

# Comparative evaluation of a modified endodontic approach using *Curcuma longa* L. and conventional pulpectomy in primary molars: A randomized clinical trial

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## Abstract

**Background:** Turmeric (*Curcuma longa*) is known for its anti-inflammatory and anti-septic properties. **Aim:** The aim is to compare a modified endodontic approach using turmeric and conventional Metapex® pulpectomy in primary molars. **Materials and methods:** Thirty children, in the age range of 4–9 years, with at least one primary mandibular molar indicated for pulpectomy, were included. Teeth were randomly assigned to turmeric and Metapex® groups. For those that were assigned to turmeric, after coronal and radicular pulp extirpation, a freshly prepared paste of turmeric powder and methyl cellulose (2:1) with saline was packed in the coronal pulp chamber. In the Metapex® group, a conventional pulpectomy was performed. Clinical and radiographic success was recorded at 3-, 6-, and 12-month follow-up visits. The data was statistically analyzed using the Chi-square test. **Results:** There were no clinical and radiographic failures at 3- and 6-month visits in both groups. The 12-month evaluation revealed clinical success rates of 92% (12 out of 13) and 100% (14 out of 14) for turmeric and Metapex®, respectively, whereas, the radiographic success rates were 85% (12 out of 13) for turmeric and 93% (13 out of 14) for Metapex®. No statistically significant differences were found between the groups at different follow-ups ( $P > 0.05$ ). **Conclusions:** A modified endodontic approach using turmeric and conventional Metapex® pulpectomy did not differ significantly in total success after 12 months.

**Keywords:** Obturation, primary teeth, pulpectomy, turmeric

## Introduction

The pulpectomy of primary teeth with irreversibly inflamed or necrotic pulp is a reasonable approach to retain these teeth as natural space maintainers, in a symptom-free state until exfoliation.<sup>[1,2]</sup> Despite the many deterrent factors that affect the prognosis of pulpectomized teeth,<sup>[1]</sup> high success rate of the procedure is well reported.<sup>[3-7]</sup> The morphology of root canals, physiological root resorptions, and proximity to the permanent successor are the major tooth-related factors that impede the prognosis. In addition, factors such as child's immaturity to relate their symptoms, obtaining quality radiographs, behavioral guidance problems, and poor parent compliance should be considered. Therefore, a continued thrive for alternative approaches exist in pediatric endodontics. The effectiveness of noninvasive techniques was explored, as the success of pulpectomy depends primarily on microbial elimination from the root canals and periapical region.<sup>[8,9]</sup> This directed the pediatric dentists toward two procedures,

the first being, lesion sterilization and tissue repair (LSTR), with a reported high success rate.<sup>[10,11]</sup> Another noninvasive technique was Pulpotec® pulpotomy on primary molars with partial necrosis or abscess that has revolutionized pediatric endodontics.<sup>[12]</sup> Consequently, a modified Pulpotec® endodontic approach on primary molars with necrotic pulp and furcation bone loss was investigated.<sup>[13]</sup> According to this, the radicular infected pulp is extirpated, canals irrigated and Pulpotec® material placed only in the coronal pulp chamber.<sup>[13]</sup> As a significant clinical improvement was observed with

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this procedure and it has been suggested as an alternative to conventional pulpectomy. The advantage of this modified endodontic approach over conventional pulpectomy is the reduction in time spent on instrumentation and obturation.

Another emerging field in endodontics, is the research toward natural/herbal alternatives to synthetic substances. Natural substances avoid undesirable properties that can be triggered by synthetic substances.<sup>[14]</sup> Hence, the modified endodontic approach with alternative traditional medicines can be the scope for investigation. One such substance with numerous therapeutic benefits is turmeric, scientifically known as *Curcuma longa* L. Zingiberaceae.<sup>[15,16]</sup> The active components of this material are flavonoid curcumin and volatile oils.<sup>[17]</sup> It has been used extensively in Ayurvedic medicine due to its nontoxic properties.<sup>[18-24]</sup> The primary therapeutic role of this material is an antioxidant, analgesic, anti-inflammatory, antiseptic, and anti-carcinogenic activity.<sup>[21-24]</sup> Various dental applications with this material have been studied, which include dental pain management, topical application for treating gingivitis and periodontitis; as a mouthwash, subgingival irrigant and in the local drug delivery system for relieving periodontal problems, as a colorant in pit and fissure sealants, pulpotomy medicament as well as in the treatment of precancerous lesions.<sup>[25-31]</sup> The action of this material against endodontic bacteria has also been studied in literature with positive results.<sup>[32-34]</sup> The efficacy of this material as a medicament in the modified endodontic approach has been considered in the present study due to its therapeutic benefits, safety, negligible cost, and ease of availability. Thus, this randomized clinical trial evaluated the effectiveness of the modified endodontic approach using turmeric powder, as an alternative to conventional pulpectomy in the primary molars.

