medicaments have to be investigated. Propolis is a natural and biocompatible material which has been successfully used in dentistry. Further studies have to be conducted using larger sample sizes and longer periods of follow up to investigate the proper method of using propolis in pulpotomising primary teeth. Also, there is a need to standardize the form and concentration of Propolis to be used as a pulpotomy agent. The exact mechanism of action of propolis needs to be determined so as to use propolis successfully and reap all its benefits in dentistry.

Conclusion: Propolis is a promising medicament in the pulpotomy of primary molars. However, further investigations with a larger sample size and longer follow up periods have to be carried out to determine its use as a pulpotomy agent.

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