## Materials and methods

### Trial design

This was an exploratory, noninferiority open label, randomized trial with a parallel study design and balanced allocation ratio of 1:1.

### Participants

Children, in the age range of 4–9 years, attending the Department of Paedodontics and preventive dentistry were selected based on the following inclusion criteria: at least one carious primary mandibular molar diagnosed with having irreversible pulpitis/with radiographic signs of furcal abscess which is indicated for pulpectomy; the tooth that is restorable with at least two-third of intact root length; children who gave their assent along with the parent's written informed consent.

Exclusion criteria include, tooth with preshedding/abnormal pathologic mobility/perforation of the pulpal floor, presence of soft tissue or dentoalveolar abscess and/or sinus, tooth with either internal or external root resorption, and children with systemic problems.

### Clinical setting

Ethical clearance was obtained from the institutional ethical committee that was approved and registered by the University of Health Sciences and the study was conducted in the department from June 2016 to March 2018.

### Interventions

Based on the inclusion criteria, teeth were selected and randomly assigned to one of the following groups:

Group 1: Modified endodontic approach using *Curcuma longa* L. Zingiberaceae (turmeric) followed by stainless steel crown (SSC) (3M ESPE, St. Paul, Minn, USA).

Group 2: Conventional pulpectomy with calcium hydroxide and iodoform paste (Metapex<sup>®</sup>, Meta<sup>®</sup> Biomed Company Ltd., Korea) followed by SSC.

Following local anesthetic administration, the teeth were isolated with a rubber dam. Dental caries and overhanging enamel were removed using a no. 330 carbide bur (SS White, Lakewood, N. J., USA). Access to the coronal pulp was obtained with # 8 round bur. Tissue from the pulp chamber was removed using a spoon excavator (B090, TDI<sup>™</sup>, USA), whereas root canals were extirpated using broaches. The working length was kept 1 mm short of the radiographic apex. The cleaning and shaping of the root canals were carried out with H files (15–20) (MANI<sup>®</sup>, Japan) using a pullback motion. During instrumentation, each canal was lubricated with ethylenediaminetetraacetic acid for the removal of the smear layer and smooth shaping of canals. Irrigation of the root canals was done alternatively with saline and 1% sodium hypochlorite solution, followed by drying the canals using absorbent paper points. The procedure that follows these steps (either placement of turmeric paste as medicament in the coronal pulp chamber/obturation with Metapex) was based on the group to which the tooth was randomly assigned to.

### Group 1

Turmeric paste was freshly prepared by mixing turmeric and methyl cellulose powders (in a ratio of 2:1) with saline to achieve a packable consistency. A small amount of barium sulfate was also added for radiopacity. The prepared mixture was carried into the pulp chamber with a plastic carrying instrument. Slight pressure was applied with dampened cotton pellet to seal the orifices of the root canals and half the pulp chamber. Excess pressure was avoided while condensing the material to refrain the entry of material into the root canal. The remaining pulp chamber was filled with zinc oxide eugenol (ZOE), followed by conventional glass ionomer cement (GIC) (GC Fuji I, GC Corp.) restoration and SSC placement. [Figure 1]

### Group 2

Conventional obturation was performed using Metapex<sup>®</sup>. The prepacked polypropylene syringe was inserted into the canals till the apex. Consequently, the paste was pressed down into the

canals, and the syringe was slowly withdrawn when the paste flowed back from the canals into the pulp chamber. Then, the material was pushed into each root canal with a suitable hand plugger and/or moist cotton pellets. Following this, the pulp chamber was filled with a thick paste of ZOE, restored with GIC, and SSC was placed. [Figure 2]

The children of both groups were recalled at 3, 6, and 12 months interval for clinical and radiographic evaluation. The data obtained were tabulated and analyzed statistically.

## Outcome measures

### Criteria for clinical success

The absence of pain or tenderness on percussion, gingival inflammation/swelling, sinus opening in the oral mucosa, or purulent exudate expressed from the gingival margin and pathological mobility were considered criteria for clinical success.<sup>[5]</sup>

### Criteria for radiographic success

The reduction or no change in preoperative pathologic interradicular radiolucency/periapical radiolucency, with no evidence of the development of new postoperative pathologic radiolucency involving the succedaneous tooth germ or extensive pathologic internal/external root resorption, were considered criteria for radiographic success.<sup>[5]</sup>

If calcified metamorphosis occurred, it was noted but not regarded as a treatment failure.

## Sample size determination

Based on the findings of the pilot study with a sample of 8 teeth (4 in each group), taking alpha error of 0.05 and 95% power, considering the clinical success at 3 months follow-up as the primary outcome, a sample size of 24 (12 in each group) was determined. Estimating a dropout rate of 20%, a sample size of 30 (15 in each group) was recruited.

## Randomization

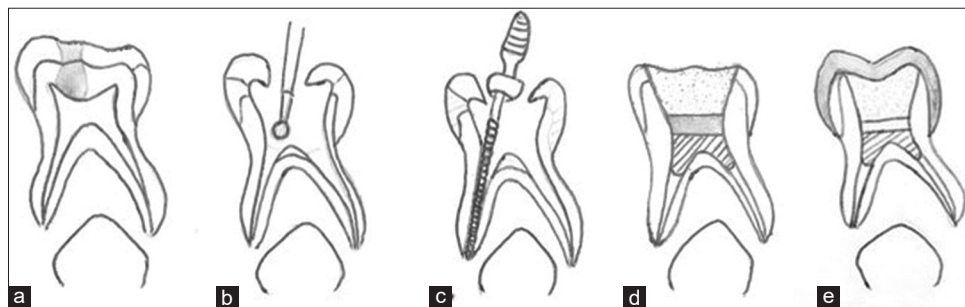
Restricted and block randomization (permuted block randomization), was employed in the study with random block sizes of 4 and 6. A table of random numbers was used to generate the random allocation sequence. To prevent selection bias, the centralized assignment was used as an allocation concealment mechanism.

## Blinding and personnel involved

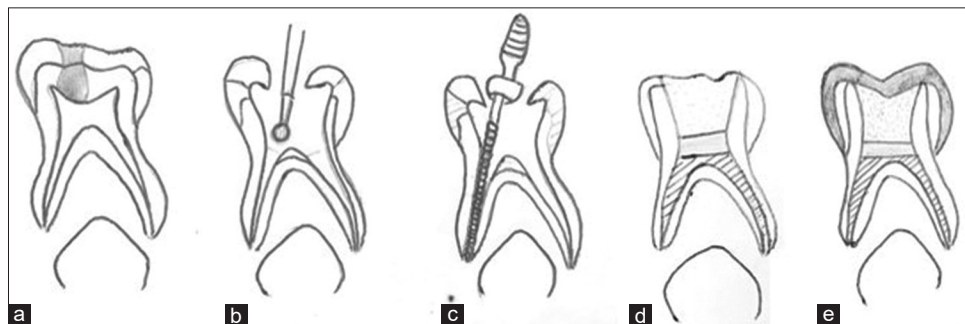
It was an open trial. All the treatment procedures were performed by the primary investigator (coded as SP). The clinical outcome measures in all the follow-up visits were assessed by a single investigator (coded as RK), whereas the radiographic assessment was done by both the investigators (RK and SP) twice, with 1 week washout period.

## Statistical analysis

The data were entered in the Microsoft excel spreadsheet 2010. The statistical analysis was performed using SPSS 17.0 version for Windows (Chicago, III, USA). The inter- and intra-examiner reliability of radiographic outcomes was



**Figure 1:** Radiographs of mandibular primary second molar treated using modified endodontic approach with turmeric. (a) Preoperative radiograph. (b) Immediate postoperative radiograph after modified endodontic approach with turmeric. (c) 3 months follow up postoperative radiograph. (d) 6 months follow up postoperative radiograph. (e) 12 months follow up postoperative radiograph



**Figure 2:** Radiographs of mandibular primary second molar treated using conventional Metapex® pulpectomy. (a) Preoperative radiograph. (b) Immediate postoperative radiograph after obturation with Metapex®. (c) 3 months follow up postoperative radiograph. (d) 6 months follow up postoperative radiograph. (e) 12 months follow up postoperative radiograph

calculated using Kappa statistics. The statistical difference in the distribution of teeth based on the considered clinical and radiographic success criteria between the turmeric and Metapex® groups, during preoperative and follow-up visits at 3, 6, and 12 months, was assessed using the Fisher’s exact test. The statistical difference in clinical, radiographic, and total success rates of turmeric and Metapex® was calculated using the Chi-square test. The level of significance was set at 0.05.

## Results

A total of 30 children participated in the study, each with a carious primary mandibular molar indicated for pulpectomy. The flow chart with the total number of participants enrolled, allocated, followed, and analyzed in both turmeric and Metapex® groups is represented in Figure 3. Children were equally allocated to two groups; the mean age of the participants randomized to turmeric and Metapex® were  $7.73 \pm 1.62$  years (range: 4–9) and  $8.2 \pm 1.24$  years (range: 4–9), respectively. There was no statistically significant difference

in the age distribution of children ( $P = 0.57$ ). Regarding gender differences, 6 boys and 9 girls were randomized to the turmeric group, whereas 10 boys and 5 girls, to the Metapex® group, with no statistically significant difference in the distribution ( $P = 0.14$ ). The number of mandibular first and second molars in the turmeric group was 8 and 7, respectively, whereas, in Metapex®, it was 6 and 9. These differences in distribution were also not statistically significant ( $P = 0.72$ ). Preoperative and postoperative radiographs of mandibular primary molar treated with a modified endodontic approach using turmeric and conventional pulpectomy with Metapex® are presented in Figures 4 and 5, respectively.

The intra- and inter-examiner reliability in the radiographic evaluation by two examiners was 0.98 and 0.93, respectively. The clinical and radiographic success criteria in the turmeric and Metapex® groups during preoperative and follow-up visits are represented in Table 1. There was no statistically significant difference between the two groups in the preoperative clinical and radiographic criteria considered. At 3 and 6 months

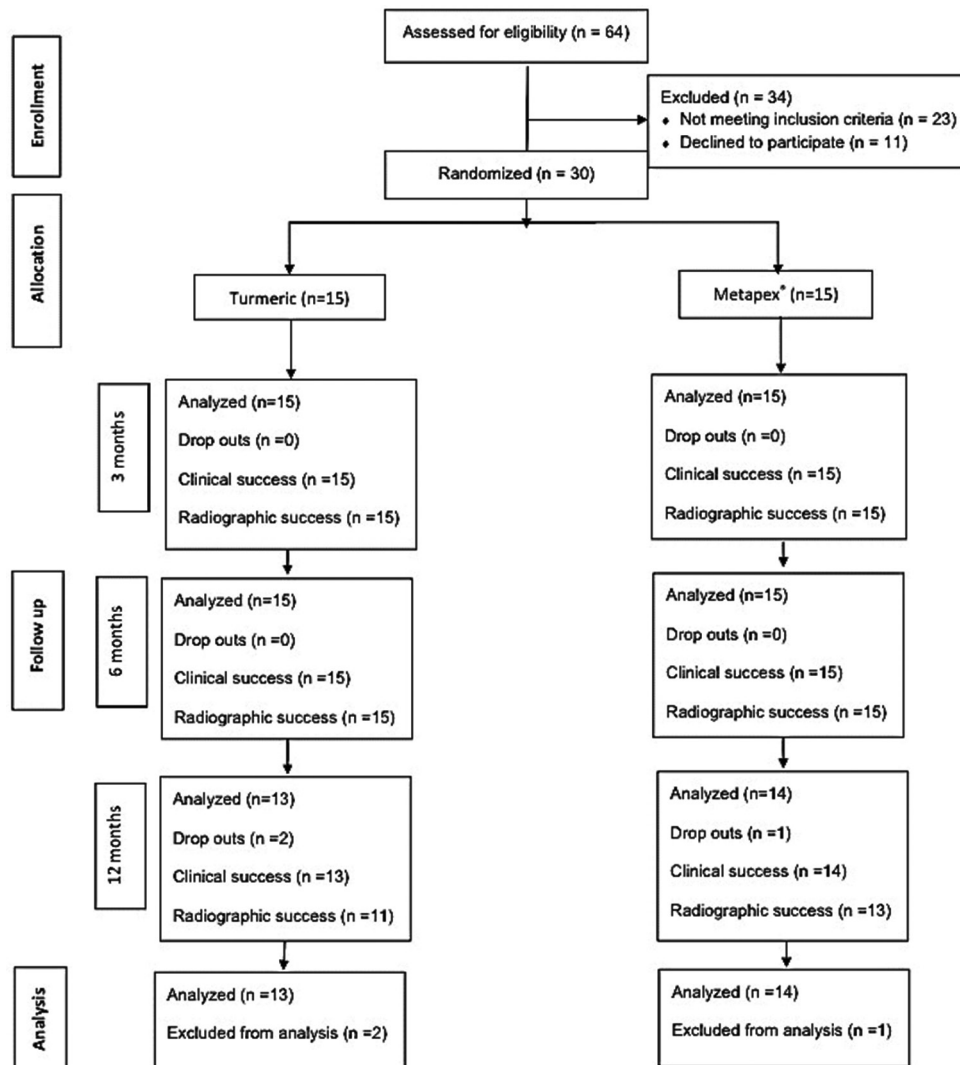
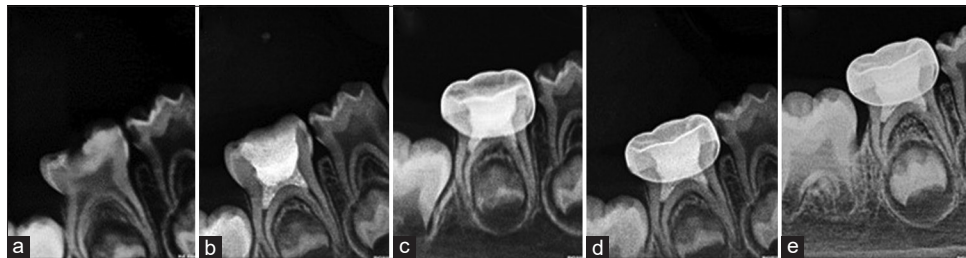


Figure 3: CONSORT flow diagram



**Table 1: Clinical and radiographic examination before and after treatment at 3, 6, and 12 months follow-up**

| Criteria                     | Preoperative (n=30)    |                        | 3 months (n=30)        |                        | 6 months (n=30)        |                        | 12 months (n=27)       |                        |
|------------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
|                              | Turmeric (n=15), n (%) | Metapex® (n=15), n (%) | Turmeric (n=15), n (%) | Metapex® (n=15), n (%) | Turmeric (n=15), n (%) | Metapex® (n=15), n (%) | Turmeric (n=13), n (%) | Metapex® (n=14), n (%) |
| <b>Clinical criteria</b>     |                        |                        |                        |                        |                        |                        |                        |                        |
| Spontaneous pain             | 12 (80)                | 13 (86)                | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      |
| Gingival swelling            | 2 (13)                 | 2 (13)                 | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      |
| Sinus opening                | 2 (13)                 | 1 (6)                  | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      |
| Abnormal mobility            | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      | 1 (8) <sup>a</sup>     | 0                      |
| Pain to percussion           | 10 (66)                | 11 (73)                | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      |
| <b>Radiographic criteria</b> |                        |                        |                        |                        |                        |                        |                        |                        |
| Bifurcation radiolucency     | 3 (20)                 | 2 (13)                 | 0                      | 0                      | 0                      | 0                      | 1 (8)                  | 1 (7)                  |
| External resorption          | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      | 1 (8) <sup>a</sup>     | 0                      |
| Periapical radiolucency      | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      |
| Internal resorption          | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      |
| Calcified metamorphosis      | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      | 0                      |

<sup>a</sup>Same tooth**Figure 4:** Modified endodontic approach using turmeric. (a) Carious primary molar involving pulp. (b) Removal of roof of pulp chamber. (c) Removal of radicular pulp tissue. (d) Placement of turmeric in the pulp chamber. (e) Cementation of stainless steel crown**Figure 5:** Conventional pulpectomy using Metapex®. (a) Carious primary molar involving pulp. (b) Removal of roof of pulp chamber. (c) Removal of radicular pulp tissue. (d) Obturation with Metapex®. (e) Cementation of stainless steel crown

follow-up visits, there were no clinical or radiographic failures in both the groups; conversely, at the 12 months visit, there were one clinical and two radiographic failures in the turmeric group, as well as one radiographic failure in the Metapex® [Table 2]. However, there was no statistically significant difference between the two groups, either clinically ( $P = 0.29$ ) or radio-graphically ( $P = 0.5$ ). The total success rate of both the procedures is represented in Table 2.

## Discussion

Conventional pulpectomy includes the removal of the accessible pulp tissue, controlling the microbiota, and restoring the canals with a resorbable filling material. Various

other techniques for treating pulpally involved primary molars have been advocated, based on the amputation of the coronal pulp and placement of medication over the radicular pulp stump to arrest infection as well as inflammation. The reported procedures are Pulpotec® pulpotomy and LSTR.<sup>[10-12]</sup> Further, a modified endodontic approach was introduced,<sup>[13]</sup> which includes the removal of accessible pulp tissue followed by minimal biomechanical preparation to remove the nidus of infection and reducing the bacterial load, followed by the placement of medication only in the pulp chamber. This approach was considered in the present study, for group 1 (turmeric), as the root canals of primary teeth at the phase of physiologic root resorption cannot always be prepared and obturated till the apex. Another advantage is

**Table 2: Success rates of turmeric and metapex® at 3, 6, and 12 months follow-up**

| Treatment                                   | 3 months |                |         | 6 months |                |         | 12 months* |                |                |
|---|----------|----------------|---------|----------|----------------|---------|------------|----------------|----------------|
|   | Sample   | Success, n (%) | Failure | Sample   | Success, n (%) | Failure | Sample     | Success, n (%) | Failure, n (%) |
| <b>Clinical success</b>                     |          |                |         |          |                |         |            |                |                |
| Turmeric                                    | 15       | 15 (100)       | 0       | 15       | 15 (100)       | 0       | 13         | 12 (92)        | 1 (7)          |
| Metapex®                                    | 15       | 15 (100)       | 0       | 15       | 15 (100)       | 0       | 14         | 14 (100)       | 0              |
| Success                                     | 30       | 30 (100)       | 0       | 30       | 30 (100)       | 0       | 27         | 26 (96)        | 1 (3)          |
| *Chi-square test, $P=0.29$ , nonsignificant |          |                |         |          |                |         |            |                |                |
| <b>Radiographic success</b>                 |          |                |         |          |                |         |            |                |                |
| Turmeric                                    | 15       | 15 (100)       | 0       | 15       | 15 (100)       | 0       | 13         | 11 (85)        | 2 (15)         |
| Metapex®                                    | 15       | 15 (100)       | 0       | 15       | 15 (100)       | 0       | 14         | 13 (93)        | 1 (7)          |
| Success                                     | 30       | 30 (100)       | 0       | 30       | 30 (100)       | 0       | 27         | 24 (89)        | 3 (11)         |
| *Chi-square test, $P=0.5$ , nonsignificant  |          |                |         |          |                |         |            |                |                |
| <b>Total success</b>                        |          |                |         |          |                |         |            |                |                |
| Turmeric                                    | 15       | 15             | 0       | 15       | 15             | 0       | 13         | 11 (85)        | 2 (15)         |
| Metapex®                                    | 15       | 15             | 0       | 15       | 15             | 0       | 14         | 13 (93)        | 1 (7)          |
| Success                                     | 30       | 30             | 0       | 30       | 30             | 0       | 27         | 24 (89)        | 3 (11)         |
| *Chi-square test, $P=0.5$ , nonsignificant  |          |                |         |          |                |         |            |                |                |

the simplification of the procedure, which can have a positive impact on children with behavioral problems.

The turmeric powder used in the present study was prepared by grinding the dried rhizomes into fine powder under hygienic conditions and preserved in an air-tight container. The paste with a packable consistency, during the procedure, was obtained by mixing turmeric, methylcellulose, and barium sulfate (radiopacifier) powders with saline. Methylcellulose, methyl ether of cellulose, is used for practical benefits such as high consistency and workability. It is a white to yellowish, odorless, and tasteless powder and, when added to water, forms a clear or slightly turbid viscous liquid. It is composed of nonionic water soluble cellulose ether that binds water molecules within the material and increases the cohesive strength of the material, improving its handling and mechanical properties. Thus, it has been used in the present study for several important properties such as rheology, dispersion, water demand, and water retention.<sup>[35]</sup>

The scientific name of turmeric is *Curcuma longa* L. Zingiberaceae, the crude extract of which consists of 70%–76% curcumin along with 16% demethoxycurcumin and 8% bismethoxycurcumin as well as volatile oils (tumerone, atlantone, and zingiberene).<sup>[17]</sup> The rhizome of turmeric is widely used in indigenous medicine, and extensive scientific research on *curcumin* have demonstrated a wide spectrum of therapeutic effects, the important one being anti-inflammatory activity.<sup>[17]</sup> The molecular mechanism and biochemical changes behind the anti-inflammatory activity include inhibition of arachidonic acid, cyclooxygenase, lipoxygenase, prostaglandin synthesis, cytokines, and nuclear factor-Kappa B.<sup>[24]</sup> It has also been suggested that *curcumin*, a polyphenolic compound, strongly inhibits bacterial cell proliferation by inhibiting the assembly dynamics of ‘filamenting temperature-sensitive mutant-Z’ in the Z-ring needed for bacterial cell division. It has

also been reported to show potent antibacterial activity against a number of pathogenic bacteria, including *Enterococcus*.<sup>[15,36]</sup>

In dentistry, various applications of turmeric have been depicted with successful results.<sup>[20]</sup> The efficacy of *curcumin* and turmeric oil as a chemoprotective agent in oral submucous fibrosis reported a reduction in burning sensation as well as relief from pain and trismus.<sup>[30]</sup> Turmeric has also been tested as an adjunct to mechanical plaque control, and was found to be as effective as chlorhexidine gluconate in anti-plaque, anti-inflammatory, and anti-microbial properties.<sup>[25]</sup> This material has also been used as a subgingival irrigant, after scaling and root planning, with better resolution of inflammatory signs than chlorhexidine and saline.<sup>[26,27]</sup> In a single-arm trial, turmeric was employed as a pulpotomy medicament in primary teeth, which presented a 100% pain reduction in 93.34% of cases, and no radiographic changes after 3 weeks, 2, 4, and 6 months in the furcal area.<sup>[28]</sup> Another study on pulpotomy, compared the effectiveness of turmeric gel with formocresol, propolis extract, and calcium hydroxide and concluded turmeric as a promising alternative to formocresol in pediatric endodontic treatment.<sup>[29]</sup> As a further step in expanding the scope, the effectiveness of turmeric as a medicament after pulpectomy was evaluated in the present study. A success rate of 85%, in 12 months of follow-up, was observed with turmeric, whereas it was 93% with Metapex®. However, no statistically significant difference in the outcome between turmeric and Metapex® was observed. These positive findings can be attributed to the anti-inflammatory and antibacterial properties of turmeric, as reported in previous studies.<sup>[24]</sup>

There were no clinical or radiographic failures in both Metapex® and turmeric groups during the 3 and 6 months follow-up. During the 12 months follow-up of the Metapex® group, one tooth presented with radiolucency in the furcation region, which was considered radiographic failure based on

the predetermined criteria. In the turmeric group, there were two failures; one tooth with abnormal mobility clinically, and external resorption radiographically, whereas another tooth presented only furcal radiolucency. The dropouts in Metapex® and turmeric groups were 1 and 2, respectively. This was within the expected dropout rate of 20%, hence, not considered a drawback. The major limitation of the present study is the lack of blinding. However, neither the operator nor the evaluator could be blinded due to the difference in the procedure as well as the radiographic appearance. Other limitations include small sample size and parallel study design. Therefore, there is a need for further studies, possibly with a split-mouth design, to derive proper conclusions. Furthermore, there is a scope to investigate and commercially market readymade preparation of turmeric so that the need to prepare the material freshly each time can be eliminated. Even in future studies, a combination of turmeric with antibiotics can be investigated as a material of choice for pulpectomy, as an increase in the antimicrobial potency of turmeric when combined with antibiotics such as cefixime, cefotaxime, vancomycin, and tetracycline has already been reported.<sup>[34]</sup>

## Conclusions

Within the limitations of the present study, conclusions mentioned ahead can be drawn. There was 100% clinical and radiographic success with both turmeric and Metapex® at 3 and 6 months. The clinical success rates with turmeric and Metapex® were 92% and 100%, respectively, whereas the radiographic and total success rates were 85% and 93%, respectively, at 12 months. Despite this difference in percentages, turmeric, and Metapex® did not differ statistically in their clinical and radiographic success after 12 months. Hence, the modified endodontic approach in carious primary molars using turmeric is equally efficacious as conventional Metapex® pulpectomy, followed by the application of SSC.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